

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Visanne. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Visanne against the benefits they expect it will have for you.

If you have any concerns, or are unsure about taking this medicine, ask your doctor or pharmacist for more advice.

Keep this leaflet with the medicine.

You may need to read it again.

WHAT IS VISANNE USED FOR

Visanne is used for the treatment of the painful symptoms of endometrial lesions (displaced tissue of the lining of the womb).

Visanne contains a progestogen hormone, dienogest.

Taking one Visanne tablet every day leads to the shrinking of the endometrial tissue and reduces associated complaints such as pelvic pain and painful monthly bleedings.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

BEFORE YOU TAKE VISANNE

When you must not take it

Do not take Visanne if you have an allergy to:

- dienogest (the active ingredient in Visanne)
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty in breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not take Visanne if you have or have had a blood clot in:

- the blood vessels of the legs (deep vein thrombosis - DVT)
- the lungs (pulmonary embolism - PE)
- the heart (heart attack)
- the brain (stroke)
- other parts of the body.

Do not take Visanne if you are concerned about an increased risk of blood clots.

Blood clots are rare. Very occasionally blood clots may cause serious permanent disability, or may even be fatal.

Do not take Visanne if you have or have had:

- diabetes mellitus with blood vessel damage
- severe liver disease and your liver function has not returned to normal

- cancer that may grow under the influence of sex hormones (e.g. of the breast or the genital organs)

- benign or malignant liver tumour

- unexplained vaginal bleeding.

If any of these conditions appear for the first time while taking Visanne, stop taking it at once and tell your doctor.

Do not take Visanne if you are pregnant or think you might be pregnant.

The possibility of pregnancy should be ruled out before starting Visanne.

Do not take Visanne if you are breastfeeding.

Do not give Visanne to a child.

Visanne is not for use in female children before menarche (first menstrual bleed).

Do not take Visanne after the expiry date printed on the pack and blister.

The expiry date is printed on the carton and on each blister after "EXP" (e.g. 11 18 refers to November 2018). The expiry date refers to the last day of that month. If it has expired return it to your pharmacist for disposal.

Do not take Visanne if the packaging is torn or shows signs of tampering.

If the packaging is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

If Visanne is used in the presence of any of the conditions listed below you may need to be kept under close supervision. Your doctor can explain this to you. Therefore, if any of these apply to you, tell your doctor before starting to use Visanne:

- you smoke
- you are overweight
- you have diabetes or had diabetes temporarily during previous pregnancy
- you have high blood pressure or develop high blood pressure while taking Visanne
- you have suffered from depression
- if you have had an ectopic pregnancy
- you develop a liver disease while taking Visanne.
Symptoms may include yellowing of the skin or eyes or itching all over the body. Inform your doctor also if such symptoms occurred during a previous pregnancy
- you have chloasma (yellowish-brown pigmentation patches on the skin, particularly of the face)
– if so, avoid exposure to the sun or ultraviolet radiation
- you or anyone in your immediate family has had blood clots in the legs or lungs, a heart attack, a stroke, breast cancer or high cholesterol.

Visanne contains lactose monohydrate.

If you have intolerance to some sugars, contact your doctor before you start taking Visanne.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines/foods and Visanne may interfere with each other. These include:

- medicines used to treat epilepsy such as phenytoin, primidone, barbiturates (e.g. phenobarbitone), carbamazepine, oxcarbamazepine, topiramate, felbamate
- medicines used to treat depression such as fluoxetine, fluvoxamine
- diltiazem, verapamil which are medicines used to treat high blood pressure, chest pain or irregular heartbeats
- medicines used to treat tuberculosis such as rifampicin, rifabutin
- medicines used to treat HIV or hepatitis C virus (HCV)
- medicines used to treat fungal infections such as ketoconazole, itraconazole, fluconazole, voriconazole)
- some antibiotics (e.g. erythromycin, clarithromycin)
- cimetidine, an antacid
- herbal medicines containing St. John's Wort
- grapefruit.

These medicines/foods may be affected by Visanne, or may affect how well it works. Your doctor may need to alter the dose of your medicine, or prescribe a different medicine.

Ask your doctor or pharmacist for advice before taking any other medicine.

HOW TO TAKE VISANNE

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, printed on the pharmacist label or in this leaflet, ask your doctor or pharmacist for help.

How to take it

Take one tablet daily at about the same time each day, without any break.

Follow the direction of the arrows on the blister pack until all the tablets have been taken.

Tablet-taking can be started on any day of your menstrual cycle.

Tablets must be taken continuously without regard to vaginal bleeding. This means that after the first pack has been finished the next should be started without interruption.

Swallow the tablet whole with water.

It does not matter if you take it before or after food.

How long to take Visanne

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. It is important

to keep taking your medicine even if you feel well.

If you forget to take Visanne

If you forget to take a tablet or if you suffer from vomiting and/or diarrhoea:

The efficacy of Visanne may be reduced in the event of missed tablets or vomiting and/or diarrhoea (if occurring within 3-4 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 to take the tablet at your usual time the next day. A tablet not absorbed due to vomiting or diarrhoea should likewise be replaced by one tablet.

If you take too much (overdose)

Immediately contact the Poisons Information Centre (Australia: 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Visanne.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

WHILE YOU ARE TAKING VISANNE

Things you must do

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

If you become pregnant while taking this medicine, tell your doctor immediately.

Things you must not do

Do not take Visanne to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Things to be careful of

To avoid becoming pregnant, you should use non-hormonal contraceptive precautions, such as a condom or another barrier method.

You must not use sex-hormone containing contraceptives of any form (tablet, patch, intrauterine system) while taking Visanne.

Do not use rhythm or temperature methods. These methods can be unreliable.

If in an exceptional case you should become pregnant during the use of Visanne, there is a higher likelihood in users of progestogen containing preparations like Visanne to have an ectopic pregnancy (the embryo develops outside the womb).

Tell your doctor before you start taking Visanne, if you had an ectopic pregnancy in the past, or have an impaired function of the fallopian tubes.

If you experience unexplained abdominal complaints that are different to the symptoms you commonly experience from your endometriosis, you should contact your doctor immediately because an ectopic pregnancy must be considered.

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Visanne.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may not need medical attention if you get some of the side effects.

Do not be alarmed by this list of possible side effects, you may not experience any of them.

The following list includes the more common side effects of Visanne. These are usually mild and lessen with time.

If you notice any of the following side effects and they worry you, tell your doctor or pharmacist:

- headache or migraine
- breast discomfort,
- hot flushes
- mood changes, including depression, irritability, nervousness, problems sleeping, loss of interest in sex
- acne, hair loss
- nausea, abdominal pain, wind, swollen tummy or vomiting
- weight gain
- back pain
- uterine/vaginal bleeding including spotting
- unusual weakness

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed may also occur in some people.

Thrombosis

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

Thrombosis sometimes occurs in the deep veins of the legs (DVT). If this blood clot breaks away from the veins where it is formed, it may reach and block the arteries of the lungs, causing pulmonary embolism (PE).

Deep venous thrombosis is a rare occurrence. It can develop whether or not you are taking Visanne. It can also happen if you become pregnant.

The risk of venous thromboembolism (DVT or PE) appears to be slightly higher in users of hormonal (progestogen containing) preparations like Visanne, than in non-users, but is not as high as during pregnancy or during use of combined oral contraceptives (the Pill).

The risk for venous thromboembolism increases for example:

- with increasing age
- if you are overweight
- shortly after childbirth
- if you have had a blood clot in the past
- if anyone in your immediate family has had a blood clot at a relatively early age

- during long periods of immobilisations, e.g. after surgery or having your leg(s) in plaster/splints etc.

Tell your doctor you are using Visanne well in advance of any expected hospitalisation or surgery.

Your doctor may tell you to stop taking Visanne several weeks before surgery, or at the time of immobilisation and when you can start taking Visanne again.

Blood clots can also occur in the blood vessels of the heart (causing a heart attack) or the brain (causing a stroke).

From studies there is little or no evidence for a link between progestogen containing preparations similar to Visanne and an increased risk of heart attack or stroke.

The risk of such events is rather related to increasing age, hypertension (high blood pressure), and smoking.

In women with hypertension the risk of stroke may be slightly increased by progestogen containing preparations like Visanne.

If you develop high blood pressure while using Visanne, you may be told to stop using it.

If you notice possible signs of a blood clot, stop taking Visanne and consult your doctor immediately.

Possible signs of a blood clot include:

- an unusual cough
- pain in the chest, arm or below the breastbone
- discomfort radiating to the back
- breathlessness and/or difficulty breathing
- swelling, pain or tenderness of one leg
- sudden weakness, numbness or bad 'pins and needles' of the face, arm or leg, especially on one side of the body
- sudden trouble walking, dizziness, loss of balance or coordination
- severe, sudden stomach pains
- a fainting attack, or you collapse
- unusual headaches or migraines that are worse than usual
- sudden problems with your speech, understanding or eyesight

Cancer

Breast cancer has been diagnosed slightly more often in women who use combined oral contraceptives (the Pill) than in women of the same age who do not use the Pill. It is not known whether the difference is caused by the Pill or whether cancers were detected earlier in Pill users.

The evidence is inconclusive for progesterone only preparations like Visanne.

It is important that you check your breasts regularly and contact your doctor if you feel any lump.

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 abdomen.

Bleeding Patterns

Visanne treatment affects the menstrual bleeding pattern in the majority of women.

Uterine bleeding in women with e.g. adenomyosis uteri or uterine leiomyomata, may be worse with Visanne.

If bleeding is heavy and continuous over time, this may lead to anaemia (severe in some cases). In such cases, your doctor may advise you to stop taking Visanne.

Bone Mineral Density (BMD)

The long term use of Visanne may affect the bone mineral density (BMD) 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 (osteoporosis) e.g.

- metabolic bone disease
- if anyone in your immediate family has ever suffered from bone loss (osteoporosis)
- if you have ever broken a bone that was not caused by a fall or accident
- use of medications that can reduce bone mass e.g. epilepsy medication or steroids
- low body mass index or eating disorders e.g. anorexia nervosa or bulimia
- alcohol use
- smoking

When using Visanne, your doctor may also recommend dietary and lifestyle modifications such as weight bearing exercise and a healthy diet including adequate calcium and vitamin D, to reduce your risk of osteoporosis. Ask your doctor for their advice to improve your bone health.

AFTER TAKING VISANNE

Storage

Keep your tablets in the blister pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 30°C.

Do not store Visanne or any other medicine in the bathroom, near a sink, or on a window-sill. Do not leave medication in the car.

Heat and damp can destroy some medicines.

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Return any unused medicine to your pharmacist.

PRODUCT DESCRIPTION

What it looks like

Visanne is a round, white to off-white tablet marked with "B" on one side. The blister pack is marked with the days of the week and contains 14 tablets.

Visanne comes in packs of 1 month, 3 months and 6 months. Not all pack sizes may be marketed.

Ingredients

Active ingredients:

- dienogest 2mg

Inactive ingredients:

- lactose monohydrate
- starch potato
- cellulose-microcrystalline
- povidone

- purified talc
- crospovidone
- magnesium stearate

Visanne tablets do not contain gluten, tartrazine or azo dyes.

Supplier

Made in Germany for:

Bayer Australia Ltd
ABN 22 000 138 714
875 Pacific Highway
Pymble NSW 2073

Australian registration number:

Visanne - AUST R 160465

Date of Preparation

26 February 2020

See TGA website (www.ebs.tga.gov.au) for latest Australian Consumer Medicine Information.

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