

Vesanoid

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Vesanoid?

Vesanoid contains the active ingredient tretinoin or retinoic acid. Vesanoid is used to treat acute promyelocytic leukemia (APL). For more information, see Section [1. Why am I using Vesanoid?](#) in the full CMI.

2. What should I know before I use Vesanoid?

Do not use if you have ever had an allergic reaction to tretinoin or any of the ingredients listed at the end of the CMI. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.** For more information, see Section [2. What should I know before I use Vesanoid?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Vesanoid and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Vesanoid?

- 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.
- Capsules should be swallowed whole with a glass of water.
- Do not open the capsules and do not take any capsules that are damaged.

More instructions can be found in Section [4. How do I use Vesanoid?](#) in the full CMI.

5. What should I know while using Vesanoid?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using 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.• Be sure to keep all of your appointments with your doctor so that your progress can be checked.• Tell your friends and family that this medicine could affect your mood and behaviour.
Things you should not do	<ul style="list-style-type: none">• 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 take any other medicines whether they require a prescription or not without first telling your doctor.
Driving or using machines	<ul style="list-style-type: none">• 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.
Looking after your medicine	<ul style="list-style-type: none">• Keep your capsules in the bottle until it is time to take them.• Keep Vesanoid in a cool dry place where the temperature stays below 30°C.

For more information, see Section [5. What should I know while using Vesanoid?](#) in the full CMI.

6. Are there any side effects?

Serious side effects: 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. **Less serious side effects:** dryness of the lips, mouth, nose, eyes and 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. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Vesanoid

Active ingredient(s): tretinoin or retinoic acid

Consumer Medicine Information (CMI)

This leaflet provides important information about using Vesanoid. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Vesanoid.**

Where to find information in this leaflet:

- [1. Why am I using Vesanoid?](#)
- [2. What should I know before I use Vesanoid?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Vesanoid?](#)
- [5. What should I know while using Vesanoid?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Vesanoid?

Vesanoid contains the active ingredient 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 used to treat acute promyelocytic leukemia (APL).

2. What should I know before I use Vesanoid?

Warnings

Do not use Vesanoid if:

- you are allergic to tretinoin or retinoic acid, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- you are allergic to vitamin A or other retinoids
- 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 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.

Check with your doctor if you:

- have ever had any mental health problems including depression, aggressive tendencies or mood changes. This is because taking Vesanoid may affect your mood.
- have high fat levels in your blood.
- have liver or kidney disease.
- have other illnesses.
- develop fever or shortness of breath or difficulties in breathing, as these can be signs of “Retinoic Acid Syndrome” in APL.
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

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

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Breastfeeding must stop before treatment begins. Do not breastfeed while taking Vesanoid.

Mental health problem

- 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.

Use in children

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

3. What if I am taking other medicines?

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

Some medicines may interfere with Vesanoid.

- 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).

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Vesanoïd.

4. How do I use Vesanoïd?

How much to take

- Your doctor will tell you how many Vesanoïd 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.

When to take Vesanoïd

- Follow the instructions provided and use Vesanoïd until your doctor tells you to stop.
- Take Vesanoïd 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 to take Vesanoïd

- Capsules should be swallowed whole with a glass of water.
- Do not open the capsules and do not take any capsules that are damaged.

If you forget to use Vesanoïd

Vesanoïd should be used regularly at the same time each day.

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

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

If you use too much Vesanoïd

If you think that you have used too much Vesanoïd, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (Australia: **by calling 13 11 26; New Zealand: telephone 0800 POISON or 0800 764 766**), or
- contact your doctor, or

- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Vesanoïd?

Things you should do

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

Call your doctor straight away if you:

- do become pregnant while you are taking Vesanoïd
- have not taken your medicine exactly as prescribed

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

Remind any doctor, dentist or pharmacist you visit that you are using Vesanoïd.

Things you should not do

- Do not stop taking Vesanoïd 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 Vesanoïd to anyone else even if their symptoms seem similar to yours.
- Do not take any other medicines whether they require a prescription or not without first telling your doctor.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Vesanoïd affects you.

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

Looking after your medicine

- Keep your capsules in the bottle until it is time to take them.
- Keep Vesanoïd in a cool dry place where the temperature stays below 30°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

When to discard your medicine

If your doctor tells you to stop taking Vesanoïd, 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.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">dryness of the lips, mouth, nose, eyes and skinswelling of hands, ankles, feetnausea, vomiting, stomach paintenderness or stiffness in your bones or musclesheadache, dizzinessrashraised painful plaques on face, limbs or neckhair lossdepressionnumbness or tingling feelingdiarrhoea, constipationvision or hearing problemsloss of libido, male sexual dysfunctionbreast enlargement in men	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">severe headachesudden feversudden difficulty in breathing or shortness of breathsudden weight gainsudden tiredness or listlessnessfast 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	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

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

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

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems (Australia) or refer to the Medsafe website <https://www.medsafe.govt.nz/safety/report-a-problem.asp> (New Zealand).

By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Vesanoïd contains

Active ingredient (main ingredient)	Tretinoin
Other ingredients (inactive ingredients)	Yellow beeswax Hydrogenated soya oil Partially hydrogenated soya oil Soya oil Gelatin Glycerol Karion 83 Titanium dioxide Iron oxide yellow Iron oxide red
Potential allergens	Vesanoïd capsules are gluten free and lactose free

Do not take this medicine if you are allergic to any of these ingredients.

What Vesanoïd looks like

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

(Aust R 53160).

Who distributes Vesanoïd

Distributed in Australia by:
Pharmaco Australia Ltd,
Level 13, 465 Victoria Avenue
Chatswood NSW 2067

Australia
Phone: 1800 210 564

Distributed in New Zealand by:
Pharmaco (NZ) Ltd
4 Fisher Crescent

Mt Wellington
Auckland 1060
Phone: 0800 804 079

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