

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 taking Viramune?

Viramune contains the active ingredient nevirapine. Viramune is used in the treatment of the infection caused by the Human Immunodeficiency Virus (HIV-1). For more information, see Section [1. Why am I taking Viramune?](#) in the full CMI.

2. What should I know before I take Viramune?

Do not take Viramune if you have ever had an allergic reaction to nevirapine or any of the ingredients listed at the end of the CMI. Do not take Viramune if you have rare inherited conditions of galactose and fructose intolerance, severe liver dysfunction or if you previously experienced serious liver or skin reactions while taking Viramune or Viramune XR.

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 take Viramune?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Viramune 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 take Viramune?

Adults 16 years and older:

- **First 14 days:** Take one nevirapine tablet or 20 mL Viramune oral suspension once daily.
- **After the first 14 days:** Take one nevirapine tablet or 20 mL Viramune oral suspension twice daily (i.e. at regular 12-hour intervals at about the same time each day: morning and night).

Children (aged 2 months or older) and adolescents to 15 years:

- Your child's doctor will determine the dose of Viramune based on your child's age and body weight, or body surface area.
- **First 14 days:** Viramune oral suspension is given once daily.
- **After the first 14 days:** Viramune oral suspension is given twice daily.

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

5. What should I know while taking Viramune?

Things you should do	<ul style="list-style-type: none">• Remind any doctor or pharmacist you visit that you are taking Viramune.
Things you should not do	<ul style="list-style-type: none">• Do not stop taking Viramune or change the dose without first checking with your doctor.
Driving or using machines	<ul style="list-style-type: none">• Viramune may cause sleepiness or drowsiness in some people. Make sure you know how you react to Viramune before you drive or operate machinery
Looking after your medicine	<ul style="list-style-type: none">• Keep Viramune oral suspension in a cool dry place where the temperature stays below 30°C and keep out of reach of children.• Viramune oral suspension should be used within 6 months after opening the bottle.

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

6. Are there any side effects?

Common side effects include fever, stomach complaints, headache, fatigue, sleepiness, muscle pain/weakness.

Serious potential side effects that require medical attention include rash, allergic reaction and symptoms of a liver problem (such as yellowing of the skin/eyes, dark coloured urine, pale coloured stools, pain in the right side of the stomach area).

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.

Viramune®

Active ingredient: nevirapine

Consumer Medicine Information (CMI)

This leaflet provides important information about using Viramune. **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 Viramune.**

Where to find information in this leaflet:

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

1. Why am I taking Viramune?

Viramune is used in the treatment of the infection caused by the Human Immunodeficiency Virus (HIV-1). HIV-1 is the main virus responsible for the development of Acquired Immunodeficiency Syndrome (AIDS).

Viramune contains the active ingredient nevirapine. Nevirapine belongs to a group of antiretroviral medicines called non-nucleoside reverse transcriptase inhibitors (NNRTIs). It works by inhibiting or interrupting the enzyme reverse transcriptase that the HIV virus needs to multiply.

Viramune does not cure or prevent HIV-1 infection or AIDS, but it does hinder the growth of HIV-1. Viramune is prescribed in combination with other antiretroviral medicines which hinder the growth of HIV-1 in other ways. When these medicines are taken with Viramune, the growth of HIV-1 is hindered more effectively.

Viramune has not been shown to reduce the likelihood that you will develop the illnesses associated with advanced HIV-1 infection. It is important for you to continue seeing your doctor regularly.

Viramune does not reduce or prevent transmission of HIV-1 to others through sexual contact or blood contamination.

2. What should I know before I take Viramune?

Warnings

Do not take Viramune if:

- You are allergic to nevirapine, 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 have rare inherited conditions of galactose and fructose intolerance.
- You have severe liver dysfunction.

- You have previously experienced serious liver or skin reactions while on Viramune or Viramune XR treatment.

Tell your doctor if you:

- Have or have had liver problem/disease or hepatitis.
- Have or have had severe kidney disease undergoing dialysis treatment.
- Have allergies to any other medicines, foods, preservatives or dyes.

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

Tell your doctor if you are pregnant or intend to become pregnant. Special care is recommended during pregnancy. The benefits of Viramune must be assessed against possible effects on you and your unborn baby.

Tell your doctor if you are breastfeeding or intend to breastfeed. Breastfeeding is not recommended during your use of Viramune because:

- Viramune enters the breast milk, so your doctor may suggest an alternate method of feeding your child
- There is a risk of passing the HIV-1 virus to your baby.

Children

Do not give this medicine to a child under the age of 2 months. Safety and effectiveness in children younger than 2 months have not been established.

Sorbitol

Viramune oral suspension contains 6.5 g of sorbitol per maximum recommended daily dose. Products containing sorbitol may have a laxative effect or cause diarrhoea.

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.

In particular, tell your doctor if you are taking:

- other anti-HIV medicines
- anti-hepatitis B and C medicines
- cimetidine
- clarithromycin
- fluconazole, itraconazole, ketoconazole
- methadone
- oral contraceptives
- corticosteroids (e.g. prednisone)
- rifampicin, rifabutin

- herbal medicines derived from St John's Wort (*Hypericum perforatum*)
- warfarin
- medicines used in the treatment of:
 - allergies (antihistamines)
 - bacterial/fungal infections
 - cancer (e.g. cyclophosphamide)
 - depression
 - epilepsy
 - gut movement disorders (e.g. cisapride)
 - high blood pressure or heart conditions (calcium channel blockers)
 - irregular heartbeats (antiarrhythmics)
 - immune disorders or to prevent rejection of transplanted organ (immunosuppressants)
 - migraine (ergot derivatives)
 - severe pain (e.g. fentanyl).

These medicines may be affected by Viramune, or may affect how well it works. You may need different amounts of the medicine, or you may need to take different medicines.

As Viramune may reduce the effectiveness of oral contraceptives, talk to your doctor about alternative methods of contraception.

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

4. How do I take Viramune?

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

Follow the dosing instructions carefully, especially the once daily dosage during the first 14 days ('lead-in' period).

Adults 16 years and older:

- **First 14 days:** Take one nevirapine tablet or 20 mL of Viramune oral suspension once daily
- **After the first 14 days:** Take one nevirapine tablet or 20 mL of Viramune oral suspension twice daily (i.e. at regular 12-hour intervals at about the same time each day: morning and night).

Children (aged 2 months or older) and adolescents to 15 years:

- Viramune can be taken by children aged 2 months or older. Your child's doctor will determine the right dose of Viramune oral suspension based on your child's age and body weight, or body surface area.
 - **First 14 days:** Viramune oral suspension is given once daily
 - **After the first 14 days:** Viramune oral suspension is given twice daily (i.e. at regular 12-hour intervals at about the same time each day: morning and night).

Ask your doctor for more information if you have been advised to take a different dose, or if you are not sure what dose to give your child.

Your doctor will closely monitor you or your child for potential side effects of taking the medicine, in particular during the first 18 weeks of treatment.

When to take Viramune

Take Viramune at about the same time each day.

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

How to take Viramune

It is important that the entire dose of Viramune oral suspension is taken. Always use a metric measure to measure the required dose of Viramune oral suspension.

Provided with each bottle of Viramune oral suspension is a 5mL dispensing syringe and bottle-syringe adapter.

Viramune oral suspension should only be taken by mouth. The suspension can be taken with or without food.

How to administer Viramune oral suspension:

1. Shake the bottle gently.
2. Remove bottle cap.
3. Fit the blue adapter onto the bottle neck. Make sure the adapter is tightly fitted.
4. Insert the syringe into the adapter. Make sure the syringe is tightly inserted.
5. Turn the bottle upside down and gently withdraw the required amount of Viramune oral suspension.
6. Take the dose of Viramune oral suspension.
7. The maximum volume which can be measured using the dispensing syringe is 5 mL. Repeat steps 4 to 6 for dosage volumes greater than 5 mL.
8. Replace cap after use.

If you choose to use another metric measure, be sure that the entire dose is taken as some Viramune oral suspension can remain in the measuring cup/device. To ensure that the entire dose is taken, rinse the measuring cup/device with water and swallow the rinse water.

Viramune oral suspension should be used within 6 months after opening the bottle. Any suspension remaining after 6 months should be returned to your pharmacist for disposal.

How long to take Viramune

Continue taking Viramune 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 Viramune

It is important to take Viramune as directed.

If you miss a dose, take it as soon as you remember. However, if you remember when it is almost time for your next dose, take only your usual dose at that time.

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

If you have missed taking Viramune for more than 7 days, contact your doctor before you start taking it again. You may need to restart using the 14 days (lead-in) once daily dosing procedure.

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

If you take too much Viramune

If you think that you have taken too much Viramune, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**in Australia telephone 13 11 26; in New Zealand telephone 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.

Symptoms of an overdose may include oedema (fluid retention), fatigue, fever, headache, insomnia, lung problems, rash, dizziness, nausea, vomiting, weight loss and erythema nodosum (a condition causing red-purple swellings on the shins, thighs and less commonly, the arms, joint and muscle pains and fever).

5. What should I know while taking Viramune?

Things you should do

- **Contact your doctor if you experience rash on any parts of the body. Contact your doctor immediately if the rash is accompanied by other symptoms such as fever, blisters, mouth sores, conjunctivitis, facial swelling, muscle or joint aches, swollen lymph glands, or tiredness.** These may be symptoms of a hypersensitivity reaction that requires urgent medical attention.
- **Contact your doctor if you experience any symptoms of liver problems, such as loss of appetite, nausea, vomiting, jaundice (yellowing of the skin and/or eyes), dark coloured urine, pale coloured stools, pain/ache or sensitivity to touch in your right abdominal area (below your ribs).** These could be signs of serious liver dysfunction which your doctor will need to monitor closely and may require stopping treatment with Viramune.
Liver function tests should be performed at regular intervals, especially during the first 18 weeks of treatment with Viramune. If the results are abnormal, your doctor will consider either performing more frequent liver function tests (in less severe cases) or stopping treatment with Viramune altogether (in more severe cases).
- In rare instances, temporary weakness or pain of muscles has been seen in Viramune patients experiencing skin and/or liver problems.

- **If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Viramune.**
- **If you are taking oral contraceptives (to prevent pregnancy) you should use additional or different type of contraception.** Viramune may reduce effectiveness of oral contraceptives.
- **If you become pregnant while taking Viramune tell your doctor immediately.**
- **If you have had a previous opportunistic infection, and you notice symptoms of inflammation occurring when you first start taking Viramune, tell your doctor immediately.** Symptoms of inflammation include redness, swelling, heat and pain. These symptoms have been reported in some patients who have previously had an infection when combination antiretroviral therapy was started.
- **Contact your doctor if you experience any symptoms of an overactive thyroid gland, such as rapid heart rate, tremors and increased sweating.** Autoimmune problems such as overactive or enlarged thyroid gland (goiter) have been reported in some patients.

Things you should not do

- **Do not give Viramune to anyone else, even if they have the same condition as you.**
- **Do not stop taking Viramune or change the dose without first checking with your doctor.** Viramune helps control your HIV infection but does not cure it. Therefore, Viramune must be taken every day as your doctor prescribed it.

Driving or using machines

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

Viramune may cause sleepiness or drowsiness in some people. Make sure you know how you react to Viramune before you drive or operate machinery.

Looking after your medicine

- **Keep your Viramune oral suspension in a cool dry place where the temperature stays below 30°C.**

Store it in a 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

Viramune oral suspension should be used within 6 months after opening the bottle.

Getting rid of any unwanted medicine

If your doctor tells you to stop taking 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?

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

It may be difficult to tell whether side effects are the result of taking Viramune, effects of the HIV disease or side effects of other medicines you may be taking. For this reason, it is very important to inform your doctor of any change in your condition. Your doctor may need to change your dose or advise you to stop taking Viramune.

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 for advice if you have any concerns about the effects of taking Viramune.

The frequently reported side effects for children were similar to those observed in adults. However, a reduction of white blood cells (granulocytopenia) or red blood cells (anaemia) has been more commonly seen in children.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • Fever • Nausea, vomiting, diarrhoea, stomach pain • Headache • Fatigue • Sleepiness • Abnormal liver function tests • Myalgia (aching muscles, muscle tenderness or weakness, not caused by exercise) • Joint pain <p><u>Associated with combination antiretroviral therapy:</u></p> <p>Changes in body shape due to changes in fat distribution, such as:</p> <ul style="list-style-type: none"> • Loss of fat from legs, arms and face • Increased fat in the abdomen and other internal organs • Breast enlargement • Fatty lumps on the back of the neck. 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Skin reactions:</p> <ul style="list-style-type: none"> • Rash. Usually mild to moderate and located on the trunk, face, arms and/or legs. However, severe and life-threatening rashes can occur. Most of the cases of rash occur in the first 6 weeks of treatment. <p>Hypersensitivity (allergic) reactions:</p> <ul style="list-style-type: none"> • Anaphylaxis (sudden life-threatening allergic reaction) - sudden signs of rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing • Rash accompanied by other side effects such as fever, blisters, mouth sores, conjunctivitis, facial swelling, muscle or joint aches, swollen lymph glands, or tiredness. <p>Symptoms of a liver problem, such as:</p> <ul style="list-style-type: none"> • Loss of appetite • Nausea, vomiting • Jaundice (yellowing of the skin and/or eyes) • Dark coloured urine • Pale coloured stools • Pain/ache or sensitivity to touch in your right abdominal area (below your ribs). 	<p>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.</p>

Tell your doctor or pharmacist if you experience any side effects or notice anything unusual during or after taking Viramune.

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. 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 Viramune contains

Viramune oral suspension 50 mg/5 mL

Active ingredient (main ingredient)	nevirapine (as nevirapine hemihydrate)
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• carbomer 934P• methyl hydroxybenzoate• propyl hydroxybenzoate• polysorbate 80• sucrose• sorbitol solution 70% (non-crystallising)• sodium hydroxide• purified water
Potential allergens	Sucrose, sorbitol, methyl hydroxybenzoate and propyl hydroxybenzoate.

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

What Viramune looks like

Viramune oral suspension is a white to off white liquid. The suspension is supplied in a bottle containing 240 mL of the suspension. A 5 mL dispensing syringe and a bottle-syringe adapter are provided with each pack (AUST R 72099).

Who distributes Viramune

Viramune oral suspension is supplied in Australia by:

Boehringer Ingelheim Pty Limited

ABN 52 000 452 308

Sydney, Australia

www.boehringer-ingelheim.com.au

Viramune oral suspension is supplied in New Zealand by:

Boehringer Ingelheim (N.Z.) Limited

Auckland

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