SCHEDULING STATUS
S4

ETHODROS film-coated tablets
Each film coated tablets contains 3 mg of Drospirenone & 0,02 mg of Ethinylestradiol.
ETHODROS contains sugar:
Each pink active tablet contains 44 mg lactose monohydrate.
Each white inactive (placebo) tablet contains 89,5 mg lactose.

Read all of this leaflet carefully before you start taking ETHODROS
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, nurse or other health care provider.
- ETHODROS has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet
1. What ETHODROS is and what it is used for
2. What you need to know before you take ETHODROS
3. How to take ETHODROS
4. Possible side effects
5. How to store ETHODROS
6. Contents of the pack and other information

1. WHAT ETHODROS IS AND WHAT IT IS USED FOR
ETHODROS is a combined oral contraceptive (“the combined pill”) and is used to prevent pregnancy. It consists of 24 pink active tablets with a small amount of two different female hormones, namely drospirenone (3 mg) and ethinylestradiol (0,02 mg) and 4 white inactive (placebo) tablets.

It can also be used to treat moderate acne and premenstrual dysphoric disorder (a health problem that is similar to premenstrual syndrome (PMS), which causes severe depression, irritability, or anxiety before menstruation in women).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ETHODROS
Before you start using ETHODROS, you should read the information on blood clots below. It is particularly important to read the symptoms of a blood clot, see ***Blood clots*** below.

Before you can begin taking ETHODROS, your doctor will ask you some questions about your personal health history and that of your close relatives. The doctor will also measure your blood pressure and, depending upon your personal situation, may also carry out some other tests.

In this leaflet, several situations are described where you should stop using ETHODROS, or where the reliability of ETHODROS may be decreased. In such situations you should either not have sex or you should take extra non-hormonal contraceptive precautions, e.g. use a condom or another barrier method. Do not use rhythm or temperature methods. These methods can be unreliable because ETHODROS alters the monthly changes of body temperature and cervical mucus.

ETHODROS does not protect against HIV infection (AIDS) or any other sexually transmitted disease.

Do not take ETHODROS:
Do not take ETHODROS if you have any of the conditions listed below. If you do have any of the conditions listed below, you must tell your doctor. Your doctor will discuss with you what other form of birth control would be more appropriate.

- if you are hypersensitive (allergic) to ethinylestradiol, drospirenone or any of the other ingredients of ETHODROS (listed in section 6). This may cause itching, rash or swelling.
- if you have (or have ever had) a blood clot in a blood vessel of your leg (deep vein thrombosis, DVT), your lungs (pulmonary embolus, PE) or other organs.
- if you know you have a disorder affecting your blood clotting – for instance, protein C deficiency, protein S deficiency, antithrombin-III deficiency, activated protein C-resistance (Factor V Leiden) or antiphospholipid antibodies (anticardiolipin-antibodies, lupus anticoagulant).
- if you need an operation or if you are off your feet for a long time.
- if you have ever had a heart attack or stroke.
- if you have (or have ever had) angina pectoris (a condition that causes severe chest pain and may be a first sign of a heart attack) or transient ischaemic attack (TIA – temporary stroke symptoms).
- if you have any of the following diseases that may increase your risk of a clot in the arteries:
  - severe diabetes with blood vessel damage
  - very high blood pressure
  - a very high level of fat in the blood (cholesterol or triglycerides)
  - a condition known as hyperhomocysteinaemia (high level of homocysteine in blood which can lead to blood clots in your blood vessels).
- if you ever had migraine accompanied by visual symptoms, speech disability, or weakness or numbness in any part of your body.
- if you have (or have ever had) liver disease and your liver function is still not normal.
- if your kidneys are not working well (kidney failure).
- if you have (or have ever had) a tumour in the liver.
- if you have (or have ever had) or if you are suspected of having breast cancer or cancer of the genital organs.
- if you have any unexplained bleeding from the vagina.
- if you are pregnant or you think you might be pregnant.
- if you are taking medicine containing ombitasvir/paritaprevir/ritonavir and dasabuvir.

Warnings and precautions
When should you contact your doctor?
Seek urgent medical attention:

- if you notice possible signs of a blood clot that may mean you are suffering from a blood clot in the leg (i.e. deep vein thrombosis), a blood clot in the lung (i.e. pulmonary embolism), a heart attack or a stroke (see *Blood clots* section below).

For a description of the symptoms of these serious side effects please see *How to recognise a blood clot*.

Take special care with ETHODROS
Talk to your doctor before taking ETHODROS. In some situations, you need to take special care while using ETHODROS or any other combination pill, and your doctor may need to examine you regularly. If the condition develops, or gets worse while you are using ETHODROS, you should also tell your doctor.

- if you smoke.
- if you are overweight.
- if a close relative has or has ever had breast cancer.
- if a close relative ever had stroke or heart attack at young age.
- if you have a disease of the liver or the gallbladder.

- if you have diabetes.
- if you have high blood pressure.
- if you have problem with your heart (valve disorder).
- if you have depression.
- if you have Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease).
- if you have haemolytic uraemic syndrome (HUS – a disorder of blood clotting causing failure of the kidneys).
- if you have sickle cell anaemia (an inherited disease of the red blood cells).
- if you have epilepsy.
- if you have disease of immune system called systemic lupus erythematosus.
- if you have elevated levels of fat in the blood (hypertriglyceridemia) or a positive family history for this condition. Hypertriglyceridemia has been associated with an increased risk of developing pancreatitis (inflammation of the pancreas, symptoms include severe upper stomach pain, often with nausea and vomiting).
- if you have just given birth, you are at an increased risk of blood clots. You should ask your doctor how soon after delivery you can start taking ETHODROS.
- if you have an inflammation in the veins under the skin (superficial thrombophlebitis).
- if you have varicose veins.
- if you have a disease that first appeared during pregnancy or earlier use of sex hormones (for example, hearing loss, a blood disease called porphyria, yellowing of the skin or eyes (jaundice), itching of the whole body (pruritis), skin rash with blisters during pregnancy (gestational herpes), a nerve disease causing sudden movements of the body (Sydenham's chorea).
- if you have ever had a discolouration of the skin especially on the face or neck known as "pregnancy patches" (chloasma). If so, avoid direct sunlight or ultraviolet light.
- if you have hereditary angioedema, products containing estrogens may cause or worsen the symptoms. You should see your doctor immediately if you experience symptoms of angioedema, such as swollen face, tongue and/or throat and/or difficulty swallowing or hives together with difficulty breathing.
- if you have increased potassium serum levels.

Blood clots

Using a combined hormonal contraceptive such as ETHODROS increases your risk of developing a blood clot compared with not using one. In rare cases a blood clot can block vessels and cause serious problems.

Blood clots can develop

- in veins (referred to as a "venous thrombosis", "venous thromboembolism" or VTE)
- in the arteries (referred to as an "arterial thrombosis", "arterial thromboembolism" or ATE).

Recovery from blood clots is not always complete. Rarely, there may be serious lasting effects or, very rarely, they may be fatal.

It is important to remember that the overall risk of a harmful blood clot due to ETHODROS is small.

How to recognise a blood clot

Seek urgent medical attention if you notice any of the following signs or symptoms.

Are you experiencing any of these signs?	**What are you possibly suffering from?**
• swelling of one leg or along a vein in the leg or foot especially when accompanied by: - pain or tenderness in the leg which may be felt only when standing or walking	Deep vein thrombosis

- increased warmth in the affected leg - - change in colour of the skin on the leg e.g. turning pale, red or blue.	
• sudden unexplained breathlessness or rapid breathing. • sudden cough without an obvious cause, which may bring up blood. • sharp chest pain which may increase with deep breathing. • severe light headedness or dizziness. • rapid or irregular heartbeat. If you are unsure, talk to a doctor as some of these symptoms such as coughing or being short of breath may be mistaken for a milder condition such as a respiratory tract infection (e.g. a “common cold”).	Pulmonary embolism
Symptoms most commonly occur in one eye: • immediate loss of vision or • painless blurring of vision which can progress to loss of vision.	Retinal vein thrombosis (blood clot in the eye)
• chest pain, discomfort, pressure, heaviness. • sensation of squeezing or fullness in the chest, arm or below the breastbone. • fullness, indigestion or choking feeling. • upper body discomfort radiating to the back, jaw, throat, arm and stomach. • sweating, nausea, vomiting or dizziness. • extreme weakness, anxiety, or shortness of breath. • rapid or irregular heartbeats.	Heart attack
• sudden weakness or numbness of the face, arm or leg, especially on one side of the body. • sudden confusion, trouble speaking or understanding. • sudden trouble seeing in one or both eyes. • sudden trouble walking, dizziness, loss of balance or co-ordination. • sudden, severe, or prolonged headache with no known cause. • loss of consciousness or fainting with or without seizure. Sometimes the symptoms of stroke can be brief with an almost immediate and full recovery, but you should still seek urgent medical attention as you may be at risk of another stroke.	Stroke
• swelling and slight blue discolouration of an extremity. • severe pain in your stomach (acute abdomen).	Blood clots blocking other blood vessels.

Blood clots in a vein or artery

What can happen if a blood clot forms in a vein?

- The use of combined hormonal contraceptives has related to an increase in the risk of blood clots in the vein (venous thrombosis). However, these side effects are rare. Most frequently, they occur in the first year of use of a combined hormonal contraceptive.
- If a blood clot forms in a vein in the leg or foot it can cause a deep vein thrombosis (DVT).
- If a blood clot travels from the leg and lodges in the lung, it can cause a pulmonary embolism.
- Very rarely a clot may form in a vein in another organ such as the eye (retinal vein thrombosis).

What can happen if a blood clot forms in an artery?

Like a blood clot in a vein, a clot in an artery can cause serious problems.
For example, it can cause a heart attack or a stroke.

When is the risk of developing a blood clot in a vein highest?

The risk of developing a blood clot in a vein is highest during the first year of taking a combined hormonal contraceptive for the first time. The risk may also be higher if you restart taking a combined hormonal contraceptive (the same product or a different product) after a break of 4 weeks or more.

After the first year, the risk gets smaller but is always slightly higher than if you were not using a combined hormonal contraceptive.

When you stop ETHODROS your risk of a blood clot returns to normal within a few weeks.

Factors that increase your risk of a blood clot in an artery/vein

It is important to note that the risk of a heart attack or stroke from using ETHODROS is very small but can increase:

- with increasing age (beyond about 35 years).
- if you smoke. When using a combined hormonal contraceptive like ETHODROS, you are advised to stop smoking. If you are unable to stop smoking and are older than 35 years your doctor may advise you to use a different type of contraceptive.
- if you are very overweight (body mass index or BMI over 30 kg/m^2);
- if you have high blood pressure.
- if a member of your immediate family has had a heart attack or stroke at a young age (less than about 50). In this case you could also have a higher risk of having a heart attack or stroke.
- if you, or someone in your immediate family, have a high level of fat in the blood (cholesterol or triglycerides).
- if you get migraines, especially migraines with aura.
- if you have a problem with your heart (valve disorder, disturbance of the rhythm called atrial fibrillation).
- if you have diabetes.
- if one of your immediate family has had a blood clot in the leg, lung or other organ at a young age (e.g. below the age of about 50). In this case you could have a hereditary blood clotting disorder.
- if you need to have an operation, or if you are off your feet for a long time because of an injury or illness, or you have your leg in a cast. The use of ETHODROS may need to be stopped several weeks before surgery or while you are less mobile. If you need to stop ETHODROS ask your doctor when you can start using it again.
- if you gave birth less than a few weeks ago.

Air travel (> 4 hours) may temporarily increase your risk of a blood clot, particularly if you have

some of the other factors listed.

If you have more than one of these conditions or if any of them are particularly severe the risk of developing a blood clot may be increased even more.

If any of the above conditions change while you are using ETHODROS, for example you start smoking, a close family member experiences a thrombosis for no known reason or you gain a lot of weight, tell your doctor.

Cancer
Breast cancer has been reported slightly more often in women using combination pills, but it is not known whether this is caused by the treatment. For example, it may be that more tumours are detected in women on combination pills because they are examined by their doctor more often. The occurrence of breast tumours becomes gradually less after stopping the combination hormonal contraceptives. It is important to regularly check your breasts and you should contact your doctor if you feel any lump.

In rare cases, benign liver tumours, and in even fewer cases malignant liver tumours have been reported in pill users. Contact your doctor if you have unusually severe stomach pain.

Psychiatric disorders
Some women using hormonal contraceptives including drospirenone/ethinyl- estradiol have reported depression or depressed mood. Depression can be serious and may sometimes lead to suicidal thoughts. If you experience mood changes and depressive symptoms contact your doctor for further medical advice as soon as possible.

Bleeding between periods
During the first few months that you are taking ETHODROS, you may have unexpected bleeding (bleeding outside the 4 white inactive (placebo) tablet days). If this bleeding occurs for more than a few months, or if it begins after some months, your doctor must find out what is wrong.

What you must do if no bleeding occurs during the 4 white inactive (placebo) tablet days
If you have taken all the tablets correctly, have not had vomiting or severe diarrhoea and you have not taken any other medicines, it is highly unlikely that you are pregnant.

If the expected bleeding does not happen twice in succession, you may be pregnant. Contact your doctor immediately. Only start the next strip if you are sure that you are not pregnant.

Laboratory tests
If you need a blood test, tell your doctor or the laboratory staff that you are taking the pill, because hormonal contraceptives can affect the results of some tests.

Children and adolescents
ETHODROS is not intended for use in females whose menstrual cycle has not yet started.

Other medicines and ETHODROS
Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

Some medicines
- can have an influence on the blood levels of ETHODROS
- can make it less effective in preventing pregnancy

- can cause unexpected bleeding.

These include medicines used for the treatment of:
- epilepsy (e.g. primidone, phenytoin, barbiturates, carbamazepine, oxcarbazepine, topiramate, felbamate)
- tuberculosis (e.g. rifampicin)
- HIV and hepatitis C virus infections (so-called protease inhibitors and nonnucleoside reverse transcriptase inhibitors such as ritonavir, nevirapine, efavirenz)
- fungal infections (e.g. griseofulvin, ketoconazole)
- arthritis, arthrosis (etoricoxib)
- high blood pressure (bosentan, angiotensin-II-receptor antagonists, potassium-sparing diuretics, and aldosterone antagonists)
- the herbal remedy St John's wort (used to treat depression)
- antibiotics like penicillin, tetracycline (used to treat bacterial infections).

ETHODROS may influence the effect of other medicines, e.g.
- medicines containing ciclosporin (used for treatment of rheumatoid arthritis)
- the anti-epileptic lamotrigine (this could lead to an increased frequency of seizures)
- theophylline (used to treat breathing problems)
- tizanidine (used to treat muscle pain and/or muscle cramps).

Do not use ETHODROS if you have hepatitis C and are taking medicines containing ombitasvir/paritaprevir/ritonavir and dasabuvir as this may cause increases in liver function blood test results (increase in ALT liver enzyme). Your doctor will prescribe another type of contraceptive prior to start of the treatment with these medicines. ETHODROS can be restarted approximately 2 weeks after completion of this treatment. See section "Do not use ETHODROS".

ETHODROS with food and drink
ETHODROS may be taken with or without food, if necessary, with a small amount of water.

Pregnancy and breastfeeding
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Pregnancy
If you are pregnant, you must not take ETHODROS. If you become pregnant while taking ETHODROS you must stop taking it immediately and contact your doctor. If you want to become pregnant, you can stop taking ETHODROS at any time.

Breastfeeding
Use of ETHODROS is not recommended during breastfeeding. If you want to take the pill while you are breastfeeding, you should contact your doctor.

Driving and using machines
There is no information suggesting that use of ETHODROS affects driving or the use of machines but if you experience dizziness or internal or external spinning sensation do not engage in these activities.

ETHODROS contains lactose and lactose monohydrate
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking ETHODROS.

ETHODROS contains sodium
ETHODROS contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially sodium free.

3. How to take ETHODROS

Do not share medicines prescribed for you with any other person.
Always take ETHODROS exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Take ETHODROS every day for 28 days
ETHODROS comes in a blister strip containing 24 pink active film-coated tablets and 4 white inactive (placebo) film-coated tablets, each marked with a day of the week.

Take your tablet at the same time every day.
- Start by taking a tablet marked with the correct day of the week.
- Follow the direction of the arrows on the strip. Take one tablet each day, until you have finished all 24 pink active tablets.
- Swallow each tablet whole, with water if necessary. Do not chew the tablet.

Then have four white inactive (placebo) tablets
After you have taken all 24 pink active tablets in the strip, you have 4 days when you take the white inactive (placebo) tablets. Within a few days of starting the white inactive (placebo) tablets from the strip, you should have a withdrawal bleed like a period. This bleed may not have finished before the next pack is started.

Start taking your next strip of ETHODROS after the 4 days of white inactive (placebo) tablets – even if you are still bleeding. Always start the new strip on time. You don't need to use extra contraception during these 4 white inactive tablet days as long as you have taken your tablets correctly.

When can you start with the first strip?
If you have not used a contraceptive with hormones in the previous month
Begin with ETHODROS on the first day of the cycle (that is, the first day of your period). If you start ETHODROS on the first day of your menstruation you are immediately protected against pregnancy. You may also begin on day 2 – 5 of the cycle, but then you must use extra protective measures (for example, a condom) for the first 7 days.

Changing from a combined hormonal contraceptive, or combined contraceptive vaginal ring or patch
You can start ETHODROS preferably on the day after the last active tablet (the last tablet containing the active substances) of your previous pill, but at the latest on the day after the inactive tablet days of your previous oral contraceptive finish (or after the last inactive tablet of your previous oral contraceptive). When changing from a combined contraceptive vaginal ring or patch, follow the advice of your doctor.

Changing from a progestogen-only-method (progestogen-only pill, injection, implant or a progestogen-releasing intrauterine system (IUS))
You may switch any day from the minipill (from an implant or an IUS on the day of its removal, from an injectable when the next injection would be due) but in all of these cases use extra protective measures (for example, a condom) for the first 7 days of taking ETHODROS.

After a miscarriage or abortion
If you have had a miscarriage or abortion during the first three months of pregnancy, your doctor may tell you to start taking ETHODROS immediately. This means that you will have

contraceptive protection with your first pill.

After miscarriage in the second 3 months or after having a baby
You can start taking ETHODROS between 21 and 28 days after having a baby or miscarriage in the second 3 months. If you start later than day 28, use a so-called barrier method (for example, a condom) during the first seven days of taking ETHODROS.
If, after having a baby, you have had sex before starting ETHODROS (again), you must first be sure that you are not pregnant or wait until your next period.

If you are breastfeeding and want to start ETHODROS after having a baby
Use of ETHODROS is generally not advisable when a woman is breastfeeding. If you want to take the pill while you are breastfeeding you should contact your doctor.

If you take more ETHODROS than you should
In the event of overdosage, consult your doctor or pharmacist without delay. If neither is available, contact the nearest hospital or poison centre.
There are no reports of serious harmful results of taking too many ETHODROS tablets.
If you take several tablets at once, then you may feel sick or vomit or you may bleed from the vagina. Even girls who have not yet started to menstruate but have accidentally taken ETHODROS, may experience such bleeding.
If you have taken too many ETHODROS tablets, or you discover that a child has taken some, ask your doctor or pharmacist for advice.

If you forget to take ETHODROS
- If you are less than 12 hours late in taking a pink active tablet, the protection against pregnancy is not reduced. Take the tablet as soon as you remember and take the next tablet at the usual time.
- If you are more than 12 hours late in taking a pink active tablet, the protection against pregnancy may be reduced. The greater the number of tablets that you have forgotten, the greater is the risk of becoming pregnant.

The risk of incomplete protection against pregnancy is greatest if you forget a pink active tablet at the beginning or at the end of the strip. Therefore, you should keep to the following rules:
- *More than one tablet forgotten in this strip*

Contact your doctor.

- *One tablet forgotten between days 1 – 7*

Take the forgotten tablet as soon as you remember, even if that means that you must take two tablets at the same time. Continue taking the tablets at the usual time and use extra precautions for the next 7 days, for example, a condom. If you have had sex in the week before forgetting the tablet you must realise that there is a risk of pregnancy. In that case, contact your doctor.

- *One tablet forgotten between days 8 – 14*

Take the forgotten tablet as soon as you remember, even if that means that you must take two tablets at the same time. Continue taking the tablets at the usual time. The protection against pregnancy is not reduced, and you do not need to take extra precautions. However, if this is not the case, or if you have missed more than 1 tablet, you will need to use extra precautions for 7 days.

- *One tablet forgotten between days 15 – 24*

You can choose between two possibilities. Provided that in the 7 days preceding the first missed tablet you have taken all tablets correctly. If this is not the case, you should follow the first of these two options, and use extra precautions for the next 7 days as well.

1. Take the forgotten tablet as soon as you remember, even if that means that you must take two tablets at the same time. Continue taking the tablets at the usual time. Instead of having 4 inactive tablets start the next strip as soon as you have taken the last tablet. Most likely, you will have a period at the end of the second strip – but you may also have light or menstruation-like bleeding during the second strip.

2. You can also stop the tablets and go directly to the inactive tablet period (record the day on which you forgot your tablet). If you want to start a new strip on the day you always start, make the inactive tablet period less than 4 days.

If you follow one of these two recommendations, you will remain protected against pregnancy.

If you have forgotten any of the tablets in a strip, and you do not have a bleeding during the first inactive tablet period, you may be pregnant. You must contact your doctor before you start the next strip.

What to do in the case of vomiting or severe diarrhoea
If you vomit within 3 – 4 hours of taking a tablet or you have severe diarrhoea, there is a risk that the active substances in the pill will not be fully taken up by your body. The situation is almost the same as forgetting a tablet. After vomiting or diarrhoea, you must take another tablet from another pack as soon as possible. If possible, take it within 12 hours of when you normally take your pill. If this is not possible or 12 hours have passed, you should follow the advice given under “If you forget to take ETHODROS”.

Delaying your period: what you need to know
Even if it is not recommended, you can delay your period by skipping the 4 inactive white tablets and going straight to a new strip of ETHODROS and finishing it. You may experience light or menstruation-like bleeding while using this second strip. After the usual inactive tablet period of 4 days start your next strip.

It is advisable to consult your doctor for advice before deciding to delay your menstrual period.

Changing the first day of your period: what you need to know
If you take the tablets according to the instructions, then your period will begin during the 4 inactive white tablet days. If you must change this day, make the inactive white tablet period shorter – (but never longer – 4 days is the maximum). For example, if you start the 4 inactive white tablet days on a Friday, and you want to change this to a Tuesday (3 days earlier) you must start a new strip 3 days earlier than usual. If you make the inactive tablet period very short (for example 3 days or less) you may not have any bleeding during this time. You may then experience light or menstruation-like bleeding.

If you stop taking ETHODROS
You can stop taking ETHODROS whenever you want. If you do not want to become pregnant, ask your doctor for advice about other reliable methods of birth control. If you want to become pregnant, stop taking ETHODROS and wait for a menstrual period before trying to become pregnant. You will be able to calculate the expected delivery date more easily.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS
ETHODROS can have side effects.
Not all side effects reported for ETHODROS are included in this leaflet. Should your general

health worsen or if you experience any untoward effects while taking ETHODROS, please consult your health care provider for advice.

If any of the following happens, stop taking ETHODROS and tell your doctor immediately or go to the casualty department at your nearest hospital:
Severe allergic reactions/hypersensitivity reactions: sudden swelling of your face, lips, mouth, tongue or throat, difficulty breathing or low blood pressure which may cause fainting or collapse.
Erythema Multiforme: severe condition of the skin that may affect the mouth and other parts of the body; symptoms include red, often itchy spots, similar to the rash of measles, which starts on the limbs and sometimes on the face and the rest of the body.
Signs of blood clot include sudden weakness or numbness in one side or part of your body, pain and tightness in the chest, stabbing pain when you breathe, dizziness or fainting, coughing for no apparent reason, pain or swelling in your leg, any sudden changes to your sense of hearing, speech, sense of smell, taste or touch.
Harmful blood clots in a vein or artery for example:
- in a leg or foot (i.e., DVT)
- in a lung (i.e., PE)
- heart attack
- stroke
- mini-stroke or temporary stroke-like symptoms, known as a transient ischaemic attack (TIA)
- blood clots in the liver, stomach/intestine, kidneys, or eye.

Signs of breast cancer include dimpling of the skin, changes in the nipple, any lumps you can see or feel, unusual vaginal bleeding.
Signs of cancer of the cervix include vaginal discharge that smells and/or contains blood, unusual vaginal bleeding, pelvic pain, painful sex.
Signs of severe liver problems include severe pain in your upper abdomen, yellow skin or eyes (jaundice), inflammation of the liver, your whole body starts itching.
These are all very serious side effects. If you have them, you may have had a serious reaction to ETHODROS. You may need urgent medical attention or hospitalisation.
Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:
- tachycardia (fast heartbeat)
- inflammation of vein, vascular disorder, nosebleed, fainting
- enlarged, swollen or twisting veins
- asthma (tightness in the chest, wheezing and difficulty breathing)
- increased blood pressure, decreased blood pressure.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:
Frequent side effects:
- depressive mood, emotional lability (rapid, often exaggerated changes in mood, where strong emotions or feelings (uncontrollable laughing or crying or heightened irritability or temper) occur)
- headache, migraine (throbbing headache, usually affecting one side of the head and often accompanied by nausea, vomiting and sensitivity to light)
- nausea (feeling sick)
- breast pain, menstrual problems, bleeding between periods, thick whitish vaginal discharge, vaginal yeast infection.

Less frequent side effects:
- increased appetite
- anorexia (obsession of what they eat)

- increased potassium level in blood
- decreased sodium level in blood
- fluid retention, changes in body weight
- changes in sexual drive
- nervousness, drowsiness, inability to fall asleep
- failure to experience an orgasm
- dizziness, “pins and needles”, spinning sensation, shaking
- hearing impairment
- dyspepsia (indigestion), flatulence (intestinal gas), gastritis (inflammation of the stomach, symptoms include pain, nausea, vomiting, vomiting blood, blood in the bowel motions), diarrhoea
- enlargement of abdomen (stomach), gastrointestinal disorder, abdominal fullness (due to excessive gas build up in the digestive tract)
- hiatus hernia (protrusion of upper part of stomach into the chest)
- fungal infection in mouth and throat
- constipation, dry mouth
- acne, severe itching, rash, chloasma (discolouration of the skin especially of the face or neck known as “pregnancy patches”), alopecia (hair loss), dermatitis acneiform (skin rash with a flat discoloured area or raised bumps like acne), dry skin, erythema nodosum (skin condition characterised by painful reddish skin nodules), excessive hair growth in a defined area, skin disorder, white markings on skin, contact dermatitis (local skin reaction characterised by skin redness, swelling and itching, pain or burning sensation), light-sensitive skin inflammation, skin nodules
- inflammation of the vagina, breast discharge, breast enlargement, pelvic pain, benign breast lumps, uterine/vaginal bleeding (which usually subsides during continued treatment), genital discharge, hot flushes, painful periods, reduced periods, very heavy periods, vaginal dryness, abnormal cervical smear, decreased interest in sex
- eye disorders, e.g. inflammation of the eyelid/pink eye or red eye, dry eyes
- candidiasis (fungal infection)
- anaemia (decrease in the number of red blood cells), increase in the number of platelets in the blood
- endocrine disorder (problem with the glands that secrete hormones internally into the blood stream)
- abnormally rapid heartbeat
- dull pain in the middle to upper right area of the abdomen, inflammation of the gallbladder (symptoms may include pain in the upper right abdomen, fever, nausea, yellowing of the skin and eyes (jaundice)
- aches and pains, e.g. back pain, limb pain, muscle cramps
- lack of energy, increased sweating, feeling generally unwell.

Frequency not known (cannot be estimated from available data):
- altered mood
- urticaria (nettle rash)
- intolerance to contact lenses.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist

Reporting of side effects:
If you get side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the **“6.04 Adverse Drug Reaction Reporting Form”**, found online under SAHPRA’s publications: https://www.sahpra.org.za/Publications/Index/8.
By reporting side effects, you can help provide more information on the safety of ETHODROS.

5. HOW TO STORE ETHODROS

- Store at or below 25 °C.
- Keep the blister strip in the outer carton until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the carton / blister.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What ETHODROS contains

The active substances in ETHODROS are drospirenone and ethinylestradiol.

24 pink active film-coated tablets:

Each pink active film-coated tablet contains 3 mg drospirenone and 0,02 mg ethinylestradiol.

- The other ingredients are croscarmellose sodium, lactose monohydrate, magnesium stearate, Opadry Pink (containing iron oxide black (E172), iron oxide red (E172), iron oxide yellow (E172), macrogol 3350, polyviniyl alcohol-partial hydrolyzed, talc (E553b), titanium dioxide (E171)), polysorbate 80, povidone and pregelatinised starch.

4 white inactive (placebo) film-coated tablets:

The white inactive film-coated tablets do not contain active substances.

- The other ingredients are lactose (anhydrous), magnesium stearate, Opadry White (containing titanium dioxide (E171), macrogol 3350, polyviniyl alcohol-partial hydrolyzed, talc (E553b)) and povidone.

What ETHODROS looks like and contents of the pack

The active tablets are round, pink film-coated tablets.
The inactive (placebo) tablets are round, plain, white film-coated tablets.
ETHODROS is packed in PVC/PVDC/aluminium foil blister strip, placed in an outer carton. Each blister strip contains 24 pink active film-coated tablets and 4 white placebo film-coated tablets.

- Pack size: 28 tablets.

Holder of certificate of registration

Adcock Ingram Limited
1 New Road,
Erand Gardens,
Midrand, 1685
Customer Care: 0860 ADCOCK / 232625

Marketed by:
United Pharma Marketing (Pty) Ltd

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SKEDULERINGSTATUS
S4

ETHODROS filmbedekte tablette
Elke filmbedekte tablette bevat 3 mg Drospirenoon en 0,02 mg Etinielestradiool.
ETHODROS bevat suiker:
Elke pienk aktiewe tablet bevat 44 mg laktosemonohidraat.
Elke wit onaktiewe (plasebo) tablet bevat 89,5 mg laktose.

Lees hierdie hele voubiljet noukeurig deur voordat u ETHODROS begin neem
- Hou hierdie voubiljet. U sal dit dalk weer moet lees.
- Indien u enige verdere vrae het, raadpleeg u dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer.
- ETHODROS is aan u persoonlik voorgeskryf en u moet nie u medisyne met ander mense deel nie. Dit kan hulle benadeel, selfs al ervaar hul dieselfde simptome as u.

Wat in hierdie voubiljet is
1. Wat is ETHODROS en waarvoor word dit gebruik
2. Wat u moet weet voordat u ETHODROS neem
3. Hoe om ETHODROS te neem
4. Moontlike newe-effekte
5. Hoe om ETHODROS te bêre
6. Inhoud van die verpakking en ander inligting

1. WAT ETHODROS IS EN WAARVOOR WORD DIT GEBRUIK
ETHODROS is 'n gekombineerde orale voorbehoedmiddel ("die gekombineerde pil") en word gebruik om swangerskap te voorkom. Dit bestaan uit 24 pienk aktiewe tablette met 'n klein hoeveelheid van twee verskillende vroulike hormone, naamlik drospirenoon (3 mg) en etinielestradiool (0,02 mg), en 4 wit onaktiewe (placebo) tablette.

Dit kan ook gebruik word om matige aknee en premenstruele disforiese versteuring te behandel ('n gesondheidsprobleem wat soortgelyk is aan premenstruele sindroom (PMS), wat ernstige depressie, prikkelbaarheid of angs voor menstruasie by vroue veroorsaak).

2. WAT U MOET WEET VOORDAT U ETHODROS NEEM
Voordat u ETHODROS begin gebruik, moet u die inligting oor bloedklonte hieronder lees. Dit is veral belangrik om die simptome van 'n bloedklont te lees, sien ***Bloedklonte*** hieronder.

Voordat u ETHODROS kan begin neem, sal u dokter u 'n paar vrae vra oor u persoonlike geskiedenis van u gesondheid en dié van u naasbestaandes. Die dokter sal ook u bloeddruk meet en, afhangende van u persoonlike situasie, ook 'n paar ander toetse uitvoer.

In hierdie voubiljet word verskeie situasies beskryf waarin u die gebruik van ETHODROS moet staak, of waar die betroubaarheid van ETHODROS verminder kan word. In sulke situasies moet u óf nie seks hê nie, óf u moet ekstra nie-hormonale voorbehoedmaatreëls tref, byvoorbeeld 'n kondoom of 'n ander versperringsmetode gebruik. Moenie ritme- of temperatuurmetodes gebruik nie. Hierdie metodes kan onbetroubaar wees omdat ETHODROS die maandelikse veranderinge van liggaamstemperatuur en servikale slym verander.

ETHODROS beskerm nie teen MIV-infeksie (VIGS) of enige ander seksueel oordraagbare siekte nie.

Moenie ETHODROS neem nie:
Moenie ETHODROS neem indien u aan enige van die onderstaande toestande lei nie. indien u wel enige van die toestande hieronder het, moet u u dokter inlig. U dokter sal met u bespreek watter ander vorm van geboortebeperking meer gepas sal wees.

- indien u hipersensitief (allergies) is vir etinielestradiool, drospirenoon of enige van die ander bestanddele van ETHODROS (gelys in afdeling 6). Dit kan jeukerigheid, veluitslag of swelling veroorsaak.
- indien u 'n bloedklont in 'n bloedvat van u been (diep-veneuse trombose, DVT), u longe (longembolus, LE) of ander organe het (of al ooit gehad het).
- indien u weet u het 'n afwyking wat u bloedstolling beïnvloed – byvoorbeeld proteïen C-tekort, proteïen S-tekort, antitrombien-III-tekort, geaktiveerde proteïen C-weerstand (Faktor V Leiden) of antifosfolipied-teenliggaampies (antikardiolipien-teenliggaampies, lupus antikoagulant).
- indien u 'n operasie benodig of indien u vir 'n lang tyd nie op u voete is nie.
- indien u al ooit 'n hartaanval of beroerte gehad het.
- indien u angina pectoris het (of al ooit gehad het) ('n toestand wat erge borspyn veroorsaak en 'n eerste teken van 'n hartaanval kan wees) of verbygaande iskemiese aanval (TIA – tydelike beroerte simptome).
- Indien u enige van die volgende siektes het wat u risiko van 'n klont in die are kan verhoog:
  - ernstige diabetes met bloedvatskade
  - baie hoë bloeddruk
  - 'n baie hoë vlak van vet in die bloed (cholesterol of trigliseriede)
  - 'n toestand bekend indien hiperhomosisteïnemie (hoë vlak van homosisteïen in bloed wat kan lei tot bloedklonte in u bloedvate).
- indien u ooit migraine gehad het wat gepaard gaan met visuele simptome, spraakgestremdheid of swakheid of gevoelloosheid in enige deel van u liggaam.
- indien u lewersiekte het (of ooit gehad het) en u lewerfunksie is steeds nie normaal nie.
- indien u niere nie goed werk nie (nierversaking).
- indien u 'n gewas in die lewer het (of ooit gehad het).
- indien u het (of ooit gehad het), of indien u vermoed word dat u borskanker of kanker van die geslagsorgane het.
- indien u enige onverklaarbare bloeding uit die vagina het.
- indien u swanger is of u dink u is dalk swanger.
- indien u medisyne neem wat ombitasvir/paritaprevir/ritonavir en dasabuvir bevat.

Waarskuwings en voorsorgmaatreëls
Wanneer moet u, u dokter kontak?
Soek dringende mediese hulp:

- indien u moontlike tekens van 'n bloedklont opmerk wat kan beteken dat u ly aan 'n bloedklont in die been (d.i. diep-veneuse trombose), 'n bloedklont in die long (d.i. ‘n longembolus), 'n hartaanval of 'n beroerte (sien *Bloedklonte* afdeling hieronder).

Vir 'n beskrywing van die simptome van hierdie ernstige newe-effekte, sien asseblief *Hoe om 'n bloedklont te herken*.

Wees veral versigtig met ETHODROS
Raapleeg u dokter voordat u ETHODROS neem. In sommige situasies moet u veral versigtig wees terwyl u ETHODROS of enige ander kombinasiepil gebruik, en u dokter moet u gereeld ondersoek. Indien die toestand ontwikkel, of erger word terwyl u ETHODROS gebruik, moet u ook u dokter inig.

- indien u rook.
- indien u oorgewig is.
- indien 'n nabye familielid borskanker het, of ooit gehad het.
- indien 'n nabye familielid ooit op jong ouderdom beroerte of hartaanval gehad het.

- indien u 'n siekte van die lewer of die galblaas het.
- indien u diabetes het.
- indien u hoë bloeddruk het.
- indien u probleme met u hart het (klepversteuring).
- indien u depressie het.
- indien u Crohn se siekte of ulseratiewe kolitis (chroniese inflammatoriese dermsiekte) het.
- indien u hemolitiese uremiese sindroom het (HUS – 'n versteuring van bloedstolling wat versaking van die niere veroorsaak).
- indien u sekelsel-anemie het ('n oorerflike siekte van die rooibloedselle).
- indien u epilepsie het.
- Indien u siekte van immuunstelsel genaamd sistemiese lupus eritematose het.
- indien u verhoogde vlakke van vet in die bloed het (hipertrigliseridemie), of 'n positiewe familiegeskiedenis vir hierdie toestand het. Hipertrigliseridemie word geassosieer met 'n verhoogde risiko om pankreatitis te ontwikkel (ontsteking van die pankreas, simptome sluit in erge pyn in die boonste maag, dikwels met naarheid en braking).
- Indien u pas geboorte geskenk het, het u 'n groter risiko vir bloedklonte. U moet u dokter vra hoe gou na u bevalling u ETHODROS kan begin neem.
- indien u 'n ontsteking in die are onder die vel het (oppervlakkige tromboflebitis).
- indien u spatare het.
- indien u 'n siekte het wat die eerste keer tydens swangerskap of vroeëre gebruik van geslagshormone verskyn het (byvoorbeeld gehoorverlies, 'n bloedsiekte genaamd porfirie, vergeling van die vel of oë (geelsug), jeuk van die hele liggaam (pruritus), veluitslag met blase tydens swangerskap (swangerskap-herpes), 'n senuweesiekte wat skielike bewegings van die liggaam veroorsaak (Sydenham se chorea).
- indien u al ooit 'n verkleuring van die vel gehad het, veral op die gesig of nek bekend as "swangerskap kolle" (chloasma). Indien wel, vermy direkte sonlig of ultraviolet lig.
- Indien u oorerflike angio-edeem het, kan produkte wat estrogeen bevat die simptome veroorsaak of vererger. U moet u dokter onmiddellik raadpleeg indien u simptome van angio-edeem ervaar, soos geswelde gesig, tong en/of keel en/of sukkel om te sluk of galbulte tesame met moeilike asemhaling.
- indien u verhoogde kaliumserumvlakke het.

Bloedklonte
Die gebruik van 'n gekombineerde hormonale voorbehoedmiddel soos ETHODROS verhoog u risiko om 'n bloedklont te ontwikkel, in vergelyking met geen gebruik daarvan nie. In seldsame gevalle kan 'n bloedklont vate blokkeer en ernstige probleme veroorsaak.
Bloedklonte kan ontwikkel
- in are (genoem 'n "veneuse trombose", "veneuse trombo-embolus" of VTE)
- in die are (genoem 'n "arteriële trombose", "arteriële trombo-embolus" of ATE).

Herstel van bloedklonte is nie altyd volledig nie. Daar kan selde ernstige blywende gevolge wees of, baie selde, kan dit dodelik wees.

Dit is belangrik om te onthou dat die algehele risiko van 'n skadelike bloedklont as gevolg van ETHODROS klein is.

Hoe om 'n bloedklont te herken
Soek dringende mediese hulp indien u enige van die volgende tekens of simptome opmerk.

Ervaar u enige van hierdie tekens?	**Waaraan ly u moontlik?**
• swelling van een been of langs 'n aar in die been of voet, veral wanneer dit gepaard gaan met: - pyn of teerheid in die been wat slegs	Diep veneuse trombose

gevoel kan word wanneer u staan of loop - verhoogde warmte in die aangetaste been - verandering in kleur van die vel op die been, byvoorbeeld bleek, rooi of blou.	
• skielike onverklaarbare asemloosheid of vinnige asemhaling. • skielike hoes sonder 'n duidelike oorsaak, met bloed wat moontlik ophoes word. • skerp borspyn wat kan toeneem met diep asemhaling. • erge lighoofdigheid of duiseligheid. • vinnige of onreëlmatige hartklop. Indien u onseker is, raaadpleeg 'n dokter, aangesien sommige van hierdie simptome soos hoes of kortasem verwar kan word met 'n minder ernstige toestand soos 'n lugweginfeksie (bv. ‘n “verkoue”)	Pulmonêre embolus
Simptome kom meestal in een oog voor: • onmiddellike verlies van visie of • pynlose versteuring van visie wat kan vererger tot verlies van visie.	Retinale veneuse trombose (bloedklont in die oog)
• borspyn, ongemak, drukking, swaar-gevoel. • sensasie van drukking of volheid in die bors, arm of onder die borsbeen. • volheid, slegte spysvertering of verstikkende gevoel. • ongemak in die bolyf wat na die rug, kakebeen, keel, arm en maag uitstraal. • sweet, naarheid, braking of duiseligheid. • uiterste swakheid, angs of kortasem. • vinnige of onreëlmatige hartklop.	Hartaanval
• skielike swakheid of gevoelloosheid van die gesig, arm of been, veral aan die een kant van die liggaam. • skielike verwarring, probleme om te praat of te verstaan. • skielike probleme om met een of albei oë te sien. • skielike probleme met loop, duiseligheid, verlies aan balans of koördinasie. • skielike, ernstige of langdurige hoofpyn sonder enige bekende oorsaak. • verlies van bewussyn of floute met of sonder ‘n stuipaanval. Soms kan die simptome van beroerte van korte duur wees met 'n byna onmiddellike en volkome herstel, maar u moet steeds dringende mediese hulp soek, aangesien u die risiko van nog 'n beroerte kan hê.	Beroerte
• swelling en effense blou verkleuring van 'n	Bloedklonte blokkeer ander bloedvate.

ledemaat. • erge pyn in u maag (akute buik).	

Bloedklonte in 'n aar of slagaar
Wat kan gebeur indien 'n bloedklont in 'n aar vorm?
- Die gebruik van gekombineerde hormonale voorbehoedmiddels hou verband met 'n toename in die risiko van bloedklonte in die aar (veneuse trombose). Hierdie newe-effekte is egter skaars. Dit kom mees algemeen voor in die eerste jaar van gebruik van 'n gekombineerde hormonale voorbehoedmiddel.
- Indien 'n bloedklont in 'n aar in die been of voet vorm, kan dit 'n diep-veneuse trombose (DVT) veroorsaak.
- Indien 'n bloedklont van die been wegbeweeg en in die long vassit, kan dit 'n longembolus veroorsaak.
- Baie selde sal 'n klont in 'n aar in 'n ander orgaan, soos die oog, vorm (retinale trombose).

Wat kan gebeur indien 'n bloedklont in 'n slagaar vorm?
Soos 'n bloedklont in 'n aar, kan 'n klont in 'n slagaar ernstige probleme veroorsaak.
Dit kan byvoorbeeld 'n hartaanval of 'n beroerte veroorsaak.

Wanneer is die risiko om 'n bloedklont in 'n aar te ontwikkel, die hoogste?
Die risiko om 'n bloedklont in 'n aar te ontwikkel, is die hoogste gedurende die eerste jaar tydens die eerste gebruik van 'n gekombineerde hormonale voorbehoedmiddel. Die risiko kan ook hoër wees indien u na 'n rusperiode van 4 weke of langer weer 'n gekombineerde hormonale voorbehoedmiddel (dieselfde produk of 'n ander produk) neem.

Na die eerste jaar word die risiko kleiner, maar is altyd effens hoër as wanneer u nie 'n gekombineerde hormonale voorbehoedmiddel gebruik nie.

Wanneer u die gebruik van ETHODROS staak, keer u risiko van 'n bloedklont terug na normaal binne 'n paar weke.

Faktore wat u risiko vir 'n bloedklont in 'n slagaar / aar verhoog
Dit is belangrik om daarop te let dat die risiko van 'n hartaanval of beroerte as gevolg van die gebruik van ETHODROS baie klein is, maar kan toeneem:
- met toenemende ouderdom (ouer as ongeveer 35 jaar).
- indien u rook. Wanneer u 'n gekombineerde hormonale voorbehoedmiddel soos ETHODROS gebruik, word u aangeraai om op te hou rook. indien u nie kan ophou rook nie en ouer as 35 jaar is, kan u dokter u aanraai om 'n ander tipe voorbehoedmiddel te gebruik.
- indien u baie oorgewig is (liggaamsmassa-indeks of LMI van meer as 30 kg/m^2);
- indien u hoë bloeddruk het.
- indien 'n lid van u onmiddellike familie op 'n jong ouderdom (jonger as ongeveer 50 jaar) 'n hartaanval of beroerte gehad het. In hierdie geval kan u ook 'n groter risiko hê om 'n hartaanval of beroerte te kry.
- indien u, of iemand in u onmiddellike familie, 'n hoë vlak van vet in die bloed het (cholesterol of trigliseriede).
- indien u migraines kry, veral migraines met aura.
- indien u 'n probleem met u hart het (klepversteuring, versteuring van die ritme wat atriale fibrillasie genoem word).
- indien u diabetes het.
- indien een van u onmiddellike familie op 'n jong ouderdom 'n bloedklont in die been, long of ander orgaan gehad het (bv. jonger as ongeveer 50 jaar). In hierdie geval kan u 'n oorerflike bloedstollingsversteuring hê.
- indien u 'n operasie moet ondergaan, of indien u vir 'n lang tyd nie op u voete gaan wees

nie as gevolg van 'n besering of siekte, of u het u been in gips. Die gebruik van ETHODROS moet dalk 'n paar weke voor die operasie gestaak word, of terwyl u minder beweeglik is. Indien u ETHODROS moet staak, vra u dokter wanneer u dit weer kan begin gebruik.
- indien u minder as 'n paar weke gelede geboorte gegee het.

Lugreise (> 4 ure) kan u risiko van 'n bloedklont tydelik verhoog, veral indien u van die ander faktore wat gelys word, het.

Indien u meer as een van hierdie toestande het, of indien enige van hulle besonder ernstig is, kan die risiko om 'n bloedklont te ontwikkel selfs meer verhoog word.

Indien enige van die bogenoemde toestande verander terwyl u ETHODROS gebruik, byvoorbeeld u begin rook, 'n nabye familielid ervaar 'n trombose sonder bekende rede of u tel baie gewig op, raadpleeg u dokter.

Kanker
Borskanker is effens meer algemeen aangemeld by vroue wat kombinasiepille gebruik, maar dit is nie bekend of dit deur die behandeling veroorsaak word nie. Dit kan, byvoorbeeld, wees dat meer gewasse by vroue op kombinasiepille opgespoor word, omdat hulle meer gereeld deur hul dokter ondersoek word. Die voorkoms van borsgewasse word geleidelik minder nadat die kombinasie hormonale voorbehoedmiddels gestaak is. Dit is belangrik om gereeld u borste na te gaan en u moet u dokter kontak indien u enige knop voel.

In seldsame gevalle is nie-kwaadaardige lewergewasse, en in nog minder gevalle kwaadaardige lewergewasse by pil-gebruikers aangemeld. Kontak u dokter indien u buitengewoon erge maagpyn het.

Psigiatriese afwykings
Sommige vroue wat hormonale voorbehoedmiddels gebruik, insluitend drospirenoon / etiniel-estradiol, het depressie of depressiewe buie aangemeld. Depressie kan ernstig wees en kan soms tot selfdoodgedagtes lei. Indien u gemoedsveranderinge en depressiewe simptome ervaar, kontak u dokter vir verdere mediese advies so gou as moontlik.

Bloeding tussen menstuasie-periodes
Gedurende die eerste paar maande wat u ETHODROS neem, kan u onverwagte bloeding ervaar (bloeding buite die 4 wit onaktiewe (plasebo) tablet-dae). Indien hierdie bloeding langer as 'n paar maande voorkom, of indien dit na 'n paar maande begin, moet u dokter uitvind wat verkeerd is.

Wat u moet doen indien geen bloeding voorkom gedurende die 4 wit onaktiewe (plasebo) tablet-dae nie
Indien u al die tablette korrek geneem het, nie braking of ernstige diarree gehad het nie, en u het geen ander medisyne geneem nie, is dit hoogs onwaarskynlik dat u swanger is.

Indien die verwagte bloeding twee keer agtereenvolgens nie plaasvind nie, kan u dalk swanger wees. Kontak u dokter dadelik. Begin eers die volgende strook indien u seker is dat u nie swanger is nie.

Laboratoriumtoetse
Indien u 'n bloedtoets benodig, lig u dokter of die laboratoriumpersoneel in dat u die pil neem, want hormonale voorbehoedmiddels kan die resultate van sommige toetse beïnvloed.

Kinders en adolessente
ETHODROS is nie bedoel vir gebruik by vroue wie se menstruele siklus nog nie begin het nie.

Ander medisyne en ETHODROS
Lig altyd u gesondheidsorgverskaffer in indien u enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in.)

Sommige medisyne
- kan 'n invloed hê op die bloedvlakke van ETHODROS
- kan dit minder effektief maak om swangerskap te voorkom
- kan onverwagte bloeding veroorsaak.

Dit sluit medisyne in wat gebruik word vir die behandeling van:
- epilepsie (bv. primidoon, fenitoïen, barbiturate, karbamasepien, okskarbasepien, topiramaat, felbamaat)
- tuberkulose (bv. rifampisien)
- MIV- en hepatitis C-virusinfeksies (sogenaamde protease-inhibeerders en nie-nukleosied omgekeerde transkriptase-remmers soos ritonavir, nevirapien, efavirens)
- swaminfeksies (bv. griseofulvien, ketokonasool)
- artritis, artrose (etoricoksib)
- hoë bloeddruk (bosentaan, angiotensien-II-reseptor antagoniste, kaliumbesparende diuretika en aldosteroonantagoniste)
- die kruiemiddel “St. John's wort” (gebruik om depressie te behandel)
- antibiotika soos penisillien, tetrasiklien (gebruik om bakteriële infeksies te behandel).

ETHODROS kan die effek van ander medisyne beïnvloed, bv.
- medisyne wat siklosporien bevat (gebruik vir die behandeling van rumatoïede artritis)
- die antiëpileptiese middel lamotrigien (dit kan lei tot 'n verhoogde frekwensie van stuipaanvalle)
- teofillien (word gebruik om asemhalingsprobleme te behandel)
- tisanidien (word gebruik om spierpyn en / of spierkrampe te behandel).

Moenie ETHODROS gebruik indien u hepatitis C het en medisyne gebruik wat ombitasvir / paritaprevir / ritonavir en dasabuvir bevat nie, aangesien dit 'n toename in lewerfunksie-bloedtoetsresultate kan veroorsaak (toename in ALT-lewerensiem). U dokter sal 'n ander tipe voorbehoedmiddel voorskryf voor die aanvang van die behandeling met hierdie medisyne. Gebruik van ETHODROS kan ongeveer 2 weke na voltooiing van hierdie behandeling weer begin word. Sien afdeling "Moenie ETHODROS gebruik nie".

ETHODROS saam met kos en drank
ETHODROS kan met of sonder kos geneem word, indien nodig, met 'n klein hoeveelheid water.

Swangerskap en borsvoeding
Indien u swanger is of borsvoed, dink u mag swanger wees, of van plan is om 'n baba te hê, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat u hierdie medisyne neem.

Swangerskap
Indien u swanger is, moet u nie ETHODROS neem nie. Indien u swanger raak terwyl u ETHODROS neem, moet u dadelik die gebruik daarvan staak en u dokter kontak. Indien u swanger wil raak, kan u enige tyd ophou om ETHODROS te neem.

Borsvoeding
Die gebruik van ETHODROS word nie aanbeveel tydens borsvoeding nie. Indien u die pil wil neem terwyl u borsvoed, moet u dokter gekontak word.

Bestuur en gebruik masjinerie
Daar is geen inligting wat daarop dui dat die gebruik van ETHODROS bestuur van ‘n voertuig of die gebruik van masjinerie beïnvloed nie, maar indien u duiseligheid of interne of eksterne spin-sensasie ervaar, moenie aan hierdie aktiwiteite deelneem nie.

ETHODROS bevat laktose en laktosemonohidraat
Indien u dokter u ingelig het dat u 'n onverdraagsaamheid teenoor sommige suikers het, kontak u dokter voordat u ETHODROS neem.

ETHODROS bevat natrium
ETHODROS bevat minder as 1 mmol natrium (23 mg) per tablet, dit wil sê in wese natriumvry.

3. Hoe om ETHODROS te neem

Moenie medisyne wat aan u voorgeskryf is, met enige ander persoon deel nie.
Neem altyd ETHODROS presies soos u dokter of apteker u ingelig het. Raadpleeg u dokter of apteker indien u nie seker is nie.

Neem ETHODROS elke dag vir 28 dae
ETHODROS kom in 'n stulpstrook wat 24 pienk aktiewe filmbedekte tablette en 4 wit onaktiewe (plasebo) filmbedekte tablette bevat, elk gemerk met 'n dag van die week.

Neem u tablet elke dag op dieselfde tyd.
- Begin deur 'n tablet gemerk met die korrekte dag van die week te neem.
- Volg die rigting van die pyle op die stulpstrook. Neem een tablet elke dag, totdat u al 24 pienk aktiewe tablette gebruik het.
- Sluk elke tablet heel, met water indien nodig. Moenie die tablet kou nie.

Neem dan vier wit onaktiewe (plasebo) tablette
Nadat u al 24 pienk aktiewe tablette in die stulpstrook geneem het, het u 4 dae waartydens u die wit onaktiewe (plasebo) tablette neem. Binne 'n paar dae nadat u die wit onaktiewe (plasebo) tablette van die stulpstrook begin het, sal u onttrekkingsbloeding, soos 'n menstruasie, hê. Hierdie bloeding mag dalk nie verby wees voordat die volgende pakkie begin word nie.

Begin om u volgende stulpstrook ETHODROS te neem na die 4 dae van wit onaktiewe (plasebo) tablette – selfs al bloei u nog steeds. Begin altyd betyds met die nuwe stulpstrook. U hoef nie ekstra voorbehoeding te gebruik tydens hierdie 4 wit onaktiewe tablet dae nie, solank u die tablette korrek geneem het.

Wanneer kan u met die eerste stulpstrook begin?
Indien u nie 'n voorbehoedmiddel met hormone in die vorige maand gebruik het nie
Begin met ETHODROS op die eerste dag van die siklus (dit is, die eerste dag van u menstruasie). Indien u ETHODROS op die eerste dag van u menstruasie begin, word u dadelik beskerm teen swangerskap. U kan ook op dag 2 – 5 van die siklus begin, maar dan moet u ekstra beskermende maatreëls (byvoorbeeld 'n kondoom) vir die eerste 7 dae gebruik.

Verander van gebruik van 'n gekombineerde hormonale voorbehoedmiddel, of gekombineerde voorbehoedende vaginale ring of plakker
U kan ETHODROS verkieslik begin op die dag ná die laaste aktiewe tablet van u vorige pil (die laaste tablet wat die aktiewe bestanddele bevat), maar op die laatste, op die dag na die

onaktiewe tablet-dae van u vorige orale voorbehoedmiddel eindig (of na die laaste onaktiewe tablet van u vorige orale voorbehoedmiddel). Wanneer u van 'n gekombineerde voorbehoedende vaginale ring of plakker verander, volg die advies van u dokter.

Verander van 'n progestogeen-alleen-metode (progestogeen-alleen pil, inspuiting, inplanting of 'n progestogeen-vrystellende intra-uteriene stelsel (IUS))
U kan enige dag oorskakel van die minipil (van 'n inplanting of 'n IUS op die dag van die verwydering daarvan, van 'n inspuiting, wanneer die volgende inspuiting benodig sou wees), maar in al hierdie gevalle, gebruik ekstra beskermingsmaatreëls (byvoorbeeld 'n kondoom) vir die eerste 7 dae van die neem van ETHODROS.

Na 'n miskraam of aborsie
Indien u 'n miskraam of aborsie gedurende die eerste drie maande van swangerskap gehad het, kan u dokter u inlig om dadelik ETHODROS te begin neem. Dit beteken dat u voorbehoedingsbeskerming met u eerste pil sal hê.

Na miskraam in die tweede 3 maande of na geboorte van 'n baba
U kan ETHODROS begin neem tussen 21 en 28 dae ná die geboorte van 'n baba of ‘n miskraam in die tweede 3 maande gehad het. Indien u later as dag 28 begin, gebruik 'n sogenaamde versperringsmetode (byvoorbeeld 'n kondoom) gedurende die eerste sewe dae van gebruik van ETHODROS.
Indien u, nadat u 'n baba gehad het, seks gehad het voordat u (weer) met ETHODROS begin het, moet u eers seker wees dat u nie swanger is nie, of wag tot u volgende menstruasie.

Indien u borsvoed en ETHODROS wil begin gebruik nadat u 'n baba gehad het
Die gebruik van ETHODRO word oor die algemeen nie aanbeveel wanneer 'n vrou borsvoed nie. Indien u die pil wil neem terwyl u borsvoed, moet u dokter gekontak word.

Indien u meer ETHODROS neem indien wat u moes
In die geval van oordosering, raadpleeg u dokter of apteker sonder versuim. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifhulpsentrum.
Daar is geen berigte van ernstige skadelike gevolge van die neem van te veel ETHODROS tablette.
Indien u verskeie tablette gelyktydig neem, kan u naar voel of braak of u kan uit die vagina bloei. Selfs meisies wat nog nie begin menstrueer het nie, maar per ongeluk ETHODROS geneem het, kan sulke bloeding ervaar.
Indien u te veel ETHODROS tablette geneem het, of u ontdek dat 'n kind 'n paar geneem het, raadpleeg u dokter of apteker vir raad.

Indien u vergeet om ETHODROS te neem
- Indien u minder as 12 uur laat is om 'n pienk aktiewe tablet te neem, word die beskerming teen swangerskap nie verminder nie. Neem die tablet sodra u onthou en neem die volgende tablet op die gewone tyd.
- Indien u meer as 12 uur laat is om 'n pienk aktiewe tablet te neem, kan die beskerming teen swangerskap verminder word. Hoe groter die aantal tablette wat u vergeet het, hoe groter is die risiko om swanger te raak.

Die risiko van onvolledige beskerming teen swangerskap is die grootste indien u 'n pienk aktiewe tablet aan die begin of aan die einde van die stulpstrook vergeet. Daarom moet u by die volgende reëls hou:
- *Meer as een tablet vergeet in hierdie stulpstrook*

Kontak u dokter.

- *Een tablet vergeet tussen dae 1 – 7*

Neem die vergete tablet sodra u onthou, selfs al beteken dit dat u twee tablette op dieselfde tyd moet neem. Gaan voort om die tablette op die gewone tyd te neem en gebruik ekstra voorsorgmaatreëls vir die volgende 7 dae, byvoorbeeld 'n kondoom. Indien u seks gehad het in die week voordat u die tablet vergeet het, moet u besef dat daar 'n risiko van swangerskap is. Kontak in daardie geval u dokter.

- *Een tablet vergeet tussen dae 8 – 14*

Neem die vergete tablet sodra u onthou, selfs al beteken dit dat u twee tablette op dieselfde tyd moet neem. Gaan voort om die tablette op die gewone tyd te neem. Die beskerming teen swangerskap word nie verminder nie, en u hoef nie ekstra voorsorgmaatreëls te tref nie. Indien dit egter nie die geval is nie, of indien u meer as 1 tablet gemis het, sal u ekstra voorsorgmaatreëls vir 7 dae moet gebruik.

- *Een tablet vergeet tussen dae 15 – 24*

U kan kies tussen twee moontlikhede. Indien u, in die 7 dae voor die eerste oorgeslaande tablet, alle tablette korrek geneem het. Indien dit nie die geval is nie, moet u die eerste van hierdie twee opsies volg, en ook ekstra voorsorgmaatreëls vir die volgende 7 dae gebruik.

1. Neem die vergete tablet sodra u onthou, selfs al beteken dit dat u twee tablette op dieselfde tyd moet neem. Gaan voort om die tablette op die gewone tyd te neem. In plaas daarvan om 4 onaktiewe tablette te neem, begin die volgende stulpstrook sodra u die laaste tablet geneem het. Heel waarskynlik sal u 'n menstruasie aan die einde van die tweede stulpstrook hê – maar u kan ook ligte of menstruasie-agtige bloeding tydens die tweede stulpstrook hê.

2. U kan ook die tablette staak en direk na die onaktiewe tablet-periode gaan (teken die dag aan waarop u die tablet vergeet het). Indien u 'n nuwe stulpstrook wil begin gebruik op die dag wat u altyd begin, verminder die onaktiewe tablet-tydperk tot minder as 4 dae.

Indien u een van hierdie twee aanbevelings volg, sal u beskermd bly teen swangerskap.

Indien u enige van die tablette in 'n stulpstrook vergeet het, en u het nie 'n bloeding gedurende die eerste onaktiewe tablet-periode nie, kan u swanger wees. U moet u dokter kontak voordat u met die volgende stulpstrook begin.

Wat om te doen in die geval van braking of erge diarree

Indien u binne 3 – 4 uur na die neem van 'n tablet braak of u het ernstige diarree, is daar 'n risiko dat die aktiewe bestanddele in die pil nie ten volle deur u liggaam opgeneem sal word nie. Die situasie is amper dieselfde as om 'n tablet te vergeet. Na braking of diarree moet u so gou as moontlik nog 'n tablet uit 'n ander pakkie neem. Indien moontlik, neem dit binne 12 uur nadat u normaalweg u pil neem. Indien dit nie moontlik is nie, of 12 uur het verloop, moet u die advies volg wat gegee word onder "Indien u vergeet om ETHODROS te neem".

Vertraag u menstruasie: wat u moet weet

Selfs al word dit nie aanbeveel nie, kan u menstruasie vertraag deur die 4 onaktiewe wit tablette oor te slaan en reguit na 'n nuwe stulpstrook ETHODROS te gaan en dit te voltooi. U kan ligte of menstruasie-agtige bloeding ervaar terwyl u hierdie tweede stulpstrook gebruik. Na die gewone onaktiewe tablet-tydperk van 4 dae begin u volgende stulpstrook.

Dit is raadsaam om u dokter te raadpleeg vir advies voordat u besluit om u menstruasie uit te stel.

Verander die eerste dag van u menstruasie: wat u moet weet

Indien u die tablette volgens die instruksies neem, sal u menstruasie gedurende die 4 onaktiewe wit tablet dae begin. Indien u hierdie dag moet verander, maak die onaktiewe wit

tablet-tydperk korter – (maar nooit langer nie – 4 dae is die maksimum). Byvoorbeeld, indien u die 4 onaktiewe wit tablet-dae op 'n Vrydag begin, en u wil dit verander na 'n Dinsdag (3 dae vroeër), moet u 'n nuwe stulpstrook 3 dae vroeër as gewoonlik begin gebruik. Indien u die onaktiewe tablet-tydperk baie kort maak (byvoorbeeld 3 dae of minder) mag u nie enige bloeding gedurende hierdie tyd hê nie. U kan dan ligte of menstruasie-agtige bloeding ervaar.

Indien u ophou om ETHODROS te neem
U kan die gebruik van ETHODROS staak wanneer u wil. Indien u nie swanger wil raak nie, vra u dokter vir advies oor ander betroubare metodes van geboortebeperking. Indien u swanger wil raak, staak die gebruik van ETHODROS en wag vir 'n menstruasie voordat u probeer om swanger te raak. U sal die verwagte geboortedatum makliker kan bereken.

Indien u enige verdere vrae het oor die gebruik van hierdie produk, raadpleeg u dokter of apteker.

4. MOONTLIKE NEWE-EFFEKTE

ETHODROS kan newe-effekte hê.
Nie alle newe-effekte wat vir ETHODROS aangemeld is, is in hierdie voubiljet ingesluit nie. Indien u algemene gesondheid verswak of indien u enige ongewenste gevolge ervaar terwyl u ETHODROS neem, raadpleeg asseblief u gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, staak die gebruik van ETHODROS enlLig u dokter dadelik in, of gaan na die ongevalle-afdeling by u naaste hospitaal:
Erge allergiese reaksies/hipersensitiwiteitsreaksies: skielike swelling van u gesig, lippe, mond, tong of keel, moeilike asemhaling of lae bloeddruk, wat floute of ineenstorting kan veroorsaak.
Veelvormige Eriteem: ernstige toestand van die vel wat die mond en ander dele van die liggaam kan beïnvloed; simptome sluit in rooi, dikwels jeukerige kolle, soortgelyk aan die uitslag van masels, wat op die ledemate en soms op die gesig en die res van die liggaam begin.
Tekens van bloedklont sluit in skielike swakheid of gevoelloosheid aan die een kant of deel van u liggaam, pyn en styfheid in die bors, steekpyn wanneer u asemhaal, duiseligheid of floute, hoes sonder enige beduidende rede, pyn of swelling in u been, enige skielike veranderinge aan u gehoorsintuig, spraak, reuksintuig, smaak of gevoel.
Skadelike bloedklonte in 'n aar of slagaar byvoorbeeld:
- in 'n been of voet (d.i. DVT)
- in 'n long (d.i. PE)
- hartaanval
- beroerte
- mini-beroerte of tydelike beroerte-tipe simptome, bekend as 'n verbygaande iskemiese aanval (TIA)
- bloedklonte in die lewer, maag/ingewande, niere of oog.

Tekens van borskanker sluit in uitholling van die vel, veranderinge in die tepel, enige knoppe wat u kan sien of voel, ongewone vaginale bloeding.
Tekens van kanker van die serviks sluit in vaginale afskeiding wat sleg ruik en/of bloed bevat, ongewone vaginale bloeding, bekkenpyn, pyn tydens seks.
Tekens van ernstige lewerprobleme sluit in erge pyn in u boonste buik, geel vel of oë (geelsug), ontsteking van die lewer, u hele liggaam begin jeuk.
Hierdie is alles baie ernstige newe-effekte. Indien u dit ervaar, het u dalk 'n ernstige reaksie op ETHODROS gehad. U sal dalk dringende mediese hulp of hospitalisasie nodig hê.
Lig u dokter dadelik in of gaan na die ongevalle-afdeling by u naaste hospitaal indien u enige van die volgende opmerk:
- tagikardie (vinnige hartklop)
- ontsteking van aar, vaskulêre afwyking, neusbloeding, floute

- vergrote, geswelde of draaiende are
- asma (styfheid in die bors, suisende asemhaling en asemhalingsprobleme)
- verhoogde bloeddruk, verlaagde bloeddruk.

Hierdie is alles ernstige newe-effekte. U sal dalk dringend mediese hulp nodig hê.

Lig u dokter in indien u enige van die volgende opmerk:
Algemene newe-effekte:

- depressiewe bui, emosionele onstabiliteit (vinnige, dikwels oordrewe veranderinge in buie, waar sterk emosies of gevoelens (onbeheerbare lag of huil of verhoogde prikkelbaarheid of humeur) voorkom)
- hoofpyn, migraine (kloppende hoofpyn, wat gewoonlik die een kant van die kop aantas en dikwels gepaard gaan met naarheid, braking en sensitiwiteit vir lig)
- naarheid (naar gevoel)
- borspyn, menstruele probleme, bloeding tussen menstruasies, dik witterige vaginale afskeiding, vaginale swaminfeksie.

Minder algemene newe-effekte:

- verhoogde eetlus
- anoreksie (obsessie met wat hulle eet)
- verhoogde kaliumvlak in bloed
- verlaagde natriumvlak in bloed
- vloeistofretensie, veranderinge in liggaamsgewig
- veranderinge in seksuele drang
- senuweeagtigheid, lomerigheid, onvermoë om aan die slaap te raak
- onvermoë om 'n orgasme te ervaar
- duiseligheid, "naalde en spelde", draaiende sensasie, bewerasies
- gehoor-inperking
- dispepsie (slegte spysvertering), winderigheid (dermgas), gastritis (ontsteking van die maag, simptome sluit in pyn, naarheid, braking, braking van bloed, bloed in die stoelgang), diarree
- vergroting van buik (maag), gastro-intestinale versteuring, abdominale volheid (as gevolg van oormatige opbouing van gas in die spysverteringskanaal)
- hiatus breuk (die boonste deel van die maag druk deur na binne die bors)
- swaminfeksie in mond en keel
- hardlywigheid, droë mond
- aknee, erge jeuk, veluitslag, chloasma (verkleuring van die vel veral van die gesig of nek bekend as "swangerskap-kolle"), alopesie (haarverlies), aknee-agtige dermatitis (veluitslag met 'n plat verkleurde area of geswelde knoppe soos aknee), droë vel, nodale eriteem (veltoestand wat gekenmerk word deur pynlike rooierige velknoppies), oormatige haargroei in 'n gedefinieerde area, velafwyking, wit merke op die vel, kontak-dermatitis (lokale velreaksie wat gekenmerk word deur velrooiheid, swelling en jeuk, pyn of brandende sensasie), lig-sensitiewe velontsteking, velknoppies
- ontsteking van die vagina, bors-afskeiding, bors-vergroting, bekkenpyn, nie-kwaadaardige borsknoppe, baarmoeder/vaginale bloeding (wat gewoonlik opklaar tydens voortgesette behandeling), genitale afskeiding, warm gloede, pynlike menstruasies, verminderde menstruasies, baie swaar menstruasies, vaginale droogheid, abnormale servikale smeer, verminderde belangstelling in seks
- oogafwykings, bv. ontsteking van die ooglid/pienk-oog of rooi-oog, droë oë
- candidiase (swaminfeksie)
- bloedarmoede (afname in die aantal rooibloedselle), toename in die aantal bloedplaatjies in die bloed
- endokriene versteuring (probleem met die kliere wat hormone inwendig in die bloedstroom afskei)
- abnormale vinnige hartklop

- dowwe pyn in die middel- tot regter-boonste area van die buik, ontsteking van die galblaas (simptome kan pyn in die regter-boonste buik, koors, naarheid, vergeling van die vel en oë (geelsug) insluit)
- krampe en pyne, bv. rugpyn, ledemaat-pyn, spierkrampe
- gebrek aan energie, verhoogde sweet, voel oor die algemeen ongesteld.

Frekwensie nie bekend nie (kan nie uit beskikbare data geskat word nie):
- veranderde bui
- urtikaria (brandnetel-uitslag)
- onverdraagsaamheid teenoor kontaklense.

Indien u enige newe-effekte opmerk wat nie in hierdie voubiljet genoem word nie, stel asseblief u dokter of apteker in kennis

Aanmelding van newe-effekte:
Indien u newe-effekte ervaar, raadpleeg u dokter of apteker of verpleegkundige. Dit sluit in enige moontlike newe-effekte wat nie in hierdie voubiljet gelys word nie. U kan ook newe-effekte by SAHPRA aanmeld via die vorm **"6.04 Adverse Drug Reaction Reporting Form",** wat aanlyn gevind word onder SAHPRA se publikasies: https://www.sahpra.org.za/Publications/Index/8.
Deur newe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van ETHODROS te verskaf.

5. HOE OM ETHODROS TE BÊRE
- Bêre teen of benede 25 °C.
- Hou die stulpstrook in die buitenste kartonboksie totdat dit benodig word vir gebruik.
- BÊRE ALLE MEDISYNE BUITE BEREIK VAN KINDERS.
- Moenie gebruik ná die vervaldatum wat op die kartonboksie / stulpstrook gedruk is nie.
- Neem alle ongebruikte medisyne terug na u apteker.
- Moenie ongebruikte medisyne in afvoerpype en rioolstelsels (bv. toilette) weggooi nie.

6. INHOUD VAN DIE VERPAKKING EN ANDER INLIGTING
Wat ETHODROS bevat
Die aktiewe bestanddele in ETHODROS is drospirenoon en etinielestradiool.

24 pienk aktiewe filmbedekte tablette:
Elke pienk aktiewe filmbedekte tablet bevat 3 mg drospirenoon en 0,02 mg etinielestradiool.
- Die ander bestanddele is natriumkruiskarmellose, laktosemonohidraat, magnesiumstearaat, “Opadry” Pienk (bevat ysteroksied-swart (E172), ysteroksied-rooi (E172), ysteroksied-geel (E172), makrogol 3350, gedeeltelik-gehidroliseerde polivinielalkohol, talk (E553b), titaniumdioksied (E171)), polisorbaat 80, povidoon en vooraf-gegelatiniseerde stysel.

4 wit onaktiewe (plasebo) filmbedekte tablette:
Die wit onaktiewe filmbedekte tablette bevat nie aktiewe bestanddele nie.
- Die ander bestanddele is laktose (watervry), magnesiumstearaat, “Opadry” Wit (bevat titaandioksied (E171), makrogol 3350, gedeeltelik-gehidroliseerde polivinielalkohol, talk (E553b)) en povidoon.

Hoe ETHODROS lyk en inhoud van die verpakking
Die aktiewe tablette is ronde, pienk filmbedekte tablette.
Die onaktiewe (plasebo) tablette is rond, ongemerkte, wit filmbedekte tablette.
ETHODROS is verpak in PVC/PVDC/aluminiumfoelie stulpstrook, geplaas in 'n buitenste kartonboksie. Elke stulpstrook bevat 24 pienk aktiewe filmbedekte tablette en 4 wit plasebo

filmbedekte tablette.
- Verpakkingsgrootte: 28 tablette.

Houer van registrasiesertifikaat
Adcock Ingram Limited
New Road 1
Erand Gardens,
Midrand, 1685
Kliëntediens: 0860 ADCOCK / 232625

Bemark deur:
United Pharma Marketing (Edms) Bpk

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