

Consumer Medicine Information

Vesanoid[®]

Tretinoin

10mg capsules

What is in this leaflet

This leaflet answers some common questions about VESANOID capsules.

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 VESANOID against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What VESANOID is used for

VESANOID contains the active ingredient tretinoin, which is also called retinoic acid.

VESANOID is a retinoid which works to stop or slow the growth of cancer-causing cells. It targets cancer cells rather than normal, healthy cells.

VESANOID is given to people who have acute promyelocytic leukaemia (APL), a type of blood cancer. This disease affects the way myelocytes grow. Myelocytes are large cells in your bone marrow from which leucocytes (white blood cells) develop. VESANOID is thought to work by stopping the growth of APL cells.

Your doctor, however, may have prescribed VESANOID for another purpose.

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

This medicine is available only with a doctor's prescription.

Before you take VESANOID

Do not take VESANOID if:

- 1. you have had an allergic reaction to VESANOID, Vitamin A, other retinoids or any ingredients listed at the end of this leaflet**
- 2. you are pregnant, or within one month before you intend to become pregnant
If you fall pregnant while taking VESANOID there is an extremely high risk of having a baby that is severely deformed. You must use effective contraception for one month before, during and one month after treatment**



3. **you are breast-feeding**
Breast-feeding must stop before treatment begins. Do not breast-feed while taking VESANOID
4. **you are taking vitamin A, or preparations containing vitamin A**
5. **the packaging is torn or shows signs of tampering**
6. **the expiry date printed on the pack has passed**
If you take this medicine after the expiry date has passed, it may not work as well.

If you are not sure if you should be taking VESANOID, talk to your doctor.

Before you start to take VESANOID

Tell your doctor if:

1. **you have any other health problems, especially the following:**
 - **kidney disease**
 - **liver disease**
2. **you are taking a low-dose progestogen oral contraceptive (also called the “mini pill”)**
3. **you are allergic to any other medicines, foods, dyes or preservatives**

If you have not told your doctor about any of the above, tell them before you start taking VESANOID.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you have bought from a pharmacy, supermarket or health food shop.

Some medicines may interfere with VESANOID. These medicines include:

- antifibrinolytic agents, which help blood to form clots, such as tranexamic acid (Cyklokapron[®]) and aprotinin (Trasylo[®])
- tetracycline antibiotics, such as doxycycline (Doxine[®], Doxy-50[®]), minocycline (Minomycin[®], Minotabs[®])

These medicines may be affected by VESANOID, or may affect how well it works. You may need to use different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Your doctor or pharmacist may have more information on medicines to be careful with or avoid while taking VESANOID.

Ask your doctor or pharmacist if you are not sure about this list of medicines.

How to take VESANOID

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

They may differ from the information contained in this leaflet.

How much to take

Take VESANOID exactly as your doctor has prescribed.

Your doctor will tell you how many VESANOID capsules to take each day.

The usual adult dose is eight capsules per day divided into two equal doses (eg; four capsules in the morning and four in the evening). Your dose may be different, depending on your weight and height. The dose is normally reduced for children, or if you have kidney or liver disease.

How to take it

Swallow capsules whole with a glass of water.

Do not open the capsules and do not take any capsules that are damaged.

When to take it

Take VESANOID during or immediately after a meal, at about the same time each day.

Taking your capsules at the same time each day will have the best effect. It will also help you remember when to take the capsules.

How long to take it

Continue taking VESANOID until your doctor tells you to stop.

Treatment is usually 30 to 90 days. After this, you may receive a different course of chemotherapy.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember and then go back to taking it as you would normally.

Do not take a double dose to make up for one you have missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering your dose, ask your pharmacist for some hints.

In case of an overdose

Immediately telephone your doctor or National Poisons Information Centre (telephone 0800 POISON or 0800 764 766) for advice or go to your nearest Accident and Emergency Centre if you think you or anyone else may have taken too much VESANOID. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Keep telephone numbers for these places handy.

If you are not sure what to do, contact your doctor or pharmacist.

While you are taking VESANOID

Things you must do



Tell all doctors, dentists and pharmacists who are treating you that you are taking VESANOID.

Women

You must use strict birth control for at least one month before you start VESANOID, for the whole time you are taking VESANOID and for at least one month after you finish taking VESANOID.

The low-dose progestogen oral contraceptive (also called the "mini pill") may not be an effective method of contraception during treatment with VESANOID.

You must have a pregnancy test once a month while you are taking VESANOID.

Stop taking VESANOID immediately and tell your doctor if you do become pregnant while you are taking VESANOID.

You must tell your doctor immediately if you develop fever, light-headedness, shortness of breath or difficulties in breathing, retained fluid and/or weight gain as these can be signs of a serious condition called "Retinoic Acid Syndrome".

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Be sure to keep all of your appointments with your doctor so that your progress can be checked.

Your doctor may want to check your blood pressure and do some blood and other tests from time to time to check on your progress and detect any unwanted side effects.

Things you must not do

Do not stop taking VESANOID or change the dose without first checking with your doctor.

Do not let yourself run out of VESANOID over the weekend or on holidays.

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

Do not use VESANOID to treat other complaints unless your doctor says to.

Do not take any other medicines whether they require a prescription or not without first telling your doctor or consulting a pharmacist.

Things to be careful of

Your ability to drive cars or operate machinery may be impaired particularly if you experience dizziness or severe headache. Disturbed night vision and other visual disturbances may occur. Patients should be sure they do not have these conditions before they drive a car or operate machinery.

Wearing contact lenses during treatment with VESANOID may cause discomfort and you may temporarily need to wear glasses instead.

Avoid excessive sun exposure and apply a sunscreen while taking VESANOID.

Side effects

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

VESANOID helps most people with acute promyelocytic leukaemia (APL) but it may have unwanted side effects in some people.

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

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- dryness of the lips, mouth, nose, eyes and skin. A moisturiser or petroleum jelly can be used to soften the lining of the nose, lips and the skin
- redness of the skin, rash, sweating
- raised painful plaques on face, limbs or neck
- hair loss
- headache, dizziness
- fever, shivering, generally feeling unwell
- depression, anxiety, confusion or inability to sleep (insomnia), fatigue
- nausea, vomiting, stomach pain
- constipation or diarrhoea
- lack of appetite
- hearing difficulties, vision changes, double vision
- pain in the lower legs or feet, chest pain
- tenderness or stiffness in your bones or muscles
- numbness or tingling feeling in fingers and/or toes
- itchiness
- increased bruising and/or bleeding

Tell your doctor immediately or go to your nearest Accident and Emergency Centre if you experience any of the following:

- severe headache
- sudden fever
- sudden difficulty in breathing or shortness of breath
- fast or irregular heart beat, flushing, swelling of ankles, hands and feet, sudden chest pain or pain in the neck, back or arm, appearing during the first month of therapy.
- shooting pains from your stomach to your back (inflamed pancreas)

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

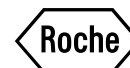
This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor or pharmacist if you don't understand anything in this list.

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

After taking VESANOID



Storage

Keep your capsules in the bottle until it is time to take them.

If you take the capsules out of the bottle they may not keep well.

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

Do not store it, or any other medicine, in a bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Protect VESANOID capsules from light.

Keep VESANOID where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking VESANOID, or the capsules have passed their expiry date, return any remaining capsules to your pharmacist.

Product Description

Availability

VESANOID comes in one capsule strength, 10mg.

VESANOID comes in bottles of 100 capsules.

What it looks like

VESANOID capsules are soft, oval and are one half orange-yellow and one half reddish-brown.

Ingredients

Active ingredient - tretinoin

- each capsule contains 10 mg tretinoin

Inactive ingredients -

- yellow beeswax, hydrogenated soybean oil, partially hydrogenated soybean oil, soybean oil, gelatin, glycerol, sorbitol, mannitol, starch, titanium dioxide, yellow and red iron oxide.

VESANOID Capsules are gluten free and lactose free.

Distributor

VESANOID is distributed by:

Roche Products (New Zealand) Limited
P O Box 12-492



Penrose
AUCKLAND

Telephone: (09) 633 0700
Toll Free: 0800 656 464

This leaflet was prepared 22 June 2007.

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