PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

PRODUCT NAME, STRENGTH AND DOSAGE FORM

MARVELON® 150/30 Tablets, contains 0,15 mg desogestrel and 0,03 mg ethinylestradiol.

Contains sugar: lactose.

Read all of this leaflet carefully before you start taking MARVELON 150/30

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- MARVELON 150/30 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.

If any side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

What is in the Leaflet

1. **What MARVELON 150/30 is and what is it used for**
2. **What you need to know before you take MARVELON 150/30**
3. **How to take MARVELON 150/30**
4. **Possible side effects**
5. **How to store MARVELON 150/30**
6. **Contents of the pack and other information**

1. What MARVELON 150/30 is and what is it used for

MARVELON 150/30 is a combined oral contraceptive ('the combined Pill') used to prevent pregnancy.

2. What you need to know before you take MARVELON 150/30

Do not take MARVELON 150/30:

- If you have, or have had in the past a blood clot (thrombosis) in a blood vessel of the leg, lung (embolus) or other organs.
- If you have or have had a heart attack or stroke in the past.
- If you have or have ever had a condition that may be a first sign of a heart attack (such as angina pectoris or chest pain) or stroke (such as transient ischaemic attack or small reversible stroke).
- If you have a disturbance of blood clotting (e.g., protein C deficiency).
- If you need major surgery (e.g., an operation) and your ability to move around is limited for a long period of time (see **The Pill and Thrombosis**).
- If you have (had) a type of migraine called "migraine with aura".
- If you have diabetes mellitus with blood vessel damage.
- If you have a serious risk factor, or several risk factors for developing thrombosis, this may also be a reason why you cannot use MARVELON 150/30 (See **The Pill and Thrombosis**).
- If you have or have had a pancreatitis (an inflammation of the pancreas) associated with high levels of fatty substances in your blood.
- If you have jaundice (yellowing of the skin) or have (had) severe liver disease and your liver is not yet working normally.
- If you have or have had a cancer that may grow under the influence of sex hormones (e.g., of the breast or the genital organs).
- If you have or have had a liver tumour.
- If you have any unexplained vaginal bleeding.
- If you are pregnant or think you might be pregnant.
- If you are allergic to any of the ingredients of MARVELON 150/30.

Do not use MARVELON 150/30 if you have Hepatitis C and are taking the combination medicine regimen ombitasvir/paritaprevir/ritonavir, with or without dasabuvir (see **Other medicines and MARVELON 150/30**).

Warnings and Precautions

General notes

In this leaflet, several situations are described where you should stop taking the Pill, or where the reliability of the Pill may be decreased. In such situations you should not have sexual intercourse or you should take extra non-hormonal contraceptive precautions e.g. use a condom or another barrier method. Do not use rhythm or temperature methods. These methods can be unreliable because the Pill alters the usual changes in temperature and cervical mucus that occur during the menstrual cycle.

MARVELON 150/30 like all contraceptive Pills, does not protect against HIV infection (AIDS) or any other sexually transmitted disease.

What you need to know before taking MARVELON 150/30

If the combined Pill is used in the presence of any of the conditions listed below you may need to be kept under close observation. Your doctor can explain this to you. Therefore, if any of these apply to you, tell your doctor before starting to use MARVELON 150/30.

- you smoke
- you have diabetes
- you are overweight
- you have high blood pressure
- you have a heart valve disorder or a certain heart rhythm disorder
- you have an inflammation of your veins (superficial phlebitis)
- you have varicose veins

- anyone in your immediate family has had a thrombosis, a heart attack or a stroke
- you suffer from migraine
- you suffer from epilepsy
- you or someone in your immediate family have or have had high cholesterol or triglycerides (fats in the blood)
- anyone in your immediate family has had breast cancer
- you have liver or gallbladder disease
- you have Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease)
- you have systemic lupus erythematosus (SLE; a chronic connective tissue disease affecting the skin all over the body)
- you have haemolytic uraemic syndrome (HUS; a disorder of blood clotting causing failure of the kidneys)
- you have sickle cell disease (a rare blood disease)
- you have an operation or if your ability to move around is limited for a long period of time (see **The Pill and Thrombosis**).
- if you have recently given birth you are at an increased risk of blood clots. You should ask your doctor how soon after delivery you can start using MARVELON 150/30 (see **The Pill and Thrombosis**).
- you have a condition that occurred for the first time or got worse during pregnancy or previous use of sex hormones (e.g., hearing loss, a disease called porphyria, a skin disease called herpes gestationis, a disease called Sydenham's chorea)
- you have or have had chloasma (yellowish-brown pigmentation patches on the skin, particularly of the face); if so, avoid too much exposure to the sun or ultraviolet light
- If you are experiencing mood changes and depressive symptoms or are being treated for depression
- That you have had depression with previous use of oestrogen and/or progesterone/progestogen containing medicines.

If any of the above conditions appear for the first time, come back or get worse while using the Pill, you should contact your doctor.

The efficacy of combined oral contraceptives may be reduced in the event of missed tablets, vomiting or concomitant medication.

The Pill and Thrombosis

A thrombosis is the formation of a blood clot which may block a blood vessel.

A thrombosis sometimes occurs in the deep veins of the legs (deep venous thrombosis). If this blood clot breaks away from the veins where it is formed, it may reach and block the arteries of the lungs, causing a so-called "pulmonary embolism". Deep venous thrombosis is a rare occurrence. It can develop whether or not you are taking the Pill. The risk is higher in Pill-users than in non-users. The chance of getting a thrombosis is highest during the first year after you started using the Pill for the very first time. The risk is also higher if you restart using the Pill (the same product or a different product) after a break of 4 weeks or more. The risk is not as high as the risk of developing a thrombosis during pregnancy.

Blood clots can also occur very rarely in the blood vessels of the heart (causing a heart attack) or the brain (causing a stroke). Extremely rarely blood clots can occur in the liver, gut, kidney or eye.

Very occasionally a thrombosis may cause serious permanent disabilities or may even be fatal.

The risk of venous thrombosis in users of combined pills increases:

- with increasing age
- if you are overweight
- if one of your close relatives has had a blood clot (thrombosis) in the leg, lung or other organ at a young age

- if you must have an operation (surgery), any prolonged period of immobilisation, or if you have had a serious accident. It is important to tell your doctor in advance that you are using MARVELON 150/30 as the treatment may have to be stopped. Your doctor will tell you when to start MARVELON 150/30 again. This is usually about 2 weeks after you are able to move around (see **What you need to know before taking MARVELON 150/30**)
- If you gave birth less than a few weeks ago.

The risk of arterial thrombosis in users of combined pills increases:

- **If you smoke. You are strongly advised to stop smoking when you use MARVELON 150/30, especially if you are older than 35 years**
- if you have an increased fat content in your blood (cholesterol or triglycerides)
- if you have high blood pressure
- if you have migraine
- if you have a problem with your heart (valve disorder, a disturbance of the heart rhythm).

If you notice possible signs of a thrombosis, stop taking the Pill and consult your doctor immediately.

The Pill and Cancer

The information given below was obtained from studies of women who used combined oral hormonal contraceptives, such as the combined pill, and from an additional study that included both oral and non-oral hormonal contraceptive-users. In studies with the combined pill, 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 number of breast cancer diagnoses gradually disappears during the course of the 10 years after stopping use of the Pill. It is not known whether the difference is caused by the Pill. It may be that the women were examined more often, so that the breast cancer was noticed earlier.

In the additional study that included both oral and non-oral hormonal contraceptive users, the occurrence of breast cancer was reported to increase the longer the women used the

contraceptive. The difference in the reported risk of breast cancer between women who had never used the contraceptive and those who had used the contraceptive was small: 13 additional cases of breast cancer per 100,000 women years.

In rare cases benign liver tumours and even more rarely, malignant liver tumours have been reported in users of the Pill. These tumours may lead to internal bleeding. Contact your doctor immediately if you have severe pain in your stomach.

Cervical cancer is caused by an infection with the human papilloma virus. It has been reported to occur more often in women using the Pill for a long time. It is unknown if this finding is due to the use of hormonal contraceptives or to sexual behaviour and other factors (such as better cervical screening).

Other medicines and MARVELON 150/30

Always tell your health care provider if you are taking any other medicine, even those not prescribed. (This includes all complementary or traditional medicines.)
Also tell any other doctor or dentist who prescribes another medicine (or your pharmacist) that you use MARVELON 150/30.

Some medicines may prevent MARVELON 150/30 from working properly. These include medicines used for the treatment of:

- epilepsy (e.g., primidone, phenytoins, phenobarbital, carbamazepine, oxcarbamazepine, topiramate, felbamate)
- tuberculosis (e.g., rifampicin)
- HIV infections (e.g., ritonavir, nelfinavir, nevirapine, efavirenz)
- Hepatitis C virus infection (e.g., boceprevir, telaprevir)
- other infectious diseases (e.g., griseofulvin)
- high blood pressure in the blood vessels of the lungs (e.g., bosentan)
- depressive moods (the herbal remedy St. John’s wort).

If you are taking medicines or herbal products that might make MARVELON 150/30 less effective, a barrier contraceptive method should also be used. Since the effect of another medicine on MARVELON 150/30 may last up to 28 days after stopping the medicine, it is necessary to use the additional barrier contraceptive method for that long.

MARVELON 150/30 may also interfere with how other medicines work, causing either an increase in effect (e.g., ciclosporin) or a decrease in effect (e.g., lamotrigine).

Do not use MARVELON 150/30 if you have Hepatitis C and are taking the combination medicine regimen ombitasvir/paritaprevir/ritonavir, with or without dasabuvir as this may cause increases in liver function blood test results (increase in ALT liver enzyme). MARVELON 150/30 can be restarted approximately 2 weeks after completion of treatment with the combination medicine regimen. (See **What you need to know before you take MARVELON 150/30, Do not take MARVELON 150/30**).

When should you contact your doctor?

Regular check-ups

When you are using the Pill, your doctor will tell you to return for regular check-ups. In general, you should have a check-up every year.

Contact your doctor as soon as possible if:

- you notice any changes in your own health, especially involving any of the items mentioned in this leaflet (see also **Do not take MARVELON 150/30** and **What you need to know before you take MARVELON 150/30**); do not forget about the items related to your immediate family
- you feel a lump in your breast
- you experience symptoms of angioedema such as swollen face, tongue and/or throat and/or difficulty swallowing or hives together with difficulty breathing

- you are going to use other medications (see also **Other medicines and MARVELON 150/30**).
- you are to be immobilised or to have surgery (tell your doctor at least 4 weeks in advance)
- you have unusual, heavy vaginal bleeding
- you forgot tablets in the first week of the pack and had intercourse in the 7 days before
- you miss your period twice in a row or suspect you are pregnant (do not start the next pack until your doctor tells you).

Stop taking tablets and see your doctor immediately if you notice possible signs of thrombosis:

- an unusual cough
- severe pain in the chest which may reach the left arm
- breathlessness
- any unusual, severe, or prolonged headache or migraine attack
- partial or complete loss of vision, or double vision
- slurring or speech disability
- sudden changes to your hearing, sense of smell or taste
- dizziness or fainting
- weakness or numbness in any part of your body
- severe pain in your abdomen
- severe pain or swelling in either of your legs

Pregnancy and Breastfeeding

MARVELON 150/30 must not be used by women who are pregnant, or who think they may be pregnant, and is not usually recommended for use during breastfeeding. If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking MARVELON 150/30.

Driving and Using machines

There are no observed effects.

Important information about some of the ingredients of MARVELON 150/30

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before you start taking MARVELON 150/30.

3. How to take MARVELON 150/30

When and how to take the tablets

The MARVELON 150/30 pack contains 28 tablets. On the pack, each tablet is marked with the day of the week on which it is to be taken. One tablet is to be taken daily for 28 consecutive days. Take your tablet at about the same time each day, with some liquid if necessary. The first tablet should be taken from the blister in the green section of the calendar pack marked with the appropriate day of the week. Follow the direction of the arrows until all 28 tablets have been taken. A period should begin during the 7 days that you use the placebo tablets (the withdrawal bleed). Usually, it will start on day 2 to 3 after the last large tablet. Start taking your next pack on the 8th day 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.

Starting your first pack of MARVELON 150/30

When no hormonal contraceptive has been used in the past month

Start taking MARVELON 150/30 on the first day of your cycle i.e. the first day of menstrual bleeding. Take a tablet marked with that day of the week. For example, if your period starts on a Friday, take a tablet marked Friday. Then follow the days in order.
MARVELON 150/30 will work immediately, it is not necessary to use an additional contraceptive method. You may also start on days 2 to 5 of your cycle, but in that case make sure you also use an additional contraceptive method (barrier method) for the first 7 days of tablet-taking in the first cycle.

When changing from another combined Pill

You can start taking MARVELON 150/30 the day after you take the last tablet from your present Pill pack (this means no tablet-free break). If your present Pill pack also contains inactive (placebo) tablets you can start MARVELON 150/30 on the day after taking the last active tablet (if you are not sure which this is, ask your doctor or pharmacist). You can also start later, but never later than the day following the tablet-free break of your present Pill (or the day after the last inactive tablet of your present Pill).

When changing from a progestogen-only pill (mini pill)

You can stop taking the mini pill any day and start taking MARVELON 150/30 the next day, at the same time. But if you are having intercourse, make sure you also use an additional contraceptive method (a barrier method) for the first 7 days that you are taking MARVELON 150/30.

When changing from an injectable or implant

Start using MARVELON 150/30 when your next injection is due or on the day that your implant is removed. But if you are having intercourse, make sure you also use an additional contraceptive method (a barrier method) for the first 7 days that you are taking MARVELON 150/30.

After having a baby

If you have just had a baby, your doctor may tell you to wait until after your first normal period before you start taking MARVELON 150/30. Sometimes it is possible to start sooner. Your doctor will advise you. If you are breastfeeding and want to take MARVELON 150/30, you should discuss this first with your doctor.

After a miscarriage or an abortion

Your doctor will advise you.

If you take more MARVELON 150/30 than you should

There have been no reports of serious harmful effects from taking too many MARVELON 150/30 tablets at one time. If you have taken several tablets at a time, you may have nausea, vomiting or vaginal bleeding. If you discover that a child has taken MARVELON 150/30, ask your doctor for advice.

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

What to do if

If you forget tablets:

- **If you are less than 12 hours late** in taking a tablet, the reliability of the Pill is maintained. Take the tablet as soon as you remember and take the next tablets at the usual times.
- **If you are more than 12 hours late** in taking an active tablet, the reliability of the Pill may be reduced. The more consecutive tablets you have missed, the higher the risk that the contraceptive efficacy is decreased. There is a particularly high risk of becoming pregnant if you miss large (active) tablets at the beginning of the pack or in the third week (the week before you start taking the small tablets). Therefore, you should follow the rules given below.

More than one tablet forgotten in a pack

Ask your doctor for advice.

1 tablet missed in week 1 (active tablets)

Take the missed tablet as soon as you remember (even if this means taking 2 tablets at the same time) and take the next tablet at the usual time. Use extra contraceptive precautions (barrier method) for the next 7 days. If you had sexual intercourse in the week before missing the tablets, there is a possibility of becoming pregnant. Tell your doctor immediately.

1 tablet missed in week 2 (active tablets)

Take the missed tablet as soon as you remember (even if this means taking 2 tablets at the same time) and take the next tablet at the usual time. The reliability of the Pill is maintained. You need not use extra contraceptive precautions.

1 tablet missed in week 3 (active tablets)

You may choose either of the following options, without the need for extra contraceptive precautions.

1. Take the missed tablet as soon as you remember (even if this means taking 2 tablets at the same time) and take the next tablets at the usual time. Start the next pack as soon as the large (active) tablets in the current pack are finished, so skip the smaller placebo tablets. You may not have a withdrawal bleed until you take the placebo tablets at the end of the second pack but you may have spotting or breakthrough bleeding on active tablet-taking days.

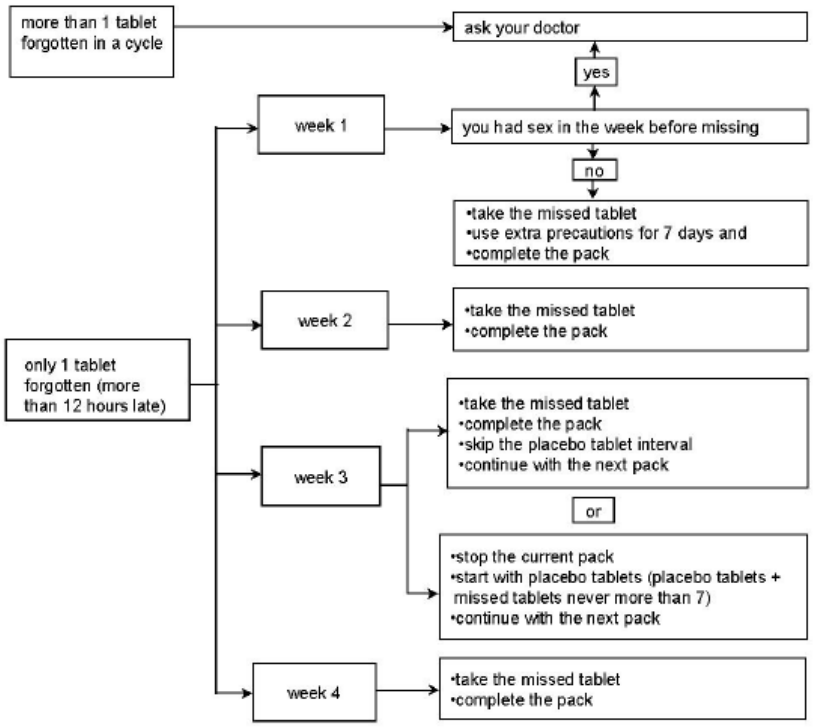
or

2. Stop taking the large (active) tablets from your current pack and immediately continue with the smaller placebo tablets (**a maximum of 6 days, the total number of placebo plus missed tablets may not be more than 7**). Then continue with the next pack. When following this method, you can always start your next pack on the same day of the week as you usually do.

1 tablet missed in week 4 (inactive tablets)

The reliability of the Pill is maintained. Take the tablet as soon as you remember and take the next tablets at the usual times.

If you have forgotten tablets in a pack and you do not have the expected period in the first normal placebo tablet interval, you may be pregnant. Consult your doctor before you start with the next pack.



If you suffer from gastrointestinal disturbances (e.g., vomiting, severe diarrhoea)

If you vomit or have severe diarrhoea, the active ingredients of your MARVELON 150/30 tablet may not have been completely absorbed. If you vomit within 3 to 4 hours after taking your tablet, this is like missing a tablet. You must follow the advice for missed tablets. If you have severe diarrhoea, please tell your doctor.

If you want to delay your period

You can delay your period if you continue with the large (active) tablets in your next pack of MARVELON 150/30 immediately after finishing the large (active) tablets in your current pack. You can continue with this pack for as long as you wish, until this pack is empty. When you wish your period to begin, just stop tablet-taking. While using the second pack you may have some breakthrough bleeding or spotting on active tablet-taking days. Start with your next pack after the usual 7-day placebo tablet interval.

If you want to change the starting day of your period

If you take your tablets as directed, you will have your period on about the same day every 4 weeks. If you want to change this, just shorten, (never lengthen) the next placebo tablet interval. For example, if your period usually starts on a Friday and in future you want it to start on Tuesday (3 days earlier) you should now start your next pack 3 days sooner than you usually do. If you make your placebo tablet interval very short (e.g., 3 days or less), you may not have a bleeding during the interval. You may have some breakthrough bleeding or spotting during the use of the large tablets in the next pack.

If 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 2 tablet-taking cycles). If bleeding continues, becomes heavy or starts again, tell your doctor.

If you have missed a period

If you have taken all of your tablets at the right time, and you have not vomited, or used other medicines then it is unlikely that you are pregnant. Continue to take MARVELON 150/30 as usual. If you miss your period twice in a row, you may be pregnant. Tell your doctor immediately. Do not start the new pack of MARVELON 150/30 until your doctor has checked that you are not pregnant.

When you want to stop taking MARVELON 150/30

You can stop taking MARVELON 150/30 at any time you want. If you do not want to become pregnant, ask your doctor about other methods of birth control.

If you stop taking MARVELON 150/30 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.

4. Possible side effects

MARVELON 150/30 can have side effects.

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

Tell your doctor if you notice any unwanted effect, especially if severe or persistent, or if there is a change in your health that you think might be caused by the Pill.

Serious Side Effects

Serious reactions associated with the use of the Pill, as well as the related symptoms, are described in the sections **The Pill and Thrombosis** and **The Pill and Cancer**. Please read these sections for additional information and consult your doctor at once where appropriate.

Other Possible Side Effects

The following side effects have been reported by users of the Pill, although they need not be caused by the Pill. These side effects may occur in the first few months that you are using the Pill and usually lessen with time.

Common (occurring in more than one per 100 users):

- depressed mood, mood changes
- headache
- nausea, abdominal pain
- breast pain, breast tenderness
- increase or decrease in body weight

Uncommon (occurring in more than one per 1000 users but not more than one per 100 users):

- fluid retention
- decreased or increased sexual drive
- migraine
- vomiting, diarrhoea
- rash, hives
- breast enlargement

Rare (occurring in less than one per 1000 users):

- hypersensitivity reactions
- blood clot in a vein
- blood clot in an artery
- contact lens intolerance
- erythema nodosum, erythema multiforme (these are skin conditions)
- breast secretion, vaginal secretion

Unknown (frequency cannot be estimated from the available data):

- suicidal thoughts/behaviour and suicide

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of MARVELON 150/30.

5. How to store MARVELON 150/30

Store at or below 30 °C. Protect from light and moisture.

Keep all medicines out of the reach and sight of children.

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 MARVELON 150/30 contains

Active ingredients: Each larger white tablet contains 0,15 mg desogestrel and 0,03 mg ethinylestradiol. The smaller white tablet does not contain any active ingredients.

Inactive ingredients: In the larger white tablet: Colloidal silicon dioxide, lactose, magnesium stearate, potato starch, povidone, stearic acid and dl-alpha-tocopherol. In the smaller white tablet: Lactose, magnesium stearate, potato starch.

Contains sugar: lactose.

What MARVELON 150/30 looks like and contents of the pack

MARVELON 150/30 consists of two types of tablets distinguished by mark and size. The 21 larger white tablets contain the active ingredients and are round and biconvex. They have bevelled edges, coded ORGANON and a star on one side and the tablet code TR above 5 on the reverse side. The 7 smaller white tablets are round and flat with bevelled edges coded KH above 2 on one side and a square on the reverse side.

Push-through strips contain 21 active white tablets and 7 smaller white placebo (inactive) tablets, the latter being circled in red on the strip foil.

Holder of certificate of registration

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