PATIENT INFORMATION LEAFLET FOR NESSIFEM

SCHEDULING STATUS:

S3

NESSIFEM 60 µg / 15 µg film-coated tablets

Gestodene / Ethinylestradiol

Contains sugar: each active yellow film-coated tablet contains 57,61 mg lactose monohydrate and each inactive white tablet contains 70,70 mg lactose monohydrate.

Read all of this leaflet carefully before you start taking NESSIFEM

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

1. What NESSIFEM is and what it is used for

NESSIFEM is used to prevent pregnancy.

Each of the 24 yellow tablets contain a small quantity of two different female hormones, called gestodene and ethinylestradiol. The 4 white tablets do not contain active ingredients and are called placebo (inactive) tablets.

Contraceptive pills that contain two hormones are called “combination” pills (COC’s).

Because of the small quantity of hormones NESSIFEM is considered a low-dose contraceptive.

2. What you need to know before you take NESSIFEM

Do not take NESSIFEM:

if you are hypersensitive (allergic) to gestodene or ethinylestradiol, or any of the other ingredients of NESSIFEM (listed in section 6).

Do not use NESSIFEM if you have any of the conditions listed below. If any of these apply to you, tell your doctor before starting NESSIFEM. Your doctor may advise you to use a different type of contraceptive pill or an entirely different (non-hormonal) method of birth control.

- If you have (or have had in the past) blood clots (thrombosis) in a blood vessel of the leg (deep vein thrombosis), lungs (pulmonary embolism) or other organs. (See also the section “The contraceptive pill and thrombosis”);
- if you have (or have had in the past) a disorder of the blood vessels such as a heart attack or a stroke. (See also the section “The contraceptive pill and thrombosis”);
- if you have (or have had in the past) any illness which could lead to a heart attack in the future (for example, angina pectoris which causes serious pain in the chest) or a stroke (for example a temporary or minor stroke without residual effects);
- if you have any illness which could increase the risk of developing a clot in the arteries. This refers to the following illnesses: diabetes with damaged blood vessels, very high blood pressure, very high fat levels in the blood (cholesterol or triglycerides);
- if you have (or have had in the past) cardiovascular disorders: hypertension, coronary disease, valve disorder, heart rhythm disorder;
- if you have (or have ever had) a certain form of migraine (with so called focal neurological symptoms e.g. visual symptoms, speech disability, or weakness or numbness in any part of your body);
- if you have (or have had in the past) a liver illness or jaundice and your liver function is still not normal;
- if you have (or have ever had) a liver tumour;
- if you have (or have ever had), or you suspect you have breast cancer or cancer of the sexual organs;
- if you have vaginal bleeding and the cause is unknown;
- if you are pregnant or think you might be pregnant.

If any of these conditions occur for the first time while using the pill, stop taking it at once and consult your doctor. Use non-hormonal contraceptive measures in the meantime. See “Take special care with NESSIFEM” in the section below.

Warnings and precautions

Take special care with NESSIFEM:

This leaflet describes various situations when you should stop using NESSIFEM or when the effect of NESSIFEM could be reduced. In such situations you should not have sexual intercourse or you should use additional non-hormonal contraceptive precautions, for example a condom or other barrier method. Do not use the rhythm or temperature method. These methods can be unreliable as the pill alters the monthly changes of body temperature and cervical mucus.

NESSIFEM will not protect you against HIV infection (AIDS) or any other sexually transmitted diseases (STI’s) (e.g. chlamydia, genital herpes, genital warts, gonorrhoea, hepatitis B and syphilis). only condoms can protect you from these diseases. Ask your doctor or healthcare provider for advice if you are worried about this.

In some situations, you will have to take special care when taking NESSIFEM or any other combination pill, and your doctor may need to carry out regular checks. If any of the following affects you, tell your doctor before starting to use NESSIFEM. You should also consult your doctor if the following occur or worsen during your use of NESSIFEM:

- If you smoke;
- if you have diabetes;
- if you are overweight;
- if you have high blood pressure;
- if you have a certain heart rhythm disorder or a heart valve disorder;
- if you have inflammation of the veins (phlebitis);
- if you have varicose veins;
- if anyone in your immediate family has had a thrombosis, a heart attack or a stroke;
- if you suffer from migraine;
- if you or someone in your immediate family has or has had high blood levels of cholesterol or triglycerides

(fatty substances);

- if a close family member has or has ever had breast cancer;
- if you have any liver or gallbladder illness;
- if you have visual disturbances;
- if you have Crohn's disease or ulcerative colitis (an inflammatory bowel disease);
- if you have HUS (haemolytic uremic syndrome; a blood illness which damages the kidneys);
- if you have epilepsy (see section: "Other medicines and NESSIFEM");
- if you have SLE (Systemic lupus erythematosus; an illness affecting the immune system);
- if you have an illness which appeared for the first-time during pregnancy or during previous use of sexual hormones; for example, hearing loss, porphyria (a blood disease), gestational herpes (skin rash with blisters during pregnancy), Sydenham's chorea (an illness affecting the nerves, producing involuntary movements);
- if you have or have ever had chloasma (patches of tan/brown skin discolouration, also called the "mask of pregnancy", especially on the face). If you experience this, you have to avoid direct sunlight and ultraviolet rays.

Hormonal contraceptives including NESSIFEM, may cause mood changes and depression, which may be severe. Severe depression is associated with a higher risk of suicidal thoughts/behaviour (e.g. talking about suicide, withdrawing from social contact, having mood swings, being preoccupied with death or violence, feeling hopeless about a situation, increasing use of alcohol/drugs, doing self-destructive things, personality changes) and suicide. If you experience mood changes and depression, contact your doctor for advice.

The contraceptive pill and thrombosis (venous and arterial blood clots)

Venous thrombosis

The use of combination pills, such as NESSIFEM increase the risk of developing venous thrombosis (blood clot in a blood vessel), compared to women who do not take any contraceptive pill.

This increased risk is highest during the first year a combination pill is used. The risk is lower than the chance for the occurrence of a venous thrombosis or lung embolism during pregnancy. The risk during a pregnancy is estimated to be 60 cases per 100,000 pregnancies. In 1 to 2 % of the cases, a venous thrombosis or lung embolism is fatal.

The risk of venous thrombosis or lung embolism occurring with combination pills that contain 30 µg ethinylestradiol and levonorgestrel is approximately 20 cases per 100,000 years of usage.

The risk of developing venous thrombosis when taking NESSIFEM increases:

- If you are overweight;
- if any of your close family members have had blood clots in the leg, lungs (pulmonary embolism) or any other organ at an early age;
- if you must have surgery, or are going to be immobilised for a long time or have suffered a serious accident. It is important to tell your doctor in advance that you are using NESSIFEM as the treatment may have to be stopped. Your doctor will tell you when to start NESSIFEM again. This is usually about two weeks after you are back on your feet;
- if you had recent delivery or second trimester abortion;
- with increasing age.

Arterial thrombosis

The use of combination pills has been linked to an increased risk of developing an arterial blood clot (arterial thrombosis), for example, in the blood vessels of the heart (heart attack) or the brain (stroke).

The risk of developing an arterial blood clot when taking NESSIFEM increases:

with increasing age;

- If you smoke. If you use NESSIFEM it is strongly advised that you quit smoking, especially if you are over 35 years of age;
- if you have high levels of blood cholesterol or triglycerides;
- if you have hyperlipidaemia (elevated levels of lipids in the body);
- if you are overweight;
- if one of your close relatives had a heart attack or stroke at a young age;
- if you have high blood pressure;
- if you have migraines;
- if you have heart problems (valve disorders, changes in your heart rhythm).

Stop taking NESSIFEM and contact your doctor immediately if you notice possible signs of a blood clot,

myocardial infarction or a stroke such as:

- Severe pain and/or swelling in one of your legs;
- severe pain in your abdomen;
- sudden severe pain in the chest which may reach the left arm;
- sudden breathlessness;
- sudden cough without an obvious cause;
- any unusual, severe or long-lasting headache or worsening of migraine;
- partial or complete blindness or double vision;
- difficulty in speaking or inability to speak;
- dizziness or fainting;
- weakness, strange feeling or numbness in any part of the body;
- sudden changes to your hearing, sense of smell, or taste.

The contraceptive pill and cancer

Women who take combination pills have a slightly higher rate of breast cancer. For example, it is possible that more tumours are detected in women who take combination pills because they are examined by their doctor more frequently.

The breast cancer rate reduces gradually after you decide to stop taking combined hormonal contraceptives.

It is important to regularly examine your breasts and go to your doctor if you find any lump.

Benign liver tumours have been found in women who use combined contraceptives in some cases, and also malignant tumours. These tumours may lead to internal bleeding. Go to your doctor if you experience sudden intense abdominal pain.

The most important risk factor for cervical cancer is persistent human papilloma virus infection. Some studies have indicated that long-term use of the pill may further contribute to this increased risk but there continues to be controversy about the extent to which this finding is attributable to other factors, e.g. cervical screening and sexual behaviour, including use of barrier contraceptives.

Bleeding between periods

During the first few months of using NESSIFEM you may bleed unexpectedly (bleeding outside the placebo days). If you experience such bleeding for more than a few months, or they begin after a few months, your

doctor must find the cause.

What you must do if no bleeding occurs during the placebo days

If you have taken all the yellow active tablets correctly, you have not vomited or did not have bad diarrhoea and have not taken any other medication, it is very unlikely you are pregnant.

If you do not have two consecutive periods, you could be pregnant. Contact your doctor immediately. Do not start taking the next pack until you are sure that you are not pregnant.

Regular check-ups

When you are using the contraceptive pill, your doctor will tell you to return for regular check-ups. Contact your doctor immediately:

- If you notice any changes in your own health (see “Do not use NESSIFEM”);
- if you feel a breast lump;
- if you are taking or going to take other medicines (see section: "Other medicines and NESSIFEM");
- if you must have surgery, or are going to be immobilised for a long time. It is important to tell your doctor in advance that you are using NESSIFEM as the treatment may have to be stopped;
- if you have unusual, heavy vaginal bleeding;
- if you forgot to take tablets in the first week of the pack and had sexual intercourse in the 7 days before;
- if you have had diarrhoea;
- if you miss your period twice in a row or suspect you are pregnant (do not start the next pack until told to by your doctor);
- when it is apparent that you have high blood pressure.

Laboratory tests

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

Children and adolescents

NESSIFEM is not for use in girls before menarche (first menstrual bleeding).

Other medicines and NESSIFEM

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

Certain medicines may lower the concentration of oestrogens in the blood. This can lower the effect of the pill. This can lead to a decreased action of the contraceptive pill. Intermenstrual bleeding or spotting and unintentional pregnancies have been reported as a result of this decreased action. These medicines include, among others, antacids (mainly those containing magnesium), laxatives, medicines for the treatment of epilepsy (such as primidone, phenytoin, barbiturates (such as phenobarbitone), carbamazepine, oxcarbazepine, topiramate, felbamate) and tuberculosis (such as rifampicin, rifabutin), antibiotics (such as penicillins, ampicillin, tetracycline, griseofulvin, erythromycin) for the treatment of certain other infections and medicines for HIV infections (ritonavir, nevirapine). Moreover, St. John's Wort (*Hypericum perforatum*) can lower the concentration of oestrogens in the blood. This decrease may continue for approximately two weeks after use. St. John's Wort should therefore not be used at the same time as NESSIFEM.

During treatment with any of these medicines, a barrier method such as a condom should be temporarily used in addition to NESSIFEM, or another method of contraception should be chosen if these medicines are going to be used for prolonged periods.

The barrier method should be used for the duration of the concomitant administration and for 28 days after discontinuation of the medicine. However, if you are taking an antibiotic (excluding rifampicin and griseofulvin), you should use the barrier method until 7 days after completing the course.

If the period during which the barrier method is used is longer than the pills in the NESSIFEM pack last, then the next pack of NESSIFEM should be started without respecting the usual interval in which no tablets are taken.

Certain medicines may increase the concentration of oestrogens in the blood. These medicines include:

- Atorvastatin;
- medicines containing ascorbic acid (vitamin C) and paracetamol;
- indinavir (an antiretroviral);
- fluconazole and voriconazole (antifungals) and troleandomycin (antibiotic).

NESSIFEM may influence the effect of other medicines, e.g.:

- Medicines which prevent coagulation (blood clotting);
- antidiabetic medicines including insulin.

Concomitant intake of certain medicines with ethinylestradiol can lead to an increase or decrease in serum concentration of these medicines. Such medicines include ciclosporin, β-blockers (metoprolol, oxprenolol, propranolol), theophylline, corticosteroids (prednisolone), flunarizine, analgesics (paracetamol), levothyroxine (used to treat low levels of thyroxin), clofibrates (used for high cholesterol), lamotrigine and valproate (used to treat epilepsy).
Taking NESSIFEM with antiretroviral medicines such ribavirin and ritonavir may affect ALT levels in laboratory results.

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 healthcare provider for advice before taking this medicine.
If you are pregnant, you must not take NESSIFEM. If you become pregnant while taking NESSIFEM you must stop immediately and contact your doctor. If you want to become pregnant, you can stop taking NESSIFEM at any time.
It is generally not recommended to take NESSIFEM when you are breastfeeding. If you want to use a contraceptive while you are breastfeeding, you should consult your doctor.

Driving and using machines

You should be aware of how you react to NESSIFEM before you drive or operate machinery. If you have a headache or feel dizzy after taking NESSIFEM, do not drive or operate machinery until these effects wear off.

NESSIFEM contains lactose monohydrate

Lactose is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking NESSIFEM.

3. How to take NESSIFEM

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

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

Each blister contains 24 yellow active tablets and 4 white inactive tablets. The two differently coloured tablets of NESSIFEM are arranged in order. A pack contains 28 tablets. Daily intake during the 28 consecutive days is important to maintain the contraceptive effect.

Take one tablet of NESSIFEM every day, at approximately the same time, with some water if needed. The first tablet should be taken from the silver section of the calendar pack by selecting the tablet corresponding to the day of the week (e.g. “MO’ for Monday). Follow the direction of the arrows until all 28 tablets have been taken.

During the 4 days when you are taking the white inactive tablets, bleeding should start (also called withdrawal bleeding).

Normally your period will begin on the 2nd or 3rd day after you have taken the last yellow active tablet of NESSIFEM.

Do not leave a gap between packs, i.e. start taking your next pack on the day after you have finished the current one, even if your period continues. This means that you will always start new packs on the same day of the week, and also that you have your withdrawal bleed on about the same days, each month

If you take NESSIFEM as indicated, you are protected against pregnancy for the 4 days you take the inactive tablets.

Starting the first pack of NESSIFEM

If you have not taken any hormonal contraceptive in the previous month

Start taking NESSIFEM on the first day of your cycle, i.e. the first day of menstrual bleeding.

The first tablet should be taken from the silver section of the calendar pack by selecting the tablet corresponding to the day of the week (e.g. “MO’ for Monday). Then take 1 tablet every day following the directions shown by the arrows.

Starting on days 2 - 7 of your menstrual cycle is allowed, but you should use additional contraceptive methods (such as condoms and spermicide) for the first 7 days of tablet-taking.

Changing from another Combination Oral Contraceptive (COC) to NESSIFEM

You should start NESSIFEM preferably on the day after your last active tablet of your previous combination oral contraceptive, but at the latest, on the day following the usual inactive tablet interval of your previous combination oral contraceptive.

The first tablet should be taken from the silver section of the calendar pack by selecting the tablet corresponding to the day of the week (e.g. “MO’ for Monday). Then take 1 tablet every day following the directions shown by the arrows.

Changing from a progestogen-only method (progestogen-only pill, injection, implant)

You can switch any day from the progestogen-only pill and should begin NESSIFEM the next day. You should start NESSIFEM on the day of an implant removal or, if using an injection, the day the next injection would be due.

The first tablet should be taken from the silver section of the calendar pack by selecting the tablet corresponding to the day of the week (e.g. “MO’ for Monday). Then take 1 tablet every day following the directions shown by the arrows.

In all of these situations, you should use additional contraceptive methods (such as condoms and spermicide) for the first 7 days tablet-taking.

After a miscarriage or first-trimester abortion

You should start NESSIFEM immediately. Additional contraceptive measures are not needed.

The first tablet should be taken from the silver section of the calendar pack by selecting the tablet corresponding to the day of the week (e.g. “MO’ for Monday).

Then take 1 tablet every day following the directions shown by the arrows.

After having a baby (if you are not breastfeeding) or second-trimester abortion

Since the immediate period just after delivery is associated with an increased risk of thrombosis (blood clots), NESSIFEM should be started no earlier than day 28 after having your baby or after second-trimester abortion.

The first tablet should be taken from the silver section of the calendar pack by selecting the tablet corresponding to the day of the week (e.g. “MO’ for Monday). Then take 1 tablet every day following the directions shown by the arrows.

You should use additional contraceptive methods (such as condoms and spermicide) for the first 7 days tablet-taking. However, if you already had sexual intercourse, you must make sure that you are not pregnant, before starting NESSIFEM or wait for your next period.

For how long should you take NESSIFEM

NESSIFEM must be taken for as long as you want to prevent pregnancy. You can stop taking NESSIFEM at any time you want. If you stop because you want to get pregnant, it is generally recommended that you wait until you have had a natural period before trying to conceive. This helps you to work out when the baby will be due. If you do not want to become pregnant, ask your doctor about other methods of birth control.

If you have the impression that the effect of NESSIFEM is too strong or too weak, tell your doctor or pharmacist.

If you take more NESSIFEM than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Symptoms that may occur in case of taking an overdose are: nausea, vomiting, breast tenderness, dizziness, abdominal pain, drowsiness, feeling tired and vaginal bleeding.

If you forget to take NESSIFEM

Management of missed tablets

Contraceptive protection may be reduced if active (yellow) tablets are missed and particularly if the missed tablets extend the inactive (white) tablet interval.

- If one active tablet is missed, but is **less than 12 hours** late, it should be taken as soon as it is remembered. Subsequent tablets should be taken at the usual time.
- If one active tablet is missed and is **more than 12 hours** late or if more than one active tablet is missed, contraceptive protection may be reduced. The last missed tablet should be taken as soon as it is remembered, even if this means taking two tablets in one day. Subsequent tablets should be taken at the usual time. In addition, a non-hormonal backup method of birth control should be used for the next seven days.
- If the seven days where backup is required run beyond the last active tablet in the current pack, the next pack must be started on the day following the intake of the last active tablet in the current pack; all inactive tablets should be discarded. This prevents an extended break in tablet-taking of active tablets that may increase the

risk of escape ovulation. You are unlikely to have a withdrawal bleed until the inactive-tablet interval of the second pack but you may experience spotting or breakthrough bleeding on days when active tablets are taken.
- If you do not have a withdrawal bleed at the end of the second pack, the possibility of pregnancy must be ruled out before resuming tablet-taking.

What you must do in case of vomiting or severe diarrhoea

If vomiting or severe diarrhoea occurs within 4 hours after tablet-taking, absorption may not be complete. This is similar to what happens when you forget to take a tablet. After vomiting or having diarrhoea, you must take another yellow tablet from a backup pack as soon as possible. If possible, take it within 12 hours of the usual time that you take the tablet. If this is not possible, or more than 12 hours have passed, follow the advice in the section “Management of missed tablets”.
If this continues for several days, you should use an additional contraceptive method (e.g. condom).

Delay of menstrual period: what you must know

Although it is not recommended, you can delay your period (withdrawal bleeding) until the end of a new pack if you do not take the white inactive tablets and immediately start a second pack of NESSIFEM and finish it. You may experience spotting (drops of blood or stains) or bleeding when taking the second pack. Finish this second pack by taking the 4 inactive white tablets. Then start the next pack. You should ask your doctor for advice before deciding to delay your menstrual period.

You have unexpected bleeding

With all pills, for the first few months, you can have irregular vaginal bleeding (spotting or breakthrough bleeding) between your periods. You may need to use sanitary protection, but continue to take your tablets as normal. Irregular vaginal bleeding usually stops once your body has adjusted to the pill (usually after about 3 tablet-taking cycles). It if continues, becomes heavy or starts again, tell a doctor.

You have missed a period

Consult a doctor.

If you stop taking NESSIFEM

*Y*ou should always consult your doctor before deciding to interrupt the course of treatment or stop taking NESSIFEM altogether.

4. Possible side effects

NESSIFEM can have side effects.

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

Serious reactions associated with the use of the pill, as well as the related symptoms are described in the following sections: “The contraceptive pill and thrombosis (venous and arterial blood clots)” / “The contraceptive pill and cancer”. Please read these sections for additional information and consult your doctor where appropriate.

If any of the following happens, stop taking NESSIFEM and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth, tongue or throat, which may cause difficulty in swallowing or breathing, blueness of the skin;
- skin rash, lesions, itchiness of the skin, blistering or peeling of the skin or any other type of skin irritation; or
- chest tightness, difficulty breathing, feeling dizzy or fainting due to low blood pressure.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to NESSIFEM. 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:

- Retinal vascular thrombosis: symptoms most commonly occur in one eye painless blurring of vision which can progress to loss of vision immediate loss of vision;
- 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.
- haemolytic uremic syndrome (a condition which affects your blood and kidneys): symptoms include vomiting, diarrhoea (which may be bloody), fever, feeling weak, passing less urine than usual;
- pancreatitis: symptoms include severe upper abdominal pain which may spread to your back;
- erythema multiforme: symptoms include a skin rash with pink-red blotches especially on palms of hands or soles of feet which may blister. You may also have ulcers in the mouth, eyes or genitals and have a fever.

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

Tell your doctor if you notice any of the following:

<u>Frequent side effects:</u>

- A vaginal infection including vaginal thrush;
- altered mood swings including depression or altered sexual appetite;
- nervousness or dizziness;
- headache, including migraine;
- nausea, vomiting;
- feeling bloated;
- abdominal pain;
- acne;
- skin rash;
- hair loss;
- bleeding between periods;
- very light or no periods;
- painful periods;
- change in blood flow during your period;
- changes to vaginal discharge or change to the cervix (ectropion);
- breast pain;
- breast tenderness;

- water retention in tissue or oedema (severe fluid retention);
- weight loss or gain.

Less frequent side effects

- Increased or decreased appetite;
- worsening of varicose veins;
- liver or biliary disorders (such as hepatitis or abnormal function of the liver);
- gallbladder disease including gallstones or worsening of this condition;
- discoloured patches on the face (chloasma);
- excessive growth of body hair;
- discharge from the nipple;
- increased breast size;
- changes in laboratory test results: increase in cholesterol, triglyceride levels, serum folate, or increased blood pressure.

Side effects with unknown frequency

- Benign liver tumour (called focal nodular hyperplasia or hepatic adenoma) or malignant liver tumour;
- intolerance to a sugar called glucose;
- inflammation of the optic nerve which can lead to partial or total loss of vision;
- worsening of an immune system disease (lupus), of a liver disease (porphyria) or of a disease known as chorea characterised by irregular, sudden, involuntary movements;
- contact lens intolerance;
- ischaemic bowel disease, possible aggravation of inflammatory bowel disease: symptoms include abdominal cramps and pain, diarrhoea (which may be bloody), weight loss;
- jaundice (yellowing of the skin or eyes);
- obstruction of the bile flow in the liver or worsening of this condition;
- tender red lumps under the skin (erythema nodosum).

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 healthcare professional. This includes any possible side effects not listed in this leaflet. You can report side effects to Cipla Medpro (Pty) Ltd at drugsafetysa@cipla.com or telephone 080 222 6662 (toll free).

You can also report side effects to SAHPRA via the "Med Safety APP" (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of NESSIFEM.

5. How to store NESSIFEM

Store at or below 25 °C in a cool, dry place.

Store the blister pack in the outer carton in order to protect from light and moisture.

Store all medicines out of reach of children.

Do not refrigerate or freeze.

Do not use after the expiry date stated on the carton and blister strip.

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 NESSIFEM contains

Active yellow film-coated tablets

The active substances are gestodene and ethinylestradiol.

Each active yellow film-coated tablet contains gestodene 60 µg and ethinylestradiol 15 µg.

The other ingredients are (tablet core): lactose monohydrate, magnesium stearate, microcrystalline cellulose, polacrilin potassium, (tablet coat - Opadry AMB yellow): iron oxide yellow (E-172), lecithin (soya), polyvinyl alcohol, talc, titanium dioxide (E-171), xanthan gum.

Inactive white tablets (placebo)

The inactive tablets are placebo and do not contain any active ingredients.

The ingredients are colloidal aluminium oxide, lactose monohydrate, magnesium stearate, povidone K25, silica colloidal anhydrous, sodium starch glycolate (type A).

What NESSIFEM looks like and contents of the pack

Active film-coated tablets

24 yellow, round, plain film-coated tablets, with a diameter of 5,5 mm approximately.

Inactive tablets (placebo)

4 white, round, biconvex, plain tablets, with a diameter of 5,5 mm approximately.

The tablets are contained in PVC-PVDC/aluminium blisters. Aluminium foil is a foil of push-through aluminium with a lacquered dull side, and a heat sealable bright side lacquered for sealing to PVC.

The blisters are contained in an outer cardboard carton.

Pack size: The 28-day pack (Every-day calendar pack) contains 24 active hormonal film-coated yellow tablets plus 4 inactive non-hormonal (placebo) white tablets.

CIPLA MEDPRO (PTY) LTD.

Building 9

Parc du Cap

Mispel Street

Bellville

7530

Customer Care: 080 222 6662.

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