PROPOSED PATIENT INFOMRATION LEAFLET: MARDESSA

SCHEDULING STATUS: **S3**

MARDESSA film-coated tablets

Desogestrel (0,15 mg) and ethinylestradiol (0,02 mg).

Active tablets – contains sugar (lactose monohydrate 54,91 mg/tablet).

Inactive tablets - contains sugar (lactose monohydrate 55,50 mg/tablet).

Read all of this leaflet carefully before you start taking MARDESSA

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.

MARDESSA 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 MARDESSA is and what it is used for

2. What you need to know before you take MARDESSA

3. How to take MARDESSA

4. Possible side effects

5. How to store MARDESSA

6. Contents of the pack and other information

1. What MARDESSA is and what it is used for

MARDESSA is a combined oral contraceptive (“the combined Pill”) used to prevent pregnancy.

2. What you need to know before you take MARDESSA

Do not take MARDESSA

- if you are allergic (hypersensitive) to desogestrel and ethinylestradiol or any of the other ingredients of MARDESSA (listed in section 6).
- 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 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 MARDESSA
  (see also "The Pill and Thrombosis"}.
- If you have or have had 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 severe liver disease.
- 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.

General notes:

In this leaflet, several situations are described where you should stop taking MARDESSA, or where the reliability of MARDESSA 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 the rhythm or temperature methods. These methods can be unreliable because MARDESSA alters the usual changes in temperature and cervical mucus that occur during the menstrual cycle.

Women should be advised that MARDESSA like all contraceptive Pills does not protect against HIV infections (AIDS) and other sexually transmitted diseases (STDs). Women should be advised that additional barrier contraceptive measures are needed to prevent transmission of STDs and HIV infection.

Warnings and precautions

Talk to your pharmacist, doctor or other healthcare provider before taking this medicine.

If 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, before starting to use MARDESSA, tell your doctor.

• if you smoke

• if you have diabetes

• if you are overweight

• if you have high blood pressure

• if you have a heart valve disorder or a certain heart rhythm disorder

• if you have an inflammation of your veins (superficial phlebitis)

• if you have varicose veins

• if anyone in your immediate family has had a thrombosis, a heart attack or a stroke

• if you suffer from migraine
• if you suffer from epilepsy
• if you or someone in your immediate family has or has had high blood levels of cholesterol or triglycerides (fatty substances)
• if anyone in your immediate family has had breast cancer
• if you have liver or gallbladder disease
• if you have Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease)
• if you have systemic lupus erythematosus (SLE, a chronic connective tissue disease affecting the skin all over the body)
• if you have haemolytic uraemic syndrome (HUS, a disorder of blood coagulation causing failure of the kidneys)
• if you have sickle cell disease (for example, sickle cell anaemia, or other sickle cell conditions)
• if you have a condition that occurred for the first time or worsened during pregnancy or previous use of sex hormones (e.g. hearing loss, a metabolic disease called porphyria, a skin disease called herpes gestationis, a neurological disease called Sydenham's chorea)
• if 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 radiation.

If any of the above conditions appear for the first time, recur or worsen while using MARDESSA, you should contact your doctor.

Depressed mood and depression are well-known undesirable effects of hormonal contraceptive use. Depression can be serious and is a well-known risk factor for suicidal behaviour and suicide. You should contact your healthcare professional if you experience mood changes and depressive symptoms, including shortly after initiating the treatment.
The efficacy of MARDESSA 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 after you started using the Pill for the very first lime. Thrombosis can also happen if you become pregnant.

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 venous or arterial thromboembolic events may cause serious permanent disabilities, may be life-threatening or may even be fatal.

The risk of 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 MARDESSA as the treatment may have to be stopped. Your doctor will tell you when to start MARDESSA again. This is usually about 2 weeks after you are back on your feet.
- **If you smoke. You are strongly advised to stop smoking when you use MARDESSA, 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 MARDESSA and consult your doctor immediately.

The Pill and 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. 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 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).

***Regular check-ups*:**

When you are using MARDESSA, 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 “Before you take MARDESSA” and “Do not take MARDESSA”; 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 MARDESSA”);
- you are to be immobilised or are to have surgery (consult your doctor at least four 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 told to by your doctor).

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 have 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.

Children and adolescents

MARDESSA is only indicated after menarche (first menstrual cycle).

Other medicines and MARDESSA

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

They can tell you if you need to take additional contraceptive precautions, and if so, for how long.

Some medicines may stop MARDESSA from working properly. These include medicines used for the treatment of epilepsy (e.g. primidone, phenytoin, barbiturates, carbamazepine, oxcarbazepine, topiramate, felbamate); tuberculosis (e.g. rifampicin, rifabutin) and HIV infections (e.g. ritonavir, nevirapine); antibiotics (e.g. penicillins, tetracyclines, griseofulvin) for some other infectious diseases; and the herbal remedy St. John's Wort (primarily used for the treatment of depressive moods).

Taking MARDESSA with food and drink:

MARDESSA tablets may be taken with or without food. They must be taken whole with a drink of some liquid if needed.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

MARDESSA 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 while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

Driving and using machines

No effects have been observed that would show that taking MARDESSA would influence your ability to drive.

MARDESSA contains lactose

Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance should not take MARDESSA.

3. How to take MARDESSA

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

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

When and how to take the tablets:

The MARDESSA pack contains 28 tablets (21 white active tablets and 7 green inactive tablets).

Take your tablet at about the same time each day, with some liquid if necessary.

The first tablet should be taken from the silver section of the calendar pack by selecting the tablet corresponding to the day of the week (e.g. “MO’ for Monday). Thereafter one tablet must be taken daily for 28 days following the direction shown by the arrows, until the pack is finished.

A period should begin during the 7 days that you use the inactive tablets (the withdrawal bleed). Usually it starts on day 2 or 3 after starting the inactive tablets and may not have finished before the next pack is started. Each subsequent pack is started in the silver section the day after the last tablet of the current pack.

This means that you will always start new packs on the same day of the week, and also that you have your period on about the same days, each month.

Starting your first pack of MARDESSA:

When no hormonal contraceptive has been used in the past month:

Start taking MARDESSA on the first day of your cycle, i.e. the first day of menstrual bleeding. The first tablet should be taken from the silver section of the calendar pack by selecting the tablet corresponding to the day of the week (e.g. “MO’ for Monday). Then take 1 tablet every day following the directions shown by the arrows. 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 should start with MARDESSA preferably on the day after the last active tablets of your present Pill pack, but at the latest on the day following the usual inactive tablet phase of your present Pill pack. The first MARDESSA tablet should be taken from the silver section of the calendar pack by selecting the tablet corresponding to the day of the week (e.g. “MO’ for Monday). Then take 1 tablet every day following the directions shown by the arrows.

When changing from a progestogen-only method (minipill):

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

When changing from an injectable or implant:

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

After having a baby:

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

After a miscarriage or an abortion:

Your doctor will advise you.

If you take more MARDESSA 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 have taken several tablets at a time, you may have nausea, vomiting or vaginal bleeding. If you discover that a child has taken MARDESSA, ask your doctor for advice. Taking the inactive tablets from the bottom row of the blister is harmless because they do not contain active ingredients.

If you forget to take MARDESSA

• 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 tablet at the usual time.

• If you are **more than 12 hours late** in taking any active tablet, the reliability of the Pill may be reduced. The more consecutive active tablets you have missed, the higher the risk that the contraceptive effect is decreased. There is a particularly high risk of becoming pregnant if you

miss tablets in the week before or in the week after the inactive 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 two 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 have had sexual intercourse in the week before missing the tablet, there is a possibility of becoming pregnant, so 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 two tablets at the same time) and take the next tablet at the usual time. The reliability of the Pill is maintained and 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 two tablets at the same time) and take the next tablet at the usual time until the active tablets are used up. The inactive tablets must be discarded. Start the next pack right away, from the silver section by selecting the appropriate tablet for that day of the week. You may not have a withdrawal bleed/period until the end of the active tablets in the second pack, but you may have spotting or breakthrough bleeding on active tablet-taking days.

or

2. Stop taking the active tablets from your current pack and immediately continue with the inactive tablets (a maximum of 6 days, the total number of inactive tablets plus missed tablets

may not be more than 7). Then continue with the next pack, starting in the silver section with the appropriate day of the week.

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 inactive tablet phase, you may be pregnant. Consult your doctor before you start the next pack.

What to do if:

You suffer from gastro-intestinal disturbances (e.g. vomiting, severe diarrhoea):

If you vomit, or have severe diarrhoea after taking active tablets, the active ingredients of your MARDESSA 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. Therefore, follow the advice for missed tablets. If you have severe diarrhoea, please contact your doctor. Vomiting or diarrhoea while taking inactive tablets does not have an influence on the contraceptive reliability.

You want to delay a period:

You can delay your period if you start with your next pack of MARDESSA tablets immediately after finishing the active tablets of your current pack (do not take the inactive tablets). You can continue with this pack for as long as you wish, e.g. 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 inactive tablet phase.

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 inactive tablet phase. 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 inactive tablet phase very short (e.g. 3 days or less), you may not have bleeding during the inactive tablet phase. You may have some breakthrough bleeding or spotting during the use of the active tablets in the next pack.

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 MARDESSA 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 MARDESSA until your doctor has checked that you are not pregnant.

When you want to stop taking MARDESSA:

You can stop taking MARDESSA 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 MARDESSA 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

MARDESSA can have side effects.

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

If you notice possible signs of thrombosis, myocardial infarction or a stroke such as:

• 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 have speech disability;

• 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.

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 reported include the following:

- Depressive mood, altered mood, headache, migraine, nausea, vomiting, diarrhoea,

abdominal pain, rash, hives, body weight changes, fluid retention.

Other less frequent side effects reported include the following:

- changes in interest in sex, contact lens intolerance, breast discharge, vaginal discharge, inflammation of the skin, hypersensitivity reactions.

Frequency unknown:

- suicidal thoughts/behaviour and suicide

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

Reporting of side effects

If you experience side effects, talk to your doctor or pharmacist.

You can report side effects to Actor Pharma (Pty) Ltd via

email: pharmacovigilance@actorpharma.co.za or telephonically on 011 312 3812.

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 MARDESSA.

5. How to store MARDESSA

Store all medicines out of reach of children.

Store at or below 25 °C in the original package in order to protect from light.

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 systems (e.g. toilets).

6. Contents of the pack and other information

What MARDESSA contains

The active substances are desogestrel and ethinylestradiol.

The other ingredients are:

Active tablets

Core:

Lactose monohydrate, maize starch, povidone, RRR-α-Tocopherol,

silica colloidal hydrated, silica colloidal anhydrous, stearic acid

Coating:

Hypromellose, polyethylene glycol, titanium dioxide.

Inactive tablets

Core:

lactose monohydrate, maize starch, povidone, silica colloidal anhydrous, magnesium stearate

Coating:

Hypromellose, triacetin, polysorbate 80, titanium dioxide , FD&C Blue 2 Aluminium Lake, yellow iron oxide

What MARDESSA looks like and contents of the pack

21 Round, white (active) film-coated tablets with C and 5 debossed on opposite sides.

7 Round, green (inactive) film-coated tablets.

Each carton contains a blister pack of 28 film-coated tablets.

Holder of Certificate of Registration

Actor Pharma (Pty) Ltd[1]

Royal Palm Business Estate

Unit 7, 646 Washington Street

Halfway House, Midrand, 1685

This leaflet was last revised in

Registration number

To be allocated

Access to the corresponding Professional Information:

The corresponding Professional Information is available electronically on www.actorpharma.co.za. Alternatively, to obtain this Professional Information please contact Actor Pharma (Pty) Ltd on 011-312 3812 or email info@actorpharma.co.za.

[1] Company Registration number: 2008/008787/07