

Viramune® XR

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 XR?

Viramune XR contains the active ingredient nevirapine. Viramune XR 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 XR?](#) in the full CMI.

2. What should I know before I take Viramune XR?

Do not take Viramune XR 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 XR if you have rare inherited conditions of galactose 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 XR?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Viramune XR 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 XR?

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 Viramune XR tablet once daily.

Children (aged 3 years or older) and adolescents to 15 years:

- Your child's doctor will determine the dose of Viramune XR 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:** Your child may be switched to Viramune XR tablet, given once daily.

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

5. What should I know while taking Viramune XR?

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

For more information, see Section [5. What should I know while taking Viramune XR?](#) 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® XR

Active ingredient: nevirapine

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I taking Viramune XR?

Viramune XR 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 XR 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 XR does not cure or prevent HIV-1 infection or AIDS, but it does hinder the growth of HIV-1. Viramune XR 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 XR, the growth of HIV-1 is hindered more effectively.

Viramune XR 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 XR 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 XR?

Warnings

Do not take Viramune XR 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 the rare inherited condition of galactose 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 XR 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 XR because:

- Viramune XR 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 3 years. Safety and effectiveness in children younger than 3 years have not been established.

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 XR 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 XR 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 XR.

4. How do I take Viramune XR?

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) of nevirapine 200 mg immediate-release tablets or Viramune oral suspension.

Adults 16 years and older:

- **First 14 days:** Take one nevirapine 200 mg immediate-release tablet or 20 mL of Viramune oral suspension once daily
- **After the first 14 days:** Take one Viramune XR 400 mg extended-release tablet once daily.

Children (aged 3 years or older) and adolescents to 15 years:

- Viramune XR can be taken by children aged 3 years or older. Your child's doctor will calculate the dose for your child. The calculation will include your child's age and body weight, or body surface area.
- For younger children starting from birth an oral suspension is available.
- **First 14 days:** Viramune oral suspension is given once daily.
- **After the first 14 days:** Your child may be switched to Viramune XR tablets once daily.

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.

If you are switching from nevirapine immediate-release tablets or oral suspension:

If you are already taking nevirapine 200 mg immediate release tablets or oral suspension twice daily in combination with other antiretroviral agents you can switch to Viramune XR 400 mg extended-release tablets once daily without the 14 day 'lead-in' period.

Take your nevirapine 200 mg immediate-release tablets or oral suspension as normal the day before you switch. Then take your Viramune XR 400 mg extended release tablet the next morning and do not take any more of the nevirapine immediate-release tablets or oral suspension.

When to take Viramune XR

Take Viramune XR 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 XR

Swallow the tablets whole with a full glass of water.

The tablets should not be broken, crushed or chewed.

The tablets can be taken with or without food.

How long to take Viramune XR

Continue taking Viramune XR 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 XR

It is important to take Viramune XR 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 XR 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 XR

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

You should immediately:

- phone the Poisons Information Centre (**in Australia telephone 13 11 26**), 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 XR?

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 XR.

Liver function tests should be performed at regular intervals, especially during the first 18 weeks of treatment with Viramune XR. 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 XR altogether (in more severe cases).

- In rare instances, temporary weakness or pain of muscles has been seen in Viramune XR 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 XR.**
- **If you are taking oral contraceptives (to prevent pregnancy) you should use additional or different type of contraception.** Viramune XR may reduce effectiveness of oral contraceptives.
- **If you become pregnant while taking Viramune XR 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 XR, 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 XR to anyone else, even if they have the same condition as you.**
- **Do not stop taking Viramune XR or change the dose without first checking with your doctor.** Viramune XR helps control your HIV infection but does not cure it. Therefore, Viramune XR 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 XR affects you.

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

Looking after your medicine

Keep your Viramune XR tablets 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.

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 XR.

It may be difficult to tell whether side effects are the result of taking Viramune XR, 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 XR.

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 XR.

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>	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<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. 	

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 XR.

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 XR contains

Active ingredient (main ingredient)	nevirapine 400 mg
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> lactose monohydrate hypromellose iron oxide yellow (CI 77492) magnesium stearate.
Potential allergens	lactose

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

What Viramune XR looks like

Viramune XR extended-release tablets 400 mg are yellow, oval, biconvex tablets. The tablets are debossed with product identification "V04" on one side and the BI tower logo on the other side.

Blister packs of 10* and 30 extended-release tablets (AUST R 176980).

* Not currently distributed in Australia.

Who distributes Viramune XR

Viramune XR extended-release tablets are supplied in Australia by:

Boehringer Ingelheim Pty Limited

ABN 52 000 452 308

Sydney, Australia

www.boehringer-ingelheim.com.au

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