PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

MINESSE®, 60/15 micrograms film-coated tablets

Gestodene and ethinylestradiol

Contains sugar

Each MINESSE 60 µg/15 µg active tablet contains 39,84 mg lactose monohydrate.

Each inactive (placebo) tablet contains 39,900 mg lactose monohydrate.

Read all of this leaflet carefully before you start taking MINESSE

- 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.
- MINESSE 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 MINESSE is and what it is used for

MINESSE is a combined hormonal oral contraceptive often referred to as the ‘Pill’ and is used for the prevention of pregnancy.

2. What you need to know before you take MINESSE

Do not take MINESSE:

- if you are hypersensitive (allergic) to gestodene, ethinylestradiol or to any of the other ingredients of MINESSE (listed in section 6)
- if you have blood clots or a history of blood clots in your legs (deep vein thrombosis [DVT]), your lungs (pulmonary embolism), your eyes or other organs
- if you have ever had a heart attack or stroke
- if you have heart disease including heart valve disorders or certain heart rhythm disorders
- if you have an inherited or acquired disorder that affects your blood clotting
- if you get headaches with sudden unexplained changes in vision
- if you have diabetes with blood vessel damage
- if you have uncontrolled high blood pressure
- if you have known or suspected breast cancer, breast lumps or an abnormal breast X-ray or mammogram
- if you have a liver tumour, liver cancer or liver disease with abnormal liver function tests
- if you have unexplained vaginal bleeding
- if you have or have previously had inflammation of the pancreas associated with high blood levels of triglycerides (fatty substances)
- if you are taking anti-viral hepatitis C virus (HCV) medicines containing ombitasvir, paritaprevir, ritonavir and dasabuvir
- if you are pregnant or you think you may be pregnant
- if you have depression, which is not well controlled with treatment
- if you have had depression with previous use of hormonal contraceptives

Warnings and precautions

Take special care with MINESSE:

- if you smoke, particularly if you smoke more than 15 cigarettes per day and are over 35 years of age

- if you are overweight
- if you have had any recent surgery or trauma
- if you have recently had a baby or had an abortion in the second trimester
- if you have been confined to your bed for long periods of time
- if you are of increasing age
- if you have heart problems
- if you have high blood pressure
- if you have high cholesterol levels in your blood
- if you experience changes in your vision
- if you have angioedema (swelling that occurs below the surface of the skin)
- if you have known or suspected cancer of the cervix
- if you have a family history of breast cancer
- if you have never had a baby
- if you have had a baby at late age for first full-term pregnancy
- if you have liver problems
- if you develop migraines or suffer from worsening migraine headaches, your doctor may discontinue MINESSE use
- if you have glucose intolerance or diabetes
- if you have uncontrolled high levels of cholesterol or fatty substances in your blood
- if you have infrequent menstrual periods
- 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 underlying psychiatric disorders such as post-traumatic stress disorder or bipolar disorder
- if you have a family history of mental disorders
- if you have a history of physical or sexual abuse

Hormonal contraceptives including MINESSE, 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.

Your doctor will complete a personal and family medical history and physical examination prior to initiating use of MINESSE. Regular follow-up visits will be scheduled, and a Pap smear may be performed if you have been sexually active or otherwise indicated.

MINESSE does not protect against HIV infection (AIDS) and other sexually transmitted diseases.

Other medicines and MINESSE

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

Some medicines may stop MINESSE from working properly. These include medicines such as:

- rifampicin and rifabutin (used for the treatment of tuberculosis)
- barbiturates (central nervous system depressants/sedatives)
- primidone, phenytoin and topiramate (used to treat epilepsy and certain seizures)
- dexamethasone (a corticosteroid used to treat many conditions including severe allergies, skin conditions, and breathing disorders)
- griseofulvin, fluconazole, (used to treat fungal infections)
- modafinil (used to treat excessive daytime sleepiness)
- St. John’s Wort (herbal medicine used to treat depression)
- ritonavir, indinavir (used to treat HIV infection)
- ampicillin, other penicillins, tetracyclines and troleandomycin (antibiotics used to treat bacterial infections). You may be at higher risk of specific liver problems if you take troleandomycin and

MINESSE at the same time

- atorvastatin (used to treat high cholesterol)
- ascorbic acid (vitamin C) and paracetamol
- ciclosporin (used to prevent organ rejection)
- theophylline (used to treat asthma and other respiratory diseases)
- corticosteroids (used to treat allergic reactions)
- lamotrigine (used to treat epilepsy)
- flunarizine (used for preventing migraine) may increase the risk of galactorrhoea. This is a condition where your breasts spontaneously leak milk when you have not been breastfeeding or recently had a baby.

If you are taking any of these medicines, for the next 7 days after stopping them, you must also use an additional nonhormonal method of contraception (such as a condom or spermicide).

If you are scheduled for any laboratory tests, tell your doctor you are taking MINESSE as some blood tests may be affected.

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.

If you fall pregnant while you are taking MINESSE; stop taking it immediately and tell your doctor.

You should not breastfeed your baby whilst taking MINESSE.

Driving and using machines

MINESSE may influence your ability to drive and operate machines.

MINESSE 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 MINESSE affects you.

MINESSE contains lactose monohydrate

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

3. How to take MINESSE

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

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

MINESSE must be taken in the order as directed on the package and at the same time every day, preferably after the evening meal or at bedtime. One yellow active tablet is to be taken daily for 24 consecutive days, then either followed by 4 days of the white inactive tablets or a 4- day tablet-free interval.

Withdrawal bleeding may occur on days 2 – 3 after the last active tablet is taken and may not have finished before the next pack is started. Each subsequent pack is started on the day after the last inactive tablet without interruption and without regard to bleeding.

Starting the first pack - when no hormonal contraceptive has been used in the past month:
On the first day of your period (i.e. the day when bleeding starts), take the first tablet marked with the appropriate day of the week from those in the red area of the package.

If you start taking the tablet on any other day of your period, you should use another method of contraception such as the condom or spermicide for the first 7 tablet-taking days, but this is only for the first pack.

Take one tablet daily, following the arrows on the package, until all 28 tablets have been taken.

If you are changing to MINESSE after taking another contraceptive pill, injection or implant:

You should start taking MINESSE preferably on the day after the last active tablet of your previous pill, but at the latest, on the day following the usual inactive tablet interval of your previous pill.

If you are changing from a progestin only pill, you can stop taking that pill on any day and start taking MINESSE the next day at the same time. An additional form of contraception, such as the condom or spermicide, should be used for the first 7 days of pill-taking.

If you are changing from an implant or injection contraceptive, you should start using MINESSE on the day your implant is removed or on the day when your next injection is due. An additional form of contraception, such as the condom or spermicide, should be used for the first 7 days of pill-taking.

Taking MINESSE after a delivery, miscarriage or abortion:

After a miscarriage or abortion in the first three months of pregnancy, you can start using MINESSE immediately. No additional forms of contraception are needed.

If you have had a baby and are not breastfeeding or you have had an abortion in months four, five or six of pregnancy, you should start taking MINESSE 28 days after the delivery or abortion. Additional contraception must be used for the first 7 days of pill-taking.

If you have already had unprotected sex, pregnancy should be excluded, and you should not start MINESSE until your first menstrual period starts.

Advice in case of vomiting or diarrhoea:

If vomiting or diarrhoea occurs within 4 hours after you have taken your pill, follow the instructions under “If you forget to take MINESSE:”. You should take the extra active tablet from a back-up pack.

How to delay a period:

If you want to delay your period, you should continue with another pack of MINESSE without the inactive tablet interval. The extension can be carried on for as long as wished until the end of the second pack. You may experience breakthrough bleeding and spotting. Regular intake of MINESSE is then resumed after the usual 4-day inactive-tablet interval.

Your doctor will tell you how long your treatment with MINESSE will last. Do not stop the treatment early. If you have the impression that the effect of MINESSE is too strong or too weak, tell your doctor or pharmacist.

If you take more MINESSE than you should

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

If you accidently take more MINESSE than you should, you may have symptoms such as nausea, vomiting, breast tenderness, dizziness, stomach pain, drowsiness/fatigue and withdrawal bleeding may occur.

If you forget to take MINESSE

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

If you are less than 12 hours late in taking your pill, take it as soon as you remember. Subsequent tablets should be taken at the usual time.

If you are more than 12 hours late in taking one or more pills, take the last missed pill as soon as you remember, even if it means taking two pills in one day. Subsequent tablets should be taken at the usual time and use extra contraception such as a condom or spermicide for the next 7 days. If these 7 days run beyond the end of the active tablets in the pack, start the next pack immediately, and discard the inactive

tablets. In this case, a withdrawal bleed (period) should not occur until the inactive-tablet interval of the second pack. You may experience spotting or breakthrough bleeding on the 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 starting the next pack.

4. Possible side effects

MINESSE can have side effects.

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

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

- A serious allergic reaction. Symptoms include sudden wheeziness, difficulty in breathing or dizziness, swelling of the eyelids, face, lips or throat, skin rash, hives.
- Haemolytic uraemic 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.
- Retinal vein thrombosis. Symptoms include painless blurring of vision which can progress to loss of vision.
- 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.
- Jaundice or a yellowing of the skin or eyeballs, often with fever, fatigue, loss of appetite, dark coloured urine or light coloured bowel movements.

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

Tell your doctor if you notice any of the following:

Frequent side effects

- headache, including migraines
- breakthrough bleeding/spotting
- vaginal infection, including thrush
- mood changes including depression
- changes in sex drive
- nervousness
- dizziness
- nausea
- vomiting
- stomach pain
- acne
- breast pain or tenderness
- breast enlargement
- secretion from the nipple
- painful, irregular or missed periods
- changes in the cervix and vaginal discharge
- fluid retention/oedema (swelling of the hands, ankles or feet)
- changes in body weight

Less frequent side effects

- changes in appetite
- stomach cramps and bloating
- rash

- brown patches of skin especially on the face
- unusual hairiness
- hair loss
- increase in blood pressure
- changes in serum lipid levels and high levels of fatty substances in your blood (hypertriglyceridaemia)
- severe allergic reaction including itching and swelling of the skin, hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- intolerance to glucose
- intolerance to contact lenses
- cholestatic jaundice (abnormal bile flow in the liver causing yellowing of the skin)
- tender red lumps under the skin (erythema nodosum)
- decrease in serum folate levels
- cancer of the liver
- worsening of systemic lupus erythematosus (an inflammatory disease which can affect many parts of the body, including the skin, joints and internal organs)
- worsening of porphyria (an inherited blood condition)
- worsening of chorea (uncontrolled or jerky body movements)
- inflammation of the optic nerve which may lead to partial or complete loss of vision
- blood clot in the eye
- aggravation of varicose veins
- inflammation of the pancreas
- ischaemic colitis (inflammation due to inadequate blood flow to large intestine)
- gallbladder disease, including gallstones
- erythema multiforme (fever and rash of the face, arms and legs)
- haemolytic uraemic syndrome (a disorder when blood clots cause the kidneys to fail)
- inflammatory bowel disease (Crohn’s disease, swelling or ulcers in the colon)
- liver diseases such as hepatitis and abnormal liver function

- suicidal thoughts/behaviour and suicide

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

Reporting side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/health-products-vigilance/. By reporting side effects, you can help provide more information on the safety of MINESSE.

5. How to store MINESSE

- Store all medicines out of reach of children.
- Store at or below 25 °C and protect from light and moisture.
- Do not use after the expiry date stated on the blister pack.
- 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 MINESSE contains

- The active substances are gestodene and ethinylestradiol. Each active yellow tablet contains 60 µg gestodene and 15 µg ethinylestradiol. The white tablets are placebo and do not contain any active ingredients.
- The other ingredients in the active yellow tablets are lactose monohydrate, magnesium stearate, microcrystalline cellulose and polacrilin potassium. The tablet coating contains montanglycol wax, Opadry yellow and polyethylene glycol 1450.
- The white inactive (placebo) tablets contain lactose monohydrate, magnesium stearate, microcrystalline cellulose and polacrilin potassium. The tablet coating contains montanglycol wax, Opadry white and polyethylene glycol 1500.

What MINESSE looks like and contents of the pack

24 pale yellow round film-coated active tablets with convex faces, approximately 5,7 mm in diameter and 4 white round film-coated inactive tablets with convex faces, approximately 6 mm in diameter.

MINESSE is packed in a carton containing a calendar pack consisting of a PVC and aluminium blister strip with 24 pale yellow and 4 white tablets.

Holder of Certificate of Registration

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