1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

MICROVAL 0,03 mg sugar-coated tablets

Levonorgestrel

Contains sugar: Lactose monohydrate 33,120 mg, sucrose 22,023 mg

Read all of this leaflet carefully before you start taking MICROVAL

- 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.
- MICROVAL has been prescribed for you personally and you should not share your medicine with other people as it may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What MICROVAL is and what it is used for

MICROVAL belongs to a group of medicines called oral contraceptive pills. You take it to prevent yourself from falling pregnant.

MICROVAL contains a type of female sex hormone, called a progestogen. This hormone stops you getting pregnant by working in three ways: by making the fluid (mucus) in your cervix thicker, which makes it more difficult for sperm to enter the womb; by preventing the lining of your womb thickening enough for an egg to grow in it; and in some women it also stops the ovary releasing an egg each month (ovulation).

2. What you need to know before you take MICROVAL

Do not take MICROVAL:

- if you are hypersensitive (allergic) to levonorgestrel or any of the other ingredients of MICROVAL (listed in section 6).
- if you have depression and this is not well controlled with treatment.
- if you have had depression with previous use of hormonal contraceptives.
- if you have (or have ever had) a blood clot in a blood vessel of your legs (deep vein thrombosis, DVT), your lungs (pulmonary embolus, PE) or other organs.
- if you need an operation or if you are off your feet for a long time (see Blood clots).
- if you have ever had a heart attack or stroke.
- if you have any of the following diseases that may increase your risk of a clot in the arteries:
  - severe diabetes with blood vessel damage
  - high blood pressure
  - a high level of fat in the blood (cholesterol or triglycerides)
  - a condition known as hyperhomocysteinaemia (high homocysteine levels which can contribute to arterial damage and blood clots in your blood vessels).
- if you have (or have ever had) a type of migraine called ‘migraine with aura’.

- if you have or have ever had breast cancer.
- If you have a family history of breast cancer.
- if you have or have ever had liver disease, and you have been told by your doctor that your liver function test results are not yet back to normal.
- if you have ever had liver tumours.
- If you are known to have inherited genetic genes called “BRCA1 and/or BRCA 2 GENES.”
- If you started your menstrual periods early (before the age of 12 years).
- If you have abnormal vaginal bleeding where the cause is unknown.
- If you have a history of non-cancerous breast disease such as atypical hyperplasia or lobular carcinoma *in situ.*
- If you had any previous treatment using radiation therapy to the 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.

General notes

Before you start using MICROVAL you should read the information on blood clots. It is particularly important to read the symptoms of a blood clot (see section 4).

It is important that you understand the benefits and risks of taking MICROVAL before you start taking it, or when deciding whether to carry on taking it. Although MICROVAL is suitable for most healthy women it isn’t suitable for everyone.

Tell your doctor if you have any of the illnesses or risk factors mentioned in this leaflet.

Warnings and precautions

Take special care with MICROVAL

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.

NOTE: UNDER NO CIRCUMSTANCES SHOULD THE MICROVAL TABLET BE STOPPED WITHOUT HAVING ADOPTED A SATISFACTORY ALTERNATIVE METHOD OF CONTRACEPTION.

Your doctor will ask about you and your family's medical problems, check your blood pressure and exclude the likelihood of you being pregnant. You may also need other checks, such as a breast examination, but only if these examinations are necessary for you, or if you have any special concerns.

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

If the following conditions develop, or get worse while you are using MICROVAL, you should also tell your doctor.

- if you experience symptoms of angioedema such as swollen face, tongue and/or throat and/or difficulty swallowing or hives potentially with difficulty breathing contact a doctor immediately. Medicines containing estrogens may cause or worsen the symptoms of hereditary and acquired angioedema.
- that you are on treatment for depression.
- that you have had depression with previous use of hormonal contraceptives.
- that you have a substance abuse problem.
- you have underlying psychiatric disorder such as post-traumatic stress disorder or

bipolar disorder.

- that you have a family history of mental disorders.
- that you have a history of physical or sexual abuse.
- if you suffer from severe kidney impairment. Your dose may need to be adjusted.
- if you have a history of liver disease or consume excessive quantities of alcohol.
- if you have Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease).
- if you have a history of ectopic pregnancy or one fallopian tube is missing.
- if you have ovarian cysts.
- 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 inflammation of the pancreas (pancreatitis).
- 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).
- if you need an operation, or you are off your feet for a long time (see Blood clots).
- 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 MICROVAL.
- if you have an inflammation in the veins (thrombophlebitis).
- if you have varicose veins.
- if you have diabetes.
- if you or your close family have ever had problems with your heart or circulation, such as high blood pressure.
- if you or your close family have ever had problems with blood clotting.
- if you have the inherited disease called porphyria.
- if you are overweight (obese).

- if you have migraines.
- if you have any illness that worsened during pregnancy or previous use of MICROVAL.

Initially when a progestogen only pill such as MICROVAL is taken, irregular or no menstrual bleeds may occur.

Hormonal contraceptives such as MICROVAL, may cause mood changes and depression, which may be severe. Severe depression is associated with a higher risk of suicidal thoughts/behaviour (eg. 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.

Tell your doctor if you notice any of the following:

The following conditions may have worsened during pregnancy or previous use of the Pill:

- Yellowing of the skin (jaundice),
- persistent itching (pruritus),
- kidney or liver problems,
- gall stones,
- an inherited disease called porphyria.

While you are taking MICROVAL

- You will need regular check-ups with your doctor or healthcare provider, usually when you need another prescription of MICROVAL.
- You should go for regular cervical smear tests.
- Check your breasts and nipples every month for changes - tell your doctor if you can see or feel anything odd, such as lumps or dimpling of the skin.
- If you need a blood test tell your doctor that you are taking MICROVAL, because

MICROVAL can affect the results of some tests.

- If you're going to have an operation, make sure your doctor knows that you are taking MICROVAL. You may need to stop taking MICROVAL about 6 weeks before the operation. This is to reduce the risk of a blood clot (see Blood clots). Your doctor will tell you when you can start taking MICROVAL again.

MICROVAL will not protect you against sexually transmitted infections, such as Chlamydia or HIV. Only condoms can help to do this.

Blood clots

Using a combined oral contraceptive such as MICROVAL increases your risk of developing a blood clot. 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. There may be serious lasting effects, or they may be fatal.

What can happen if a blood clot forms?

- 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.
- A clot may form in a vein in another organ such as the eye (retinal vein thrombosis).
- A clot in an artery can cause serious problems. For example, it can cause a heart attack

or a stroke.

What is the risk of developing a blood clot?

The risk of having a blood clot will vary according to your personal medical history (see **Factors that increase your risk of a blood clot**).

When is the risk of developing a blood clot highest?

The risk of developing a blood clot is highest during the first year of taking MICROVAL for the first time. The risk may also be higher if you restart taking MICROVAL (or a different medicine) after a break of 4 weeks or more. After the first year, the risk gets smaller but is always higher than if you were not using MICROVAL.

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

Factors that increase your risk of a blood clot

- **If you smoke.** When using MICROVAL, you are advised to stop smoking. If you are unable to stop smoking and are older than 35 your doctor may advise you to use a different type of contraceptive.
- 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 you are overweight (body mass index or BMI over 30 kg/m^2).
- 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 MICROVAL may need to be stopped several weeks before surgery or while you are less mobile. If you need to stop MICROVAL ask your doctor when you can start using it again.
- As you get older (particularly above about 35 years).
- If you gave birth less than a few weeks ago.

The risk of developing a blood clot increases the more conditions you have. 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.

Air travel (> 4 hours) may temporarily increase your risk of a blood clot, particularly if you have some of the other factors listed.

It is important to tell your doctor if any of these conditions apply to you, even if you are unsure. Your doctor may decide that MICROVAL needs to be stopped.

If any of the above conditions change while you are using MICROVAL, 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.

MICROVAL and cancer

Oral contraceptives such as MICROVAL increase your risk of cancer of the cervix. All women should have regular smear tests.

MICROVAL and breast cancer

If you have breast cancer, or have had it in the past, you should not take MICROVAL. Oral

contraceptives, such as MICROVAL increase your risk of breast cancer.

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

If you have breast cancer, or have had it in the past, you should not take MICROVAL. Oral contraceptives, such as MICROVAL increase your risk of breast cancer. This risk goes up the longer you're on the Pill but returns to normal within about 10 years of stopping it.

Your risk of breast cancer is higher:

- if you have a close relative (mother, sister or grandmother) who has had breast cancer
- if you are seriously overweight

See a doctor as soon as possible if you notice any changes in your breasts, such as dimpling of the skin, changes in the nipple or any lumps you can see or feel.

MICROVAL has also been linked to liver diseases, such as jaundice and non-cancer liver tumours. Oral contraceptives have also been linked with some forms of liver cancer in women who have taken them for a long time.

See a doctor as soon as possible if you get severe pain in your stomach, or yellow skin or eyes (jaundice). You may need to stop taking MICROVAL.

See a doctor as soon as possible if you get a migraine for the first time, a migraine that is worse than normal or unusually frequent or severe headaches. Especially if accompanied by chest pain or changes to your eyesight, hearing, speech, taste, touch or smell.

Other medicines and MICROVAL

Always tell your healthcare provider if you are taking any other medicines (this includes

complementary or traditional medicines).

Tell your doctor if you are taking any of the following as they could decrease the effect of MICROVAL:

- Medicines used to treat epilepsy (called barbiturates, including phenobarbitone), primidone, phenytoin, carbamazepine, oxcarbazepine, rifunamide, topiramate.
- Medicines used to treat HIV and hepatitis C virus infections (so called protease inhibitors and non-nucleoside reverse transcriptase inhibitors).
- Medicines used to treat serious vomiting (e.g. aprepitant).
- Medicines used to treat high blood pressure in the blood vessels in the lungs (e.g. bosentan).
- Medicines used to treat fungal infections (e.g. griseofulvin).
- Certain antibiotics used in TB treatment (e.g. rifabutin).
- St. John's Wort (a herbal remedy).

If you do need to take one of these medicines, MICROVAL may not be suitable for you or you may need to use extra contraception for a while. Your doctor, pharmacist or dentist can tell you if this is necessary and for how long.

The following medicines can increase the concentration of levonorgestrel in the body but the effect is unknown:

- Medicines used to treat fungal infections (e.g. fluconazole, itraconazole, ketaconazole, voriconazole).
- Certain antibiotics called macrolides (e.g. clarithromycin, erythromycin).
- Medicines used to treat high blood pressure and heart conditions (e.g. diltiazem, verapamil).

MICROVAL can also affect how well other medicines work

For example, taking MICROVAL can mean that the levels of some medicines in your blood may either go up (e.g. ciclosporin) or go down (e.g. lamotrigine).

MICROVAL may also increase or reduce the effects of some anticoagulant medicines (e.g. warfarin) or inhibit the anticoagulant effect (e.g. phenindione).

In addition, MICROVAL can also interfere with the results of some blood tests, so always tell your doctor that you are taking MICROVAL if you have a blood test.

MICROVAL with food and drink

MICROVAL must be taken exactly as directed and at intervals not exceeding 24 hours.

Patients should be instructed to take the tablets at the same time every day, preferably after the evening meal or at bedtime.

Grapefruit juice can increase the amount of levonorgestrel, as contained in MICROVAL, in the body but the effect is unknown.

Pregnancy, breastfeeding and fertility

You should not take MICROVAL if you are pregnant.

If you have just had a baby and you are breastfeeding, your doctor may advise you that you should start with an alternative oral contraceptive 21 days after delivery provided that you are fully mobile. You do not have to wait for a period. You will need to use another method of contraception, such as a condom, until you start the oral contraceptive your doctor has prescribed and for the first 7 days of pill taking.

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.

Driving and using machinery

MICROVAL has no known influence on ability to drive and use machines.

Since adverse reactions such as migraine, dizziness, fainting and sudden changes in eyesight have been reported in patients receiving MICROVAL, you should not drive, use machinery or perform any tasks that require concentration, until you are certain that MICROVAL does not adversely affect your ability to do so (see section 4).

MICROVAL contains lactose and sucrose

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

3. How to take MICROVAL

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

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

Take MICROVAL every day for 28 days

- MICROVAL comes in strips of 28 pills, each marked with a day of the week.
- Take your pill at the same time every day. Make sure that you are never more than three hours late with a pill otherwise the contraceptive protection may be lost.
- Start by taking a pill marked with the correct day of the week.
- Follow the direction of the arrows on the strip. Take one pill each day, until you have finished all 28 pills.
- Swallow each pill whole, with water if necessary. Do not chew MICROVAL.

Then start your next strip

Start your next strip of MICROVAL the very next day after finishing the previous pack, again taking a pill marked with the day of the week. Always start the new strip on time.

You will be taking pills through your periods and there must be no break between packs.

As long as you take MICROVAL correctly, you will always start each new strip on the same day of the week.

Starting MICROVAL

As a new user or starting MICROVAL again after a break

It is best to take your first MICROVAL pill on the first day of your next period. Another method of contraception will not be required.

Changing to MICROVAL from another contraceptive Pill

- **If you are currently on a combined oral contraceptive:** start taking MICROVAL the day after your last active pill (discarding the placebo pills or disregarding MICROVAL-free interval). Another method of contraception will not be required.

- **Changing from another progestogen-only pill (POP):** you can start taking MICROVAL at any time without the loss of contraceptive protection.

- **Changing from a progestogen-only parenteral method (implant, injection):** additional non-hormonal contraceptive protection (e.g. a condom) is not required if you start exactly when the next implant or injection is due.

Starting MICROVAL after a miscarriage or abortion

If you have had a miscarriage or an abortion during the first three months of pregnancy, your doctor may tell you to start taking MICROVAL straight away, in which case another method of contraception will not be required.

Contraception after having a baby

If you have just had a baby your doctor will advise you to start taking MICROVAL immediately after delivery. If you start taking MICROVAL later than this you should use another method of contraception, such as a condom for the first 7 days of pill taking. If you have already had intercourse, then you should exclude the possibility of pregnancy before starting MICROVAL or wait until you have your first period.

When you want to get pregnant

If you are planning a baby, it's best to use another method of contraception after stopping MICROVAL until you have had a proper period. Your doctor or midwife relies on the date of your last natural period to tell you when your baby is due. However, it will not cause you or the baby any harm if you get pregnant straight away.

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

Always take MICROVAL exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

If you take more MICROVAL than you should

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

If you forget to take MICROVAL

If you are less than 3 hours late with a pill, take it straight away. Keep taking your pills at the usual time. This may mean taking two pills in one day. Don't worry – your contraceptive protection should not be reduced.

If you are more than 3 hours late with a pill, or you have missed more than one pill, your contraceptive protection may be reduced.

- Continue to take your next pills at your usual time.
- Use extra contraception for the next 7 days, such as condoms.

If you have missed any of the tablets in a strip and had intercourse in the week before missing the tablets, there is a possibility of becoming pregnant. The more consecutive tablets you have missed, the higher the risk that the contraceptive efficacy is decreased.

A lost pill

If you lose a pill:

Either take the last pill of the strip in place of the lost pill. Then take all the other pills on their proper days. When you start your next pack you will have a new starting day, one day earlier than before.

Or if you have another pack and do not want to change the starting day of your next strip, take a pill from that pack. Then take all the other pills from your current strip as usual. You can then keep the opened spare strip in case you lose any more pills.

If you are sick or have diarrhoea

If you are sick (vomit) within 2 hours of taking a tablet your body may not get its usual dose of hormones from that pill and you should take another pill as soon as possible. Follow the instructions in section 3. *A lost pill.* If you are not able to take another pill within 3 hours use extra contraception for the next 7 days, such as condoms.

If you are persistently sick or have bad diarrhoea, use extra contraception during the illness and for the 7 days after recovery, such as condoms.

4. Possible side effects

MICROVAL can have side effects.

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

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

- Swelling of the hands, feet, ankles, face, lips and 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 MICROVAL. 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:

- Any sudden changes to your eyesight (such as loss of vision or blurred vision),
- pain or swelling in your leg,
- stabbing pain when you breathe,
- coughing for no apparent reason,
- pain and tightness in the chest,
- sudden weakness or numbness in one side or part of your body,
- any sudden changes to your hearing, speech, sense of smell, taste or touch (stroke),

- suicidal thoughts/behaviour and suicide,
- hepatic tumours,
- breast tumours.

Signs of breast cancer include:

- Dimpling of the skin,
- changes in the nipple,

- any lumps you can see or feel.

Signs of severe liver problems include:

- Severe pain in your upper abdomen,
- yellow skin or eyes (*jaundice*),
- inflammation of the liver (*hepatitis*),
- your whole body starts itching.

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

- Lower stomach (abdominal) pain,
- nausea; vomiting; diarrhoea,
- extreme tiredness (fatigue).

Less frequent side effects:

- Bleeding and spotting between your periods or changes in your bleeding pattern,
- no periods for a long period of time (amenorrhoea),
- painful periods (dysmenorrheoa),
- loss of interest or increased interest in sex,
- putting on weight or losing weight,
- skin condition that causes hives, stinging, burning or itching on the skin (urticaria),
- itchy skin (pruritus),
- vaginal itchiness with a thick white discharge (vaginal candidiasis),
- swelling of the face due to fluid build up (face oedema).

Side effects with an unknown frequency:

- Headache,
- Headache often with nausea (migraine),
- dizziness,
- gall bladder disease (pain, nausea, vomiting, fever or chills),
- high BP (blood pressure) (hypertension),
- depression and mood changes,
- water retention,
- changes of the colour of your skin (skin pigmentation),

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: https://www.sahpra.org.za/Publications/Index/8.

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088/+27(0)11 239-6200

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

5. How to store MICROVAL

Store all medicines out of reach of children

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

Keep the blisters in the carton until required for use.

Do not store in a bathroom.

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

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 MICROVAL contains

The active substance is 0,03 mg of levonorgestrel.

The other ingredients are calcium carbonate, lactose monohydrate, magnesium stearate, polyethylene glycol, povidone, starch maize, sucrose, talc, waradur

What MICROVAL looks like and contents of the pack

MICROVAL is a white, lustrous, round biconvex sugar-coated tablet.

28 tablets are packed in a clear polyvinylchloride film sealed with an aluminium foil backing.

The blister strip is packed into an outer cardboard carton together with a leaflet.

Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead, 2191

Hotline: 0800 122 912

This leaflet was last revised in

20 May 2023

Registration number

E/18.8/58

Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

Botswana: BOT0901541 S2

Namibia: NS1 90/18.8/001056

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