

PACKAGE LEAFLET: INFORMATION FOR THE USER

Vesanoid 10 mg soft capsules Tretinoin

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Vesanoid is and what it is used for
2. What you need to know before you take Vesanoid
3. How to take Vesanoid
4. Possible side effects
5. How to store Vesanoid
6. Contents of the pack and other information

1. What Vesanoid is and what it is used for

Vesanoid contains a medicine called tretinoin. This belongs to a group of medicines called 'retinoids'. These medicines are similar to vitamin A.

Vesanoid is used to treat a type of blood problem called 'acute promyelocytic leukaemia'. It works by slowing the growth of certain types of diseased blood cells.

2. What you need to know before you take Vesanoid

Do not take Vesanoid if you are allergic to:

- tretinoin or any of the other ingredients of this medicine (listed in section 6)
- other 'retinoid' medicines. These include isotretinoin, acitretin and tazarotene
- peanuts or soya. This is because Vesanoid contains soya-bean oil.

Do not take Vesanoid if:

- you are pregnant, planning to become pregnant or breast-feeding (see section 2, Pregnancy, breast-feeding and fertility)
- you are taking vitamin A, tetracyclines or retinoids.

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Vesanoid.

Warnings and precautions

Talk to your doctor or pharmacist before taking Vesanoid if:

- you have any other illness
- you have ever had any mental health problems including depression, aggressive tendencies or mood changes. This is because taking Vesanoid may affect your mood.
- you have allergies

- you have been told by your doctor that you have an intolerance to some sugars. This is because Vesanoïd contains sorbitol.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Vesanoïd.

Mental health problems

You may not notice some changes in your mood and behaviour and so it is very important that you tell your friends and family that this medicine could affect your mood and behaviour. They may notice these changes and help you identify any problems that you need to talk to your doctor about.

Look out for important side effects

Vesanoïd can cause side effects including:

- a severe headache with feeling or being sick
- difficulty in breathing
- fever
- feeling dizzy
- chest or back pain.

You will need to look out for these while you are taking Vesanoïd. See “Important side effects” in section 4 for more details. Your doctor may decide to change the dose of your medicine or to prescribe an additional medicine.

Children

There is limited safety and efficacy information on the use of tretinoin in children.

Other medicines and Vesanoïd

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription and herbal medicines.

This is extremely important, as using more than one medicine at the same time can strengthen or weaken the effect of the medicines. Therefore, you should not take Vesanoïd with any other drug unless you have told your doctor and they have agreed.

While you are taking Vesanoïd do not take:

- tetracyclines (a type of antibiotic)
- vitamin A
- low-dose progestogens for birth control (mini-pill). If you are taking low-dose progestogens for birth control, your doctor will tell you to stop and will prescribe a different oral contraceptive.

Medicines which may require particular care when taken with Vesanoïd include:

- rifampicin (antibiotic)
- macrolide antibiotics e.g. clarithromycin, erythromycin
- glucocorticoids e.g. prednisolone, dexamethasone (for allergies and inflammation)
- phenobarbital (for epilepsy)
- pentobarbital (for insomnia)
- azole antifungals e.g. ketoconazole, fluconazole, itraconazole, posaconazole
- protease inhibitors e.g. ritonavir, saquinavir (for HIV)
- cimetidine (for stomach ulcers)
- verapamil and diltiazem (for heart conditions or high blood pressure)
- ciclosporin (used following organ or bone marrow transplants)
- tranexamic acid, aminocaproic acid and aprotinin (used to reduce bleeding).

Pregnancy, breast-feeding and fertility

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

Before starting treatment with Vesanoid

Tell your doctor immediately if

- you are pregnant,
- you think you are pregnant,
- you intend to become pregnant.

You should not become pregnant during and within one month (four weeks) after stopping treatment with Vesanoid. **If you do become pregnant while taking Vesanoid, it is very likely that your baby will be born deformed.**

During treatment with Vesanoid

- **During treatment with Vesanoid and for four weeks after stopping, you and your partner should practice effective and continued contraception (birth control).** Your doctor will tell you what methods of contraception you can use. If you are taking low-dose progestogens (mini-pill) for birth control, your doctor will tell you to stop and will prescribe a different oral contraceptive for you.
- Women taking Vesanoid should take a pregnancy test every month during treatment with Vesanoid.
- **Tell your doctor immediately if you become pregnant while taking Vesanoid.** You and your doctor will discuss the right treatment for you if you are pregnant and have acute promyelocytic leukaemia.

Do not breast-feed your baby while taking Vesanoid. Vesanoid enters the breast milk, and could therefore harm your baby.

Driving and using machines

Your ability to drive or operate machinery might be impaired while you are taking Vesanoid, especially if you are feeling dizzy or have a severe headache.

Vesanoid contains soya-bean oil, sorbitol and sodium

Vesanoid contains soya-bean oil. If you are allergic to peanut or soya, do not use this medicine.

This medicine contains 1.93 - 2.94 mg sorbitol in each soft capsule.

This medicine contains less than 1 mmol sodium (23 mg) per soft capsule, that is to say essentially 'sodium-free'.

3. How to take Vesanoid

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

How much to take

Depending on the nature of your illness, your reaction to Vesanoid, your body weight and body height, your doctor will prescribe a dose that is right for you. Do not change the prescribed dose yourself. If you feel that the effect of Vesanoid is too strong or too weak, talk to your doctor or pharmacist.

Adults

The daily dose will be 45 mg/m² and will be about 8 capsules a day divided into two equal doses.

Children

The daily dose will be 45 mg/m² divided into two equal doses. For children who suffer from bad headaches during treatment a lower daily dose of 25 mg/m² should be considered.

Adults with kidney or liver diseases

The daily dose will be 25 mg/m² divided into two equal doses.

The treatment with Vesanoid can take 3 months or longer. Your doctor will tell you how long you should take Vesanoid.

Taking this medicine

Swallow the capsules whole with water, preferably with a meal or shortly thereafter. Do not chew the capsules.

If you take more Vesanoid than you should

If you or another person have taken an overdose of Vesanoid, you must contact your doctor, pharmacist or the nearest hospital immediately.

If you forget to take Vesanoid

If you forget to take one dose, take your capsules as soon as you remember and tell your doctor immediately. Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. In addition to the benefits, nearly everyone will get some undesirable effects during treatment. This is true, even when Vesanoid is used correctly.

Important side effects

Tell your doctor immediately, if you notice any of the following:

- fever, especially with breathing difficulties, coughing, feeling dizzy, chest pain and abdominal pain
- a severe headache with feeling or being sick, difficulty in breathing, fever, feeling dizzy, or chest or back pain. Your doctor may decide to change the dose of your medicine or to prescribe an additional medicine
- severe stomach pain which spreads to your back (possible sign of pancreatitis)
- fever with dark lumpy markings on your skin, most likely on your face and neck (possible sign of “Sweet’s syndrome” or acute febrile neutrophilic dermatosis)
- a painful swelling in your leg, sudden chest pain or difficulty breathing (possible sign of a blood clot)
- a pain in your chest that spreads to your arm or neck (possible sign of a heart attack)
- double vision and feeling dizzy, especially with feeling or being sick, ringing in your ears and headache (possible sign of increased pressure in your head)
- an unexplained headache or migraine, which can include disturbed vision (possible sign of a stroke).

Tell your doctor immediately if you notice any of the side effects listed above.

Other side effects

Very common (may affect more than 1 in 10 people):

- hair loss
- an irregular heartbeat
- changes to your eyesight or hearing
- bone or joint pain, chest pain or abdominal pain
- skin rash, itching, redness, peeling or inflammation
- dry skin, mouth or nose; swollen, dry or cracked lips
- breathing difficulties such as asthma, which may get worse (respiratory failure)
- conjunctivitis or dry eyes, which may be a problem if you wear contact lenses
- difficulty sleeping
- sweating more than usual
- headache or feeling dizzy
- feeling tired, cold or generally unwell
- feeling confused, worried or depressed
- pins and needles or numbness of your hands or feet
- loss of appetite, feeling or being sick, stomach upset, stomach ache, inflammation of the pancreas (pancreatitis), inflammation of the lips, vomiting, diarrhoea or constipation
- changes to your blood (shown in tests) such as higher levels of transaminases, blood creatinine or blood fats (triglycerides and cholesterol)

Not known (frequency cannot be estimated from the available data):

- genital ulcers
- serious bacterial infections (necrotising fasciitis)
- kidney problems (renal infarct)
- swollen muscles or swollen blood vessels (vasculitis)
- red painful lumps under the skin, most likely on your legs (erythema nodosum)
- loss of appetite, feeling or being sick, with a headache, feeling drowsy or weak (possible sign of too much calcium in your blood)
- other changes to your blood (shown in tests) such as too many platelets (thrombocytosis), a change in the number of white blood cells (basophilia) or increased histamine levels
- inflammation of the myocardial muscle (myocarditis) or inflammation of the pericardium outside the heart (pericarditis) which can lead to breathlessness, palpitation, or chest pain.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Vesanoid

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and bottle label after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C.

Keep the bottle tightly closed in order to protect from moisture.

Keep the bottle in the outer carton in order to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Vesanoid contains

- The active substance is tretinoin. Each soft capsule contains 10 mg tretinoin.
- The other ingredients in the soft capsule contents are yellow beeswax, hydrogenated soya-bean oil, partially hydrogenated soya-bean oil and soya-bean oil (see section 2).
- The other ingredients in the soft capsule shell are gelatin, glycerol (E 422), karion 83 containing sorbitol (see section 2), mannitol and starch (maize), and the colourants titanium dioxide (E 171), iron oxide yellow (E 172) and iron oxide red (E 172).

What Vesanoid looks like and contents of the pack

Vesanoid soft capsules are bi-coloured, orange-yellow and reddish-brown. They are packed in glass bottles containing 100 capsules.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

CHEPLAPHARM Arzneimittel GmbH
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For information about this medicine, contact the medical information department on +44 800 145 5034 or email: cheplapharm@redlinepv.co.uk.

This medicinal product is authorised in the Member States of the EEA under the following names:

Vesanoid, Tretinoin

This leaflet was last revised in December 2023