

PART III: CONSUMER INFORMATION

Pr**VISANNE**®

dienogest

This leaflet is Part 3 of a three-part "Product Monograph" published when VISANNE was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about VISANNE. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

VISANNE is a treatment for the painful symptoms caused by endometriosis in women who have had the first menstrual cycle (menarche).

What it does:

VISANNE works to help reduce pelvic pain associated with endometriosis (endometrium-like tissues outside the uterus which cause a chronic inflammation).

When it should not be used:

You should not use VISANNE if you:

- are pregnant
- are breastfeeding
- are suffering from a medical condition related to a blood clot (thromboembolic disorder). This may occur, for example, in the blood vessels of the legs (deep vein thrombosis) or the lungs (pulmonary embolism).
- have or have ever had a disease affecting the arteries, including cardiovascular disease, such as a heart attack, stroke, or heart disease which causes a reduced blood supply (angina pectoris)
- have diabetes with blood vessel damage
- have or have ever had severe liver disease (and your liver function values have not returned to normal). Symptoms of liver disease may be yellowing of the skin and/or itching of the whole body.
- have or have ever had a benign or malignant liver tumor
- have ever suffered from a malignant tumor such as cancer of the breast or the reproductive organs

- have any unexplained vaginal bleeding
- loss of vision due to blood vessel disease of the eye
- migraine headache
- are allergic to dienogest or any of the other ingredients of VISANNE (see **What the medicinal ingredient is** and **What the nonmedicinal ingredients are**)

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

What the medicinal ingredient is:

dienogest

What the nonmedicinal ingredients are:

Crospovidone, lactose monohydrate, magnesium stearate, microcrystalline cellulose, potato starch, povidone K 25, and talc.

What dosage forms it comes in:

VISANNE (dienogest) tablets are available in 28 tablet blister packs.

Each white to off-white, round tablet is embossed "B" on one side and contains 2 mg dienogest.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

VISANNE can decrease the bone mineral density (BMD) in adolescent girls (12 to < 18 years). This effect may not be completely reversible once treatment is stopped.

Effects on BMD may be greater with increasing duration of use. It is unknown if the use of VISANNE during adolescence will reduce peak bone mass and increase the risk of developing osteoporosis (brittle bones).

The risks and benefits of this treatment in adolescents should be re-evaluated on a regular basis.

Before starting VISANNE, you must be sure that you are not pregnant and must stop taking any form of birth control that contains hormones such as the pill, patch, intrauterine system, injection, or ring.

While using VISANNE you must use a nonhormonal birth control method such as condoms or a diaphragm. DO NOT use any form of birth control that contains hormones.

VISANNE is not a birth control method and will not prevent pregnancy.

VISANNE should not be used in women who have not had their first menstrual cycle.

Cigarette smoking increases the risk of serious adverse effects on the heart and blood vessels. Smoking may also increase adverse effects on bone density. You should not smoke while taking VISANNE.

BEFORE you use VISANNE, talk to your doctor or pharmacist if you:

- have ever had a medical condition related to a blood clot (thromboembolic disorder) 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
- suffer or have suffered from depression
- have uncontrolled high blood pressure
- have a history of liver disease. 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 a previous pregnancy
- have ever had chloasma (golden-brown patches on the skin, particularly on the face)
- have lactose intolerance. VISANNE tablets contain lactose.

The Risks of Using VISANNE

1. Circulatory Disorder (including blood clots in the legs, lungs, heart, eyes, or brain)

Some studies have suggested that women who use progestin-only medications might have a slightly higher risk of blood clots; however, the results are not certain. You should discuss risk factors for blood clots with your doctor.

Be alert for the following symptoms and signs of serious adverse effects associated with blood clots. Call your doctor immediately if they occur:

- Sharp pain in the chest, coughing blood, or sudden shortness of breath.
- Pain and/or swelling in the calf.
- Crushing chest pain or heaviness.
- Sudden, severe, or worsening headache or vomiting, dizziness or fainting, disturbances of vision or speech, or weakness or numbness in an arm or leg.
- Sudden partial or complete loss of vision.

2. Breast Cancer

The most significant risk factors for breast cancer are increasing age and a strong history of breast cancer in the family (mother or sister). Other established risk factors include onset of menstrual periods before age 12 years, never having children, having your first full-term pregnancy after the age of 30 years, never having breastfed a child, and daily alcohol consumption.

Some studies have shown that the risk of developing breast cancer does not appear to be increased by using progestin-only therapies like VISANNE. However, more thorough studies are needed to confirm that there is no increased risk. You should also discuss breast self-examination with your doctor and report any breast lumps. A yearly breast examination by a health care professional is recommended for all women.

3. Diabetes

Patients with diabetes who use VISANNE should have their blood glucose levels closely monitored.

4. Ectopic Pregnancy

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

5. Liver Tumors

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

6. Changes in Bone Mineral Density

The long-term use of VISANNE may decrease the bone mineral density of adolescents (12 to < 18 years) and, therefore, your doctor will carefully weigh the benefits of using VISANNE against other potential risks for bone loss. Your doctor may decide that your bone mineral density should be monitored.

If you use VISANNE, it will help your bones if you engage in regular weight-bearing exercise and have a healthy diet, including an adequate intake of calcium (e.g. in dairy products) and vitamin D (e.g. in oily fish such as salmon).

INTERACTIONS WITH THIS MEDICATION

Some medicines may interact with VISANNE. Let your healthcare professional know what other medicines you are taking.

Drugs that may interact with VISANNE include:

- Antifungals (eg, ketoconazole, itraconazole, fluconazole, voriconazole),
- Antibiotics (eg, erythromycin, clarithromycin, rifampicin)
- Anticonvulsants (eg, phenytoin, primidone, carbamazepine)
- Antacids (eg, cimetidine, ranitidine)
- Blood pressure medication (eg, diltiazem, verapamil)
- Drugs used for the treatment of HIV/Hepatitis C Virus infections (eg, ritonavir, saquinavir, indinavir, nelfinavir, boceprevir)

Herbal or food products that may interact with VISANNE include:

- St. John’s wort
- Grapefruit juice

See also **ABOUT THIS MEDICATION**: When it should not be used, and **SIDE EFFECTS AND WHAT TO DO ABOUT THEM**.

PROPER USE OF THIS MEDICATION

Usual dose

One tablet should be swallowed daily, preferably at the same time, with some liquid as needed. VISANNE can be taken with or without food.

Overdose

In cases of drug overdose talk to your doctor, or a poison control centre, or go to the emergency room of a hospital near you.

Missed Dose

VISANNE will be less effective if you miss a tablet or have vomiting or diarrhea. If you miss one or more tablets or in case of vomiting or diarrhea within 3-4 hours of taking a tablet, take a tablet as soon as you remember and then continue taking the tablet the next day at your usual time. Do not take more than one tablet per day.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, VISANNE can cause side effects. These effects are more common during the first months after you start VISANNE and usually disappear or lessen with continued use. You may also experience changes in your menstrual bleeding pattern, such as spotting, irregular bleeding, or your periods may stop completely. You should consult your physician if your periods become longer or heavier.

Common (may affect up to 1 in 10 users)

- weight gain
- depressed mood, problems sleeping, nervousness, or loss of interest in sex
- headache or migraine
- nausea or abdominal pain
- acne or hair loss
- breast discomfort
- ovarian cyst
- uterine/vaginal bleeding including spotting
- generalized weakness
- irritability

Uncommon (may affect up to 1 in 100 users)

- increase in appetite
- anxiety, depression, changed mood, or mood swings
- disturbed attention
- dry eyes
- ringing in the ears
- palpitations
- diarrhea, constipation, abdominal discomfort, gas, vomiting, inflammation of the stomach and intestines
- dry skin, severe itching of the whole body, brittle nails, dermatitis, light sensitivity or problems with skin pigmentation
- pains in your bones, back pain, muscle spasms, pains and/or a sensation of heaviness in your arms and hands or legs and feet
- urinary tract infection
- vaginal yeast infection, dryness of the genital area, vaginal discharge, pelvic pain, hot flushes, or a lump or lumps in the breast
- swelling due to fluid retention

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

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom/ Effect		Talk with your doctor or pharmacist		Stop taking drug and seek emergency medical treatment
		Only if severe	In all cases	
Common	Abdominal pain or nausea		✓	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

	Unexpected vaginal bleeding		✓	
Uncommon	Persistent sad mood		✓	
	Breast lump		✓	
	Vomiting		✓	
Rare	Pain or swelling in the leg			✓
	Unusual swelling of the extremities			✓

This is not a complete list of side effects. For any unexpected effects while taking VISANNE, contact your doctor or pharmacist.

HOW TO STORE IT

Store VISANNE in the original packaging between 15°C and 30°C. Keep out of reach of children and pets.

REPORTING SUSPECTED SIDE EFFECTS

Canada Vigilance Program

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701E
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, please contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

For more information, please contact your health professional or pharmacist first, or Bayer Medical Information at 1-800-265-7382 or canada.medinfo@bayer.com.

This document plus the full product monograph, prepared for health professionals can be found at <http://www.bayer.ca> or by contacting the manufacturer at the above-mentioned phone number and email address.

This leaflet was prepared by:



Bayer Inc.
2920 Matheson Boulevard East
Mississauga, Ontario L4W 5R6
Canada

Last revised: February 16, 2016

© 2016, Bayer Inc.

® TM see www.bayer.ca/tm-mc

Bayer