

## PATIENT INFORMATION LEAFLET

**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.

**SCHEDULING STATUS OF THE MEDICINAL PRODUCT:**

S3

**NAME OF MEDICINAL PRODUCT:**

**VISANNE®**

Tablets

### 1. 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, povidone, potato starch and talc.

### 2. WHAT VISANNE IS USED FOR:

VISANNE is a hormone preparation indicated for the treatment of the painful symptoms of endometrial lesions (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.

### 3. 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 **pregnant** or think you might be pregnant.
- If you are **breast-feeding**.
- 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 any of the ingredients of VISANNE.

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

## **Take special care with VISANNE:**

Because VISANNE is not supposed to be used in pregnancy, you are advised to use non-hormonal method for contraception (barrier contraception e.g. condom) to prevent an unwanted pregnancy. You must not use sex-hormone containing contraceptives of any form (tablet, patch, intrauterine system) while taking VISANNE. Do not use the rhythm or temperature methods. These methods can be unreliable because VISANNE alters the usual changes in temperature and cervical mucus that occur during the menstrual cycle.

If you become pregnant during the use of VISANNE, there is a higher likelihood of 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 tube.

Persistent ovarian follicle (often referred to as “functional ovarian cyst”) may occur during the use of VISANNE. Most of these follicles are not combined with any symptoms. In cases of abdominal complaints that are different from the symptoms you commonly experience from your endometriosis, inform your doctor. In most cases, the enlarged follicle disappears spontaneously during two to three months of observation.

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.

## **Taking VISANNE with food and drink:**

You can take VISANNE with or without food and with some liquid as needed.

## **Pregnancy and breastfeeding:**

VISANNE must not be used by women who are breastfeeding, or who are pregnant, or who think they may be pregnant.

Ask your doctor or pharmacist for advice before using VISANNE.

## **Driving and using machinery:**

There are no observed side effects.

## **Using other medicines with 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, oxcarbamazepine, topiramate, felbamate)
  - **Tuberculosis** (e.g. rifampicin)
  - **HIV infections: non-nucleoside reverse transcriptase inhibitors** ( e.g. nevirapine)
  - 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., ketoconazole, itraconazole, fluconazole)
  - **Antibiotics** (erythromycin, clarithromycin and roxithromycin)
  - **Medicines used for depression** (e.g. nefazodone, fluvoxamine, fluoxetine)
  - **Antacids** (e.g. cimetidine)
  - **Blood pressure medication** (e.g. diltiazem, verapamil)
  - **Protease inhibitors for HIV infections** (e.g. ritonavir, saquinavir, indinavir or nelfinavir)
- Grapefruit

#### 4. 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 dosage of VISANNE 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.

##### **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.

#### 5. 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.

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.

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

##### **Common > 1 % and < 10 %, (less than 1 per 10 but more than 1 per 100):**

- 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.

**Uncommon 0,1 % to 1 %, (less than 1 per 100 but more than 1 per 1000):**

- 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.

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.

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.

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.

## **6. STORING AND DISPOSING OF 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.

**7. PRESENTATION OF VISANNE:**

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

**8. IDENTIFICATION OF VISANNE:**

Tablets, white to off-white, round, flat-faced bevelled.

**9. REGISTRATION NUMBER:**

44/21.8.2/0159

**10. NAME AND ADDRESS OF REGISTRATION HOLDER:**

Bayer (Pty) Ltd  
Reg. No.: 1968/011192/07  
27 Wrench Road  
ISANDO  
1609

**11. DATE OF PUBLICATION:**

1 March 2013