PROPOSED PATIENT INFOMRATION LEAFLET: DRASIRA

SCHEDULING STATUS: S4

DRASIRA film-coated tablets

Drospirenone (3 mg) and ethinylestradiol (0,02 mg)

Active tablets – contains sugar (lactose monohydrate 44 mg/tablet).

Inactive tablets - contains sugar (lactose monohydrate 89,50 mg/tablet).

Read all of this leaflet carefully before you start taking DRASIRA

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- DRASIRA 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 DRASIRA is and what it is used for
2. What you need to know before you take DRASIRA
3. How to take DRASIRA
4. Possible side effects
5. How to store DRASIRA
6. Contents of the pack and other information

1. What DRASIRA is and what it is used for

DRASIRA is a combined oral contraceptive (“the combined Pill”) and is used to prevent pregnancy. It consists of 24 tablets with a small amount of two different female hormones, namely drospirenone (3 mg) and ethinylestradiol (0,02 mg) and 4 inactive 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 DRASIRA

Before you start taking DRASIRA, you should read the information on blood clots in section 2. It is particularly important to read the symptoms of a blood clot - **see section 2 “Blood clots”.**

Before you can begin taking DRASIRA, 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 taking DRASIRA, or where the reliability of DRASIRA 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 DRASIRA alters the monthly changes of body temperature and cervical mucus.

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

Do not take DRASIRA

Do not take DRASIRA 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 or drospirenone, or any of the other ingredients of DRASIRA. 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.
    - o severe diabetes with blood vessel damage
    - o very high blood pressure
    - o a very high level of fat in the blood (cholesterol or triglycerides)
    - o 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 (renal failure).
- if you have (or have ever had) 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 the medicines 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 go to "How to recognise a blood clot".

Take special care with DRASIRA

Talk to your doctor before taking DRASIRA. In some situations, you need to take special care while using DRASIRA 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 DRASIRA, you should also tell your doctor.

- if you smoke.
- if you are overweight.
- if a close relative has or has ever had breast cancer.

- 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 (hypertriglyceridaemia) or a positive family history for this condition. Hypertriglyceridaemia 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 DRASIRA;
- 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 oestrogens 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 DRASIRA 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 DRASIRA 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 -increased warmth in the affected leg -change in colour of the skin on the leg e.g. turning pale, red or blue	Deep vein thrombosis
-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.	Heart attack

-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.	
-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. -swelling and slight blue discolouration of an extremity. -severe pain in your stomach (acute abdomen) -Blood clots blocking other blood vessels	Stroke

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 DRASIRA 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 DRASIRA is very small but can increase:

- with increasing age (beyond about 35 years).
- **if you smoke**. When using a combined hormonal contraceptive like DRASIRA, 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 30kg/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 DRASIRA may need to be stopped several weeks before surgery or while you are less mobile.

-if you need to stop DRASIRA 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 DRASIRA, 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 abdominal pain.

Psychiatric disorders

Some women using hormonal contraceptives including drospirenone/ethinylestradiol 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 DRASIRA, you may have unexpected bleeding (bleeding outside the 4 inactive 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 inactive 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

DRASIRA is not intended for use in females whose menstrual cycle has not yet started.

Other medicines and DRASIRA

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

<u>Some medicines</u>

-can have an influence on the blood levels of DRASIRA

-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)

DRASIRA 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 DRASIRA 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 medicinal products. DRASIRA can be restarted approximately 2 weeks after completion of this treatment. See section ‘Do not use DRASIRA’

Taking DRASIRA with food and drink:
DRASIRA tablets 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 DRASIRA. If you become pregnant while taking DRASIRA you must stop taking it immediately and contact your doctor. If you want to become pregnant, you can stop taking DRASIRA at any time.

Breastfeeding

Use of DRASIRA 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 DRASIRA affects driving or the use of machines but if you experience dizziness or internal or external spinning sensation do not engage in these activities.

DRASIRA contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking DRASIRA.

3. How to take DRASIRA

Do not share medicines prescribed for you with any other person.

Always take DRASIRA exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Take DRASIRA every day for 28 days

DRASIRA comes in a blister strip containing 24 active pink film-coated tablets and 4 inactive white 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 active pink tablets.
- Swallow each tablet whole, with water if necessary. Do not chew the tablet.

Then have 4 inactive white tablets

After you have taken all 24 active pink tablets in the strip, you have four days when you take the inactive white tablets. Within a few days of starting the inactive white 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 DRASIRA after the four days of inactive tablets even if you are still bleeding. Always start the new strip on time.

You don’t need to use extra contraception during these four inactive white tablet days as long as you have taken your tablets correctly.

When you can start with the first strip?

If you have not used a contraceptive with hormones in the previous month

Begin with DRASIRA on the first day of the cycle (that is, the first day of your period). If you start DRASIRA 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 DRASIRA preferably on the day after the last active pink tablet (the last tablet containing the active substances) of your previous pill, but at the latest on the day after the inactive white tablet days of your previous oral contraceptive finish (or after the last inactive white 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 DRASIRA.

After a miscarriage or an abortion

If you have had a miscarriage or abortion during the first three months of pregnancy, your doctor may tell you to start taking DRASIRA straight away. 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 DRASIRA 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 DRASIRA. If, after having a baby, you have had sex before starting DRASIRA (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 DRASIRA after having a baby

Use of DRASIRA 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 DRASIRA than you should

There are no reports of serious harmful results of taking too many drospirenone 3 mg and ethinylestradiol 0,02 mg 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 this medicine may experience such bleeding.

If you have taken too many DRASIRA tablets, or you discover that a child has taken some, ask your doctor or pharmacist for advice.

If you forget to take DRASIRA

- If you are less than 12 hours late taking a tablet, the protection against pregnancy is not reduced. Take the tablet as soon as you remember and then take the following tablets again at the usual time.
- If you are more than 12 hours late taking a 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 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 2 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 realize 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 2 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 four inactive white 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 white 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 white 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 DRASIRA'.**

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 DRASIRA and finishing it. You may experience light or menstruation-like bleeding while using this second strip. After the usual inactive white 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 white 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 DRASIRA

You can stop taking DRASIRA 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 DRASIRA 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

DRASIRA can have side effects.

Not all side effects reported for DRASIRA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking DRASIRA, please consult your healthcare provider for advice.

If any of the following happens, stop taking DRASIRA 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 they occur, you may have had a serious reaction to DRASIRA. 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 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, 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 characterized 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, pharmacist or nurse.

You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website, or to Cipla Medpro (Pty) Ltd. by e-mail: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free).

By reporting side effects, you can help provide more information on the safety of DRASIRA.

5. How to store DRASIRA

Store all medicines out of reach of children.

Store at or below 25 °C in the original package.

Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What DRASIRA contains

The active substances are drospirenone and ethinylestradiol.

24 active pink film-coated tablets:

Each DRASIRA tablet contains 3 mg of Drospirenone and 0,02 mg of Ethinylestradiol.

4 placebo (inactive) white film-coated tablets:

The tablet does not contain active substances.

The other ingredients are:

Active tablets

Core:

Lactose monohydrate, pregelatinised starch (maize), povidone, sodium croscarmellose, polysorbate 80 and magnesium stearate.

Coating:

Polyvinyl alcohol-partial hydrolysed, titanium dioxide, macrogol, talc, yellow iron oxide, red iron oxide and black iron oxide.

Inactive tablets

Core:

Lactose anhydrous, povidone and magnesium stearate.

Coating:

Polyvinyl alcohol, titanium dioxide, macrogol and talc.

What DRASIRA looks like and contents of the pack

24 Round, pink (active) film-coated tablets.

4 Round, white (inactive) film-coated tablets.

Each carton contains a blister pack of 28 film-coated tablets.

Holder of Certificate of Registration

CIPLA MEDPRO (PTY) LTD.

Building 9

Parc du Cap

Mispel Street

Bellville

7530

Customer Care: 080 222 6662

This leaflet was last revised in

First authorisation: 16 August 2022

Revision: 31 May 2024

Registration number

47/21.8.2/0141

Access to the corresponding Professional Information:

To access corresponding Professional Information, scan the QR Code below.

PLACE HOLDER:

The QR Code to be generated

and included after approval.