Viramune®

Tablets and Oral Suspension

nevirapine

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Viramune.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you using Viramune against the benefits they expect it will have for you.

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

This leaflet was last updated on the date at the end of this leaflet. More recent information may be available. The latest Consumer Medicine Information is available from your pharmacist, doctor, or from www.medicines.org.au (Australia) and www.medsafe.govt.nz/Consumers/cmi/CMIForm.asp (New Zealand) and may contain important information about the medicine and its use of which you should be aware.

Keep this leaflet with your medicine.

You may need to read it again.

What Viramune is used for

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.

Before you take Viramune

When you must not take it

Do not take Viramune if you have an allergy to:

- any medicine containing nevirapine
- any of the other ingredients listed at the end of this leaflet.

Do not take Viramune if you have rare inherited conditions of galactose and fructose intolerance.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not take Viramune if you have:

- severe liver dysfunction
- previously experienced serious liver or skin reactions while on Viramune or Viramune XR treatment.

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.

Do not take this medicine after the expiry date printed on the carton or bottle or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

It is essential that your doctor knows your medical history before prescribing Viramune.

Tell your doctor if you have, or have had, any of the following conditions:

- liver problem/disease or hepatitis
- severe kidney disease undergoing dialysis treatment.

If you are not sure if you have, or have had, any of these conditions, you should raise those concerns with your doctor.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor can discuss with you the risks and benefits involved.

Special care is recommended during pregnancy. The benefits of Viramune must be assessed against possible effects on you and your unborn baby.

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.

If you have not told your doctor about any of the above, tell him/ her before you start taking Viramune.

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.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get 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
  - gastrointestinal motility disorder (e.g. cisapride)
  - hypertension 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.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

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

How to take Viramune

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

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the carton or bottle, ask your doctor or pharmacist for help.

How much to take

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

ADULT 16 YEARS AND OLDER:

- First 14 days: one Viramune tablet or 20 mL Viramune oral suspension once daily
- After the first 14 days: one Viramune 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:

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.

How to take it

VIRAMUNE TABLETS

Viramune tablets should be swallowed 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.

VIRAMUNE ORAL SUSPENSION

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.

When to take it

Take your medicine 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 long to take it

Continue taking your medicine 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 it

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 have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor, pharmacist or Poisons Information Centre (in Australia telephone 13 11 26; in New Zealand telephone 0800 764 766) for advice, or go to Emergency at your nearest hospital if you think that you or anyone else may have taken too much Viramune. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include oedema, 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).

While you are taking Viramune

Things you must 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 must 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.

Things to be careful of

Be careful driving or operating machinery 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.

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 for the advice of your doctor or pharmacist 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.

The major side effect of Viramune is rash. Rashes are usually mild to moderate, located on the trunk, face, arms and/or legs. However, severe and/or life-threatening rashes (including Stevens Johnson Syndrome and Toxic Epidermal Necrolysis) have been reported with the use of Viramune. Most of the cases of rash occur in the first six weeks of treatment.

Hypersensitivity (allergic) reactions have also been reported. Such reactions may appear in the form of:

- 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.

Contact your doctor immediately if you experience rash and/or any signs of hypersensitivity reactions.

The other most frequently reported side effects of Viramune are fever, nausea, headache, fatigue, sleepiness, vomiting, diarrhoea, stomach pain, abnormal liver function tests and myalgia (aching muscles, muscle tenderness or weakness, not caused by exercise).

Cases of jaundice (yellowing of the skin and/or eyes), hepatitis, severe and life-threatening liver dysfunction (including fulminant hepatitis and liver failure) have been reported in patients being treated with Viramune.

Contact your doctor immediately 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).

In some patients, combination antiretroviral therapy may cause changes in body shape due to changes in fat distribution. These may include:

- 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.

Tell your doctor as soon as possible if you experience any side effects during or after taking Viramune, so that these may be properly treated.

In addition, other side effects, not listed above, can occur in some patients.

You should tell your doctor or pharmacist if you notice anything unusual, during or after taking Viramune.

After taking Viramune

Storage

Keep your Viramune tablets in blister packs in a cool dry place where the temperature stays below 25°C.

Keep your Viramune tablets and oral suspension in bottles in a cool dry place where the temperature stays below 30°C.

Do not store Viramune or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat or dampness can destroy some medicines.

Keep it where children cannot reach it.

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

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

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product Description

What it looks like

Viramune is the brand name of your medicine and is available in two dosage forms:

VIRAMUNE TABLETS

The tablets are white, oval tablets. One side is marked with "54 193" with a score mark between "54" and "193". The other side has a score mark only.

Blisters of 14 tablets (sample), 60* and 100* tablets.

Bottles of 60 and 100* tablets.

* Not currently distributed in Australia.

Viramune tablets are not currently distributed in New Zealand.

VIRAMUNE ORAL SUSPENSION

The suspension is a white to off-white liquid.

The suspension is supplied in a bottle containing 240 mL of the suspension. A 5mL dispensing syringe and a bottle-syringe adapter are provided with each pack.

Ingredients

VIRAMUNE TABLETS

Each tablet contains 200 mg of nevirapine (active ingredient).

The other ingredients are:

- microcrystalline cellulose
- lactose monohydrate
- povidone
- sodium starch glycollate
- colloidal anhydrous silica
- magnesium stearate.

VIRAMUNE ORAL SUSPENSION

Each 5 mL of Viramune oral suspension contains 50 mg of nevirapine (as nevirapine hemihydrate).

The other ingredients are:

- carbomer 934P
- methyl hydroxybenzoate
- propyl hydroxybenzoate
- polysorbate 80
- sucrose
- sorbitol solution 70% (non-crystallising)
- sodium hydroxide
- purified water.

Supplier

Viramune tablets and oral suspension are 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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Australian Registration Numbers

Viramune tablets

- Blister packs AUST R 56892
- Bottles AUST R 56891

Viramune oral suspension

- Bottles AUST R 72099