SCHEDULING STATUS **S3**

FAMYNOR 500 µg/50 µg (tablets)

Norgestrel, ethinyl estradiol

Active tablets:

Contains sugar:

Sucrose: ± 27,14 mg

Lactose monohydrate: 47,14 mg

Inert tablets:

Contains sugar:

Sucrose: ± 24,5 mg

Lactose monohydrate: 71,38 mg

Read all of this leaflet carefully before you start taking FAMYNOR

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

1. What FAMYNOR is and what it is used for

FAMYNOR belongs to a group of medicines called combined oral contraceptives (COCs) used for prevention of pregnancy (fertility control) when used as instructed.

Oral contraceptives are also used for control of certain menstrual irregularities i.e. symptomatic treatment of primary dysmenorrhoea where contraception is also desired, and cases of dysfunctional uterine bleeding.

2. What you need to know before you take FAMYNOR

In deciding to use FAMYNOR, the risks of taking FAMYNOR must be weighed against the good it will do. If you are using FAMYNOR for contraception you should understand how its benefits and risks compare to those of other birth control methods. This is a decision you, your sexual partner, and your doctor will make. Before you start taking FAMYNOR your doctor should check your pelvic organs, breasts and blood pressure and these checks should be repeated regularly.

Do not take FAMYNOR

• if you are hypersensitive (allergic) to norgestrel, ethinyl estradiol or any of the other ingredients of FAMYNOR (listed in section 6).

• if you have a previous condition, or currently have a condition where a clot plugs a blood vessel in your body (e.g. heart attack or stroke caused by a clot blocking a blood vessel).

• if you have risk factors for developing a clot in a blood vessel. These risk factors include:

- if you smoke and are over the age of 35 years.
- if you have ever had, or currently have a clot in your leg (or a vein deep in the body), in your lung or have a family history of these blood clots.
- if you have an inherited disease where your blood clots easily (hypercoagulopathy).
- if you have an obstruction in one or more blood vessels that supply blood to the brain (cerebrovascular insufficiency) or a disease that causes a narrowing in the blood vessels to the brain (cerebrovascular disease). These conditions may lead to a stroke.
- if you have a disease causing narrowing of blood vessels supplying the heart with blood (coronary artery disease), heart rhythm diseases or problems with your heart valves. You should consult your doctor immediately if you experience unexplained chest pain.

- if you have uncontrolled high blood pressure.
- if you have diabetes mellitus with diseases of your blood vessels.
- if you have headaches or migraines with vision disturbances such as blurred or lost vision, weakness or speech difficulties. FAMYNOR should be stopped immediately if you develop a migraine with vision loss.
- if you are over the age of 35 and you have migraine headaches.

• if you have had a previous heart attack.

• if you have high blood cholesterol.

• if you currently have or have a history of breast cancer or other cancer that is sensitive to hormones.

• if you have a history or presence of liver tumours, impaired liver function, acute or chronic liver diseases, jaundice or a history during pregnancy of itching or jaundice.

• if you have a history during pregnancy of: chorea (abnormal involuntary movement disorder), pemphigoid gestationis (autoimmune skin disease) or deteriorating otosclerosis (an inherited disorder of the ear causing hearing loss).

• if you have abnormal bleeding from your vagina.

• if you are taking medicines for hepatitis C containing ombitasvir/paritaprevir/ritonavir with or without dasabuvir.

• if you have depression, which is not well controlled with treatment.

• if you have had depression with previous use of hormonal contraceptives.

• if you are known to have inherited genetic changes called “BRCA 1 and/or BRCA 2 genes.”

• if you started your menstrual periods before the age of 12 years.

• if you have a history of non-cancerous breast disease such as atypical hyperplasia or lobular carcinoma *in situ*.

• if you have had any treatment using radiation to your chest or breast.

• if you have been treated or exposed while in your mother’s womb to a medicine called diethylstilbestrol (DES).

• if you are pregnant or suspect that you are pregnant.

Warnings and precautions

Take special care with FAMYNOR:

CIGARETTE SMOKING

CIGARETTE SMOKING INCREASES THE RISK OF SERIOUS CARDIOVASCULAR SIDE EFFECTS FROM THE USE OF ORAL CONTRACEPTIVES. THE RISK INCREASES WITH AGE AND WITH HEAVY SMOKING (15 OR MORE CIGARETTES PER DAY) AND IS QUITE MARKED IN WOMEN OVER 35 YEARS OF AGE. YOU ARE THEREFORE STRONGLY ADVISED TO STOP SMOKING.

Under no circumstances should FAMYNOR be stopped without having adopted a satisfactory alternative method of contraception.

Tell your doctor if any of the following conditions apply to you:

If these conditions develop or get worse while you are taking FAMYNOR, you should also tell your doctor.

- If you have stopped taking FAMYNOR and you are not using an alternative method of contraception.
- If you miss a menstrual period, see your doctor. Discontinue FAMYNOR until your doctor says you can resume.
- If, while on treatment with FAMYNOR, you experience vomiting and diarrhoea. Additional contraceptive measures may be necessary during and for 7 days after recovery from such episodes. Spotting and breakthrough bleeding are possible signs of diminished contraceptive effectiveness and additional contraceptive methods should be used.
- FAMYNOR tablets are to be used only on the advice, or on the recommendation of your doctor, who will give you more complete information on the use of FAMYNOR and will advise you about possible contraindications (conditions in which you should not take this type of medicine).
- If you have epilepsy, asthma or conditions where you retain fluid in your body.
- If during your treatment with FAMYNOR you develop unexplained loss of vision, double vision or swelling of the eye nerve that may cause pain in your eye and bleeding in the eye.
- If you are due to receive a surgery or if you are not going to be mobile for an extended period of time. FAMYNOR should be stopped 4 weeks before you are due to undergo surgery or during periods where you are not mobile. FAMYNOR can be restarted approximately 2 weeks after surgery or immobilisation.
- If you have given birth and you are not breastfeeding, you should not start FAMYNOR earlier than 4 weeks after delivery.

- If you have uncontrolled high cholesterol. You may be at a higher risk of developing inflammation in your pancreas and your doctor may consider prescribing an alternative medicine for you.
- If during your treatment with FAMYNOR, you develop consistent upper stomach pain.
- If you have high blood pressure but it is well controlled with medicine, your blood pressure should be monitored regularly while taking FAMYNOR.
- If you have diabetes mellitus as you may not tolerate glucose well while on FAMYNOR.
- If you have a tumour or cancer in your liver or any type of liver disease including gallbladder problems or if your skin or the whites of your eyes appear yellow.
- If, while on treatment with FAMYNOR, you start to develop new headaches or migraine that are recurring, persistent and severe, tell your doctor immediately.
- If you experience no menstrual bleeding, very light menstrual bleeding, breakthrough bleeding or spotting that lasts for longer than 3 months of using FAMYNOR or occurs after previous regular cycles. You should tell your doctor so that he/she may test for pregnancy or another cause such as cancer.
- If you have experienced very light menstrual bleeding, infrequent menstrual bleeding or no bleeding while on other contraceptives previously, tell your doctor.
- If you are on treatment for depression.
- If you have had depression with previous use of hormonal contraceptives.
- If you have a substance abuse problem.
- If you have an underlying psychiatric disorder such as post-traumatic stress disorder or bipolar disorder.
- If you have a family history of mental disorders.
- If you have a genetic condition called hereditary angioedema where you have swelling in various parts of your body, including your hands, feet, face and throat.
- If you develop brown patches on your face (chloasma). This may especially happen if you previously developed brown patches on your face while you were pregnant. If you have developed brown patches on your face before, you should avoid exposure to sunlight or ultraviolet light while on treatment with FAMYNOR.
- If you are overweight as FAMYNOR may not work as well for you.
- If you are elderly, as FAMYNOR is not indicated for use in women who have undergone menopause.
- If FAMYNOR is prescribed in children who have not started their period as FAMYNOR is not indicated in this age group.

- If you have a rare hereditary blood disorder called porphyria.
- If you are taking antibiotic therapy: Oral contraceptive failure may occur with concomitant antibiotic therapy. For maximal protection, additional non-hormonal contraception is recommended for the duration of antibiotic therapy and for seven days thereafter. Those on long-term antibiotic therapy need only take extra precautions for the first two weeks of antibiotic therapy. Spotting and breakthrough bleeding are possible signs of diminished contraceptive effectiveness.
- If you are taking certain medicines that may decrease the effect of FAMYNOR. You will need to use alternative or additional contraception while taking these medicines and for up to 28 days after stopping these medicines. Some of these medicines include medicine for fits, antibiotics, antifungal medicines, medicine for vomiting, medicine for depression and medicine for high blood pressure caused by your lungs (see Other medicines and FAMYNOR).

  Hormonal contraceptives including FAMYNOR, may cause mood changes and depression, which may be severe. Severe depression is associated with a higher risk of suicidal thoughts/behavior (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.

FAMYNOR does not protect you against sexually transmitted diseases and the virus that causes AIDS.

FAMYNOR **and breast cancer**

Breast cancer has been diagnosed slightly more often in women who use contraceptives such as FAMYNOR than in women of the same age who do not use contraceptives. This slight increase in the numbers of breast cancer diagnoses gradually disappears during the course of the 10 years after stopping use of contraceptives. When you are taking FAMYNOR, you must perform monthly breast self-examinations. Your doctor will advise you on when to report for breast examinations and any appropriate investigations.

Other medicines and FAMYNOR

Always tell your healthcare provider if you are taking any other medicine. (This includes all

complementary or traditional medicines).

Tell your doctor if you are taking or using any of the following medicine:

• Antiepileptic medicines (e.g. phenytoin, phenobarbitone, carbamazepine, oxcarbazepine, primidone, topiramate, felbamate, rufinamide, lamotrigine): medicine used to treat fits, epilepsy or seizures.

• Modafinil: medicine used to treat sleepiness.

• Bosentan: medicine used to treat a specific type of high blood pressure caused by the blood vessels of the lungs.

• Antifungal medicine (e.g. griseofulvin, itraconazole, voriconazole, fluconazole, ketoconazole): medicine used to treat fungal infections.

• Aprepitant: medicine used to treat vomiting.

• St. John's wort: (herbal) medicine used to treat depression.

• Antibiotics (e.g. rifabutin, rifampicin, ampicillin): medicine used to treat bacterial infections including tuberculosis (TB).

• Nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g. phenylbutazone, salicylic acid): medicine used to treat pain and inflammation.

• Anti-cholesterol medicines (e.g. colesevelam, atorvastatin, rosuvastatin, clofibric acid): medicine used to lower cholesterol.

• Ascorbic acid (vitamin C): medicine to supplement the amount of vitamin C in your body.

• Analgesic medicines (e.g. paracetamol, morphine): medicine used to treat pain.

• Anti-viral medicines (e.g. ombitasvir/paritaprevir/ritonavir with or without dasabuvir, nelfinavir, ritonavir, darunavir/ritonavir, fosamprenavir/ritonavir, lopinavir/ritonavir, tipranavir/ritonavir, indinavir, atazanavir/ritonavir, nevirapine, efavirenz, etravirine): medicine used to treat HIV or the liver virus, hepatitis C.

• Immune system inhibitors (e.g. ciclosporin, prednisolone): medicine used to suppress the immune system to prevent rejection of an organ after an organ transplant or to prevent inflammation.

• Theophylline: medicine used to treat asthma or diseases where there is an obstruction of the airways.

• Tizanidine: medicine used to treat muscle spasms after a spinal cord injury or because of a multiple sclerosis.

• Temazepam: medicine used to treat sleeplessness (insomnia).

• Thyroid hormone replacement medicine (e.g. levothyroxine): medicine used to treat a low level of

thyroid hormone in the body.

- Several other medicines may be affected by concomitant use with FAMYNOR (e.g. anticoagulants, antidepressants, antidiabetics (such as sulfonylureas and insulin), antihypertensives, benzodiazepines, clofibrate, corticosteroids, lignocaine, selegiline, xanthines).
- FAMYNOR may interfere with the result of some laboratory tests, in particular hormones, glucose tolerance, thyroid function, binding proteins, blood coagulation factors, serum triglycerides and liver function tests.

FAMYNOR with food and drink

Do not take FAMYNOR with grapefruit juice as it may increase the level of hormones in your blood.

Pregnancy, breastfeeding and fertility

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.

Pregnancy

You should not take FAMYNOR if you are pregnant.

Pregnancy should be ruled out before a course of FAMYNOR is started.

If the correct dosing schedule was followed and two consecutive menstrual cycles have been missed, the use of FAMYNOR should be discontinued, until the possibility of pregnancy has been ruled out.

If the correct dosing schedule was not followed, pregnancy should be ruled out after the first missed menstrual period.

If you are taking oral contraceptive and wish to start a family, you should discontinue FAMYNOR and use non-hormonal contraceptive method (like a condom or a spermicide gel). It is recommended that attempting to conceive be delayed for 3 months after discontinuation of FAMYNOR or until after the first regular menstrual cycle.

Breastfeeding

Oral contraception is recommended to begin 3 months after delivery for mothers who are exclusively

breastfeeding and in the third week after delivery for mothers who are only partially or not breastfeeding.

Driving and using machines

FAMYNOR has no influence on the ability to drive and use machines.

It is not always possible to predict to what extent FAMYNOR may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which FAMYNOR affects you (see section 4).

FAMYNOR contains sucrose and lactose

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

Patients with rare hereditary problems of fructose intolerance, galactose intolerance, total lactase deficiency, sucrase-isomaltase insufficiency or glucose-galactose malabsorption should not take FAMYNOR.

FAMYNOR contains sucrose and lactose, which may have an effect on the control of your blood sugar if you have diabetes mellitus.

3. How to take FAMYNOR

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

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

This memo pack has been specially designed to help you to remember to take your tablets. Each tablet is placed in its own bubble.

FAMYNOR tablets must be taken as directed and at intervals not exceeding 24 hours to achieve maximum effectiveness. The tablets are to be taken at the same time every day, preferably after the evening meal or at bedtime. Withdrawal bleeding can be expected within 2 to 3 days after the last white tablet has been taken.

If one has started the tablets after day 5 of a normal menstrual cycle, or the 3rd postpartum week, the possibility of pregnancy must be checked prior to commencement of administration as conception or

ovulation might have occurred before starting, and other methods of contraception must be used.

1. **Beginning on day 1 of the menstrual cycle, i.e. the first day of bleeding**.

2. First 21 consecutive days: Take one white tablet daily following the arrows until all the white tablets are finished.

3. Next 7 consecutive days: Take one red, inert, tablet daily, following the arrows until all the red tablets are finished.

4. On the following day start a new package, taking the first white tablet of the next course as described under point 2.

NOTE: There must be no delay/interval between finishing one course and starting the next.
The next and all subsequent courses will begin on the day after the last tablet in the package was completed, even if withdrawal bleeding has not occurred or is still in progress. Each course of FAMYNOR will start on the same day of the week and follows the same schedule (21 days of white tablets, 7 days of red, inert, tablets).
If for some reason, the tablets are not started on day 1 of the menstrual cycle, an additional method of contraception (mechanical) should be used until 14 tablets of the first course of FAMYNOR have been taken.

Patients changing from another oral contraceptive medicine:
When changing from another oral contraceptive to FAMYNOR, begin the first active tablet of FAMYNOR on the day after the last active tablet of the previous contraceptive's course has been taken. If a tablet-free interval is taken, then other contraceptive precautions are advised for the first 7 days. If the inert tablets are inadvertently taken first, other contraceptive precautions are necessary during the first 14 days. If transient spotting or breakthrough bleeding occurs, continue with the course. If the bleeding is persistent or prolonged, a medical practitioner should be consulted.

TAKING YOUR FIRST PACK OF FAMYNOR

• You must start by taking tablet with Start Mark. It is important to realise that all tablets are not the same and that they must therefore be taken in the right order, starting with Start mark.

- After taking your first tablet, take one tablet each day, following the direction of the arrows, until you have finished all white 21 tablets in pack and then take 7 red tablets.
- You should try to take the tablet at the same time every day.
- Swallow each tablet whole, with water if necessary.
- By starting in this way, you will have contraceptive protection.

TAKING YOUR NEXT PACK OF FAMYNOR

Start taking your next pack of FAMYNOR the day after you have finished the current pack.

Advice in case of gastrointestinal disturbances

If, while on **FAMYNOR** you develop severe vomiting and diarrhoea, the absorption of **FAMYNOR** may be decreased. You should use additional methods of contraception at a time of such disorders. If vomiting or diarrhoea occurs within 3 to 4 hours after taking an active tablet of **FAMYNOR**, handle this as a missed tablet.

If you take more FAMYNOR than you should

If you have taken more than one tablet, you may experience nausea and withdrawal bleeding. You should consult your doctor who will be able to advise you what action is necessary.
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take FAMYNOR

If a tablet is missed, the risk of pregnancy is greatest when it happens at the beginning or end of a cycle. The missed white tablet should be taken as soon as possible. If tablets are missed for two consecutive days, both tablets should be taken as soon as possible. In either case, the next tablet should be taken at the usual time. Other contraception methods (mechanical) are required for the next 7 days. If one or more tablets are missed during the last week of active (white) tablets, the inert (red) tablets must be discarded and the next cycle of FAMYNOR started immediately. A menstrual period should not be expected until the end of the next cycle.
If three consecutive white tablets are missed, FAMYNOR should be discontinued, and the remaining

tablets should be discarded. A new package should be started on the eighth day after the last tablet was taken. Other contraception methods (mechanical) are required for the 7 days while no tablets are taken and for the 7 days after the new course has been started. If the patient does not have a period at the end of the second pack, she must return to her doctor to exclude the possibility of pregnancy. Missing any of the inert tablets is not important, but the next course must be started at the right time.

4. Possible side effects

FAMYNOR can have side effects.

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

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

• Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,

• rash or itching,

• fainting.

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

• bleeding of the brain, a clot in the brain or a stroke with symptoms such as numbness of the face and limbs on one side of the body,

• a clot in the blood vessel that supplies the eye with blood with symptoms such as sudden onset of vision loss generally only in one eye,

• inflammation of the eye nerve which could lead to partial or complete loss of vision,

• heart attack with symptoms such as tightness or pain in the chest, abnormal heartbeat, anxiety, shortness of breath and light-headedness,

• a clot in a blood vessel (arterial or venous thromboembolism),

• a clot in the lung (pulmonary embolism) with symptoms such as shortness of breath, chest pain and cough,

• inflammation of the pancreas (pancreatitis) with symptoms such as severe nausea and stomach pain,

• a clot in the blood vessels supplying the small intestines with blood with symptoms such as severe stomach pain, nausea and vomiting,

• liver and gallbladder problems with symptoms such as yellowing of the skin and whites of the eyes (jaundice) or a very rare liver condition called Budd-Chiari syndrome that effects the drainage of the liver, with symptoms such as liver enlargement, a build-up of fluid in the stomach and stomach pain,

• bleeding under the skin,

• suicidal thoughts/behavior and suicide.

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:

• Increased appetite, fluid retention,

• depression, nervousness,

• headache,

• worsening of varicose veins,

• nausea and/or vomiting, stomach pain, cramps and bloating,

• acne, brown patches on the face,

• backache,

• vaginal infection, vaginal discharge, painful menstruation, changes in menstrual flow, unscheduled menstrual bleeding (spotting or breakthrough bleeding), absence of menstrual flow, breast changes (including tenderness, pain, enlargement and secretion from the breast),

• fatigue/tiredness.

Less frequent side effects:

• Cancer of the reproductive organs, breasts or liver,

• decreased glucose tolerance, effects on the carbohydrates and fats (lipids), weight gain,

• worsening or increasing frequency of headache or migraines, chorea (abnormal involuntary movement

disorder),

• high blood pressure,

• skin rashes, gain or loss of body or facial hair,

• changes in sex drive (libido),

• vaginal thrush.

Side effects with unknown frequency:

• Unwanted male-pattern hair growth in women (hirsutism),

• decreased appetite, porphyria (an inherited blood disorder) or a worsening of existing porphyria, increased triglyceride/fat levels in the blood,

• mood changes, mood swings, migraine,

• lesions in the eye, change in the curve of your eye, intolerance to contact lenses,

• irritation in the stomach and gut, inflammation of the inner lining of the colon,

• skin pigmentation, bull's-eye-shaped lesions on the skin, nodules or tender bumps under the skin,

• premenstrual syndrome (PMS), temporary infertility after discontinuation of treatment,

• change in weight.

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. 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 FAMYNOR.

5. How to store FAMYNOR

- Store at or below 30 °C. Protect from light.
- KEEP THE BLISTERS IN THE CARTON UNTIL REQUIRED FOR USE.
- In order to protect from light and moisture do not store in bathroom.
- 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 system (e.g. toilet).

Store all medicines out of reach of children.

6. Contents of the pack and other information

What FAMYNOR contains

Active white tablets:

The active substances are norgestrel 500 micrograms and ethinyl estradiol 50 micrograms

The other ingredients are: Acacia, disodium edetate, ethyl cellulose, lactose monohydrate, magnesium stearate, maize starch, methyl hydroxybenzoate, microcrystalline cellulose, polacrilin potassium, polyethylene glycol, purified talc, sucrose, titanium dioxide (CI no. 77891).

Inert red tablets:

Carnauba wax, disodium edetate, ethyl cellulose, gum acacia, lactose monohydrate, magnesium stearate, maize starch, methyl hydroxybenzoate, polacrilin potassium, ponceau 4R lake (CI no. 16255), purified talc, sodium benzoate, sucrose, titanium dioxide (CI no. 77891).

What FAMYNOR looks like and contents of the pack

21 active white, circular, biconvex, sugar-coated tablets and 7 red inert, circular, biconvex, sugar-coated tablets.

Aluminium/PVdC/PVC foil blister packs of 28 tablets (21 white and 7 red tablets) packed in a cardboard carton together with a leaflet.

Holder of Certificate of Registration

Viatris Healthcare (Pty) Ltd

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