

VESANOID

contains the active ingredient tretinoin

Consumer Medicine Information

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 called tretinoin or retinoic acid.

VESANOID belongs to a group of medicines called chemotherapeutic agents which works by stopping or slowing the growth of cancer-causing cells.

It is specially developed to target cancer cells rather than normal, healthy cells.

VESANOID belongs to a class of drugs known as retinoids, which are very similar to Vitamin A.

VESANOID is given to people who have acute promyelocytic leukaemia (APL). This is a disease which affects the way the 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. VESANOID may be used whether or not you have had chemotherapy before.

Your doctor 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

When you must not take it

Do not take VESANOID if:

- 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.**
- you are breastfeeding. Breastfeeding must stop before treatment begins. Do not breastfeed while taking VESANOID.**

- you have an allergy to VESANOID, Vitamin A, other retinoids or any ingredients listed at the end of this leaflet.

- you are taking tetracycline antibiotics (such as Doryx®, Vibramycin®, Achromycin®, Tetrex®, Minomycin®).
- you are taking a low-dose progestogen oral contraceptive (also called the "mini-pill").
- you are taking vitamin A, or preparations containing vitamin A.
- the packaging is torn or shows signs of tampering.**
- the expiry date (EXP) 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.

Use in Children

There is limited information available on the use of VESANOID in children.

Before you start to take it

You must tell your doctor if:

- you are pregnant or intend to become pregnant**
- you are breastfeeding**
- you are allergic to any other medicines, foods, dyes or preservatives**
- 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 any other health problems including:**
 - high fat levels in your blood
 - liver or kidney disease
 - other illnesses
 - you develop fever or shortness of breath or difficulties in breathing, as these can be signs of "Retinoic Acid Syndrome" in APL.

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 include:

- some medicines used to treat acne
- progestogen oral contraceptive
- vitamin A or any other vitamin preparations
- some antibiotics (such as doxycycline, erythromycin, minocycline, rifampicin, tetracycline)
- medicines that help to reduce or prevent bleeding (antifibrinolytic agents)
- some antifungals (such as fluconazole, ketoconazole)
- some medicines used to treat heart disease (such as diltiazem, verapamil)
- some anticonvulsants (such as phenobarbitone)
- glucocorticoids
- some immunosuppressants (such as cyclosporine)
- some medicines used for stomach ulcers (such as cimetidine).

These medicines may be affected by VESANOID, or may affect how well it works. You may need to take 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 avoid or to be careful with 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

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

The dose is usually 8 capsules per day split into two equal doses. This depends on your condition and your weight and whether or not you are taking any other medicines.

How to take it

Capsules should be swallowed 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.

This is usually 30 to 120 days, until the APL completely disappears. After this, you will 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.

This may increase the chance of you getting an unwanted side effect.

If you have forgotten to take a dose of VESANOID, contact your doctor.

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

In case of an overdose

Immediately telephone your doctor or pharmacist or Poisons Information Centre (Australia: telephone 13 11 26, New Zealand: telephone 0800 POISON or 0800 764 766) for advice or go to Accident and Emergency at your nearest hospital if you think that 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.

While you are taking VESANOID

Things you must do

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

You must use strict birth control for at least 1 month before you start VESANOID and for the whole time you are taking VESANOID and for at least 1 month after you finish taking VESANOID.

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

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.

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.

Things you must not do

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

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

Do not give VESANOID to anyone else even if their symptoms seem similar to yours.

Do not use VESANOID to treat any 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.

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.

Your skin may be more prone to sunburn while on VESANOID. 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.

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*
- *swelling of hands, ankles, feet*
- *nausea, vomiting, stomach pain*
- *tenderness or stiffness in your bones or muscles*
- *headache, dizziness*
- *rash*
- *raised painful plaques on face, limbs or neck*
- *hair loss*
- *depression*
- *numbness or tingling feeling*
- *diarrhoea, constipation*
- *vision or hearing problems*
- *loss of libido, male sexual dysfunction*
- *breast enlargement in men.*

Stop taking VESANOID and see your doctor immediately, or go to Accident and Emergency at your nearest hospital if you experience any of the following:

- *severe headache*
- *sudden fever*
- *sudden difficulty in breathing or shortness of breath*
- *sudden weight gain*
- *sudden tiredness or listlessness*
- *fast or irregular heartbeats, 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.*

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

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.

Protect VESANOID from light.

Heat and dampness can destroy some medicines.

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, you should return any capsules remaining at the end of treatment to your specialist, GP or pharmacist.

Product description

What it looks like

VESANOID capsules are soft, oval and have an orange-yellow top and a reddish-brown bottom.

Ingredients

Active ingredient - tretinoin

- each 10 mg capsule contains 10 mg tretinoin

Inactive ingredients -

- yellow beeswax, hydrogenated soya oil, partially hydrogenated soya oil, soya oil, gelatin, glycerol, Karion 83, titanium dioxide, iron oxide yellow and iron oxide red.

VESANOID Capsules are gluten free.

VESANOID Capsules are lactose free.

VESANOID Capsules come in bottles of 100.

Manufacturer

Distributed in Australia by:

Pharmaco (Australia) Ltd,
Gordon NSW 2072

Distributed in New Zealand by:

Pharmaco (NZ) Ltd,
Auckland

Australian Registration Number:

- AUST R 53160

This leaflet was prepared in July 2019.