PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

VISANNE® 2 mg dienogest tablets

The active substance is dienogest
(Contains 63 mg lactose monohydrate per tablet)

Read all of this leaflet carefully before you start taking VISANNE.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- VISANNE 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 you get any side effects talk to your doctor or pharmacist. This includes any possible side effects listed in this leaflet. See section 4.

What is in this leaflet

1. What VISANNE is and what it is used for:

VISANNE is a hormone preparation for the treatment of endometriosis (painful symptoms due to displaced tissue of the lining of the womb). VISANNE contains a hormone, the progestogen dienogest. VISANNE tablets cause the shrinking of the endometrial tissue and reduces associated complaints such as pelvic pain and painful monthly bleedings.

2. What you need to know before you take VISANNE

Do not take VISANNE:

(You must not use VISANNE if you have any of the conditions listed below. If any of these apply to you, tell your doctor before starting to use VISANNE.)

- If you are suffering from **blood clot** (thromboembolic disorder) in your veins. Thrombosis is the formation of a blood clot which may block a blood vessel. Thrombosis sometimes occurs in the deep veins of the legs (deep vein thromboembolism). If this blood clot breaks away from the veins where it

is formed, it may reach and block arteries of the lungs, causing a so-called "pulmonary embolism". This may occur for example in the blood vessels of the legs (deep vein thrombosis) and the lungs (pulmonary embolism).

- If you have or have ever had **several arterial diseases**, including cardiovascular diseases such as a **heart attack, stroke or heart diseases** which cause reduced blood supply to the heart (angina pectoris).
- If you have **diabetes mellitus**.
- If you suffer or have ever suffered from **severe liver disease** (as long as your liver function values have not returned to normal). Symptoms of liver diseases may be, for instances, yellowing of the skin and/ or itching of the whole body.
- If you have or have ever had a non-invasive or invasive cancer of the liver.
- If you suffer or have ever suffered from invasive sex hormone-dependent tumour such as cancer of the breast or the genital organs.
- If you have unexplained **vaginal bleeding**.
- If you are **allergic** to dienogest or any of the other ingredients of VISANNE see section "What VISANNE" contains".

If any of these conditions appear for the first time while using VISANNE, stop taking it at once or consult your doctor.

Warnings and precautions:

You must not use hormonal contraceptives of any form (tablet, patch, intrauterine system) while taking VISANNE.

VISANNE is NOT a contraceptive. If you want to prevent pregnancy, you should use condoms or other nonhormonal contraceptive precautions.

In some situations you need to take special care while using VISANNE, and your doctor may need to examine you regularly. Tell your doctor if any of the following conditions applies to you:

If you:

- have ever had a **blood clot** (venous thromboembolism) or anyone in your immediate family has had a blood clot at a relatively early age
- have a close relative who has had **breast cancer**
- have ever suffered from **depression**
- have **high blood pressure** or develop high blood pressure while taking VISANNE
- develop a **liver disease** while taking VISANNE. Symptoms may include yellowing of the skin or eyes or itching all over your body. Inform your doctor also if such symptoms occurred during a previous pregnancy
- have diabetes or had **diabetes** temporarily during previous pregnancy
- have ever had **chloasma** (golden-brown patches on the skin, particularly of the face); if so, avoid too much exposure to the sun or ultraviolet radiation
- suffer from **pain in your lower abdomen** while taking VISANNE.

While taking VISANNE your chance of becoming pregnant is reduced because VISANNE may affect ovulation.

If you become pregnant while taking VISANNE you are at **a slightly increased risk** of having an extrauterine pregnancy (the embryo develops outside the womb). Tell your doctor before you start taking VISANNE, if you had an extrauterine pregnancy in the past or have an impaired function of the Fallopian tubes.

VISANNE and serious uterine bleeding

Uterine bleeding, for example in women with a condition where the mucous membrane of your uterus (endometrium) grows into the muscle layer of your uterus, called adenomyosis uteri or **benign tumours of the womb** sometimes called uterine fibroids (uterine leiomyomata), may become worse with the use of VISANNE. If bleeding is heavy and continuous over time, this may lead to low red blood cell levels (anaemia), which may be severe in some cases. In the event of anaemia, you should discuss with your doctor if you should stop taking VISANNE.

VISANNE and changes in bleeding pattern

Most women treated with VISANNE experience changes in their menstrual bleeding pattern (see section 4, Possible side effects).

VISANNE and venous blood clots

Some studies indicate that there may be a slight, but not statistically significant, increased risk of a **blood clot in the legs (venous thromboembolism)** associated with the use of preparations with progestagens like VISANNE. Very rarely, blood clots may cause serious permanent disabilities or may even be fatal.

The risk of a **venous blood clot** increases:

- with increasing age
- if you are overweight
- if you or one of your close relatives had a blood clot in the leg (thrombosis), lung (pulmonary embolism), or other organ at a young age
- if you must have surgery, if you have had a serious accident or if you are immobilized for a long time. It is important to tell your doctor in advance that you are using VISANNE as the treatment may have to be stopped. Your doctor will tell you when to start VISANNE again. This is usually about two weeks after you are back on your feet

VISANNE and arterial blood clots

There is little evidence for an association between preparations with progestagens like VISANNE and an increased risk of a blood clot in, for example, the blood vessels of the heart (heart attack) or the brain (stroke). In women with hypertension the risk of stroke may be slightly enhanced by these preparations.

The risk of an **arterial blood clot** increases:

- **if you smoke. You are strongly advised to stop smoking when you use VISANNE, especially if you are older than 35 years.**
- if you are overweight
- if one of your close relatives had a heart attack or stroke at a young age

- if you have high blood pressure

Talk to your doctor before taking VISANNE

Stop taking VISANNE and contact your doctor immediately if you notice possible signs of a blood clot, such as:

- severe pain and/or swelling in one of your legs
- sudden severe pain in the chest which may reach the left arm
- sudden breathlessness
- sudden cough without an obvious cause
- any unusual, severe or long-lasting headache or worsening of migraine
- partial or complete blindness or double vision
- difficulty in speaking or inability to speak
- giddiness or fainting
- weakness, strange feeling, or numbness in any part of the body

VISANNE and cancer

It is not clear from the data currently available whether or not VISANNE increases the risk of breast cancer. Breast cancer has been observed slightly more often in women taking hormones compared to those not taking hormones, but it is not known whether this is caused by the treatment. For example, it may be that more tumours are detected and detected earlier in women taking hormones because they are examined by their doctor more often. The occurrence of breast tumours becomes gradually less after stopping the hormone treatment. **It is important to regularly check your breasts** and you should contact your doctor if you feel any lump.

In rare cases, benign liver tumours, and in even fewer cases malignant liver tumours have been reported in women taking hormones. Contact your doctor if you have unusually severe stomach pain.

VISANNE and osteoporosis

Changes in bone mineral density (BMD)

The use of VISANNE may affect the strength of the bone of adolescents (12 to under 18 years). If you are under 18 your doctor will, therefore, carefully weigh the benefits and risks of using VISANNE for you as an individual patient, taking into account possible risk factors for bone loss (osteoporosis).

If you use VISANNE, it will help your bones if you have an adequate intake of calcium and vitamin D either via your food or via supplements.

If you have an increased risk of getting osteoporosis (weakening of bones due to loss of bone minerals), your doctor will carefully weigh the risks and benefits of treatment with VISANNE because VISANNE has

a moderate suppressing effect on the production of oestrogen (another type of female hormone) by your body.

Contact your doctor as soon as possible if:

- you notice any changes in your own health, especially involving any items mentioned in the leaflet.
- you are going to use other medication (see also "Using other medicines").
- you are to be immobilised or are to have surgery (consult your doctor at least four weeks in advance).
- you suspect you are pregnant (do not start the next pack until told to by your doctor).

When you are using VISANNE, you need to have regular check-ups, your doctor will tell you when to return for your check-up.

Children and adolescents

VISANNE is not for use in female children before menarche (first menstrual bleeding).

Elderly population(65 years or older)

There is no relevant use for VISANNE in elderly patients

Patients with impaired liver function

Do not take VISANNE if you suffer from impaired liver function (see section "Do not take VISANNE")

Other medicines and VISANNE:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of VISANNE with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

The following may **reduce** the effects of VISANNE:

- Medicines used for the treatment of:
  - **Epilepsy** (e.g. phenytoin, barbiturates, primidone, carbamazepine, oxcarbazepine, topiramate, felbamate)
  - **Tuberculosis** (e.g. rifampicin)
  - Other **infections** (antibiotics such as griseofulvin)
- Herbal remedy St. John's wort

The following may **increase** the levels of VISANNE in your blood:

- Medicines such as
  - **Medicines used to treat fungal infections** (e.g., itraconazole, voriconazole, fluconazole)
  - **Antibiotics** (erythromycin, clarithromycin)
  - **Blood pressure medication** (e.g. diltiazem, verapamil)

The following may have variable effects on the levels of VISANNE in your blood:

- **Protease inhibitors and non-nucleoside reverse transcriptase inhibitors for HIV / Hepatitis C Virus infections**

Ask your doctor or pharmacist before taking any medicine

VISANNE with food and drink:

During treatment with VISANNE, you should avoid drinking grapefruit juice, because this may increase the levels of VISANNE in your blood. This may increase the risk of getting side effects.

Pregnancy, breastfeeding and fertility:

Limited data from women exposed to dienogest during pregnancy reveal no special risk. However, VISANNE should not be taken by pregnant women because there is no need to treat endometriosis during pregnancy. Your doctor will make sure you are not pregnant before you start VISANNE treatment.

Treatment with VISANNE during breastfeeding is not recommended. Available data indicate that dienogest passes into breast milk.

Ask your doctor or pharmacist for advice before using VISANNE.

Driving and using machines:

There are no observed side effects.

VISANNE contains:

VISANNE contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take VISANNE:

Always take VISANNE exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The following statement applies to VISANNE unless otherwise prescribed by your physician. Please observe these instructions for use, otherwise you will not fully benefit from VISANNE.

Tablet-taking from the very first pack has to start on day 1 of the natural cycle (i.e. the first day of your menstrual bleeding).

The recommended dose is one tablet daily without any break, taken preferably at the same time each day with some liquid as needed. Tablets must be taken throughout 28 days without regard to bleeding. This means that after the first pack has been finished, the next should be started without interruptions.

Patients with impaired kidney function

There is no data suggesting the need for a dosage adjustment in patients with impaired kidney function.

If you take more VISANNE than you should:

You should not take more than your doctor tells you to.
In the event of overdosage consult your doctor or pharmacist. If neither is available, seek help from the nearest hospital or poison control centre.

If you forget to take VISANNE/ If you suffer from vomiting and/or diarrhoea:

The efficacy of VISANNE may be reduced in the event of missed tablets, vomiting and/or diarrhoea (if occurring within 3 to 4 hours after tablet taking). In the event of missed tablet(s), you should take one tablet only, as soon as you remember, and should then continue the next day to take the tablet at your usual time. A tablet not absorbed due to vomiting or diarrhoea should likewise be replaced by one tablet.
Do not take a double dose to make up for forgotten individual doses.

If you stop taking VISANNE:

If you stop taking VISANNE, your original endometriosis complaints may re-occur.
Your doctor will tell you for how long you should take VISANNE.

4. Possible side effects:

VISANNE can cause side effects. You may experience changes in your bleeding patterns, such as infrequent or frequent bleeding, irregular bleeding, prolonged bleeding, or your periods may stop completely.

Stop taking VISANNE and see your doctor immediately if you notice possible signs of thrombosis which include:

- breathlessness;
- an unusual cough;
- severe pain in the chest which may reach the left arm;
- 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.

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

Tell your doctor if you notice any of the following:

- a lump in your breast;
- unusual, heavy vaginal bleeding;
- other abdominal complaints that are different to the symptoms you commonly experience from your endometriosis.

In addition to the adverse effects listed in the other sections below, we list possible side effects:

Frequent:
- weight gain;
- depressed mood, problems sleeping, nervousness, loss on interest in sex, or changed mood;
- headache or migraine;
- nausea, abdominal pain, wind, swollen tummy or vomiting;
- acne or hair loss;
- back pain;
- breast discomfort, ovarian cyst or hot flushes;
- uterine/vaginal bleeding including spotting;
- weakness (asthenic conditions) or irritability.

Less frequent:
- weight loss or increased appetite;
- anxiety, depression or mood swings;
- imbalance in the autonomic nervous system (controls unconscious bodily functions e.g. perspiration) or disturbed attention;
- dry eyes;
- tinnitus;
- unspecified circulatory problems or palpitations (e.g. transient feeling of fatigue or dizziness);
- low blood pressure;
- shortness of breath;
- diarrhoea, constipation, abdominal discomfort, inflammation of the stomach and intestines (gastrointestinal inflammation), inflammation of the gums (gingivitis);
- dry skin, excessive sweating, itching of the whole body, male pattern hair growth (hirsutism), brittle nails, dandruff, dermatitis, abnormal hair growth, hypersensitive response to light or problem with skin pigmentation (e.g. patches of darker pigmentation in the facial area);
- pain in your bones, muscle spasm, pains and/ or sensation of heaviness in your arms and hands or legs and feet;
- urinary tract infection;
- vaginal thrush, dryness of the genital area, vaginal discharge, pelvic pain, atrophic inflammation of the genitals with discharge (atrophic vulvovaginitis) or a lump or lumps in the breast (breast mass, fibrocystic breast disease, breast induration);
- swelling due to fluid retention.

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

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

Reporting of side effects

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

5. How to store VISANNE

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.
Store at or below 30 °C.
Do not use VISANNE after the expiry date which is stated on the pack.

Medicine should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicine no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What VISANNE contains:

- The active substance is dienogest. Each tablet contains 2 mg dienogest.

- The other ingredients are:
  - Crospovidone
  - Lactose monohydrate
  - Magnesium stearate
  - Microcrystalline cellulose
  - Potato starch
  - Povidone
  - Talc.

What VISANNE looks like and contents of the pack

White to off-white, round, flat-faced, bevelled tablets, marked with the letter "B" on one side and no embossing on the other side.

- The tablets are packed into blisters consisting of a transparent, green-coloured polyvinyl chloride (PVC) film sealed onto aluminium foil and containing 14 white uncoated tablets.

- The tablets are packed into blisters consisting of a transparent, green-coloured polyvinyl chloride

(PVC) film sealed onto aluminium foil and containing 14 white uncoated tablets. The blisters are then packed in a hermetic pouch

Pack sizes are 2 X 14', 6 X 14', and 12 X 14'.

Holder of Certificate of Registration:

Bayer (Pty) Ltd
Reg. No.: 1968/011192/07
27 Wrench Road
ISANDO
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