Viramune® XR

Extended-Release Tablets

nevirapine

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Viramune XR.

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 XR 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 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 XR is used for

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.

Before you take Viramune XR

When you must not take it

Do not take Viramune XR 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 XR if you have the rare inherited condition of galactose 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 XR 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 3 years.

Safety and effectiveness in children younger than 3 years 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 XR.

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 XR must be assessed against possible effects on you and your unborn baby.

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.

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

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

How to 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.

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)

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

Adults 16 years and older:

- First 14 days: one Viramune 200 mg immediate-release tablet or 20 mL Viramune oral suspension once daily
- After the first 14 days: one Viramune XR 400 mg extended-release tablet once daily (taken at about the same time each day).

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 (taken at about the same time each day). The tablets should not be broken, crushed or chewed.

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 Viramune immediate-release tablets or oral suspension:

If you are already taking Viramune 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 Viramune 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 Viramune immediate-release tablets or oral suspension.

How to take it

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.

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 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 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 (Australia telephone 13 11 26) for advice, or go to Emergency at your nearest hospital if you think that you or anyone else may have taken too much Viramune XR. 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 XR

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 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 the 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 must 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.

Things to be careful of

Be careful driving or operating machinery 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.

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 for the advice of your doctor or pharmacist 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.

The major side effect of Viramune XR 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 XR. 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 XR 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 XR.

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 XR, 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 XR.

After taking Viramune XR

Storage

Keep your tablets in a cool dry place where the temperature stays below 30°C.

Do not store Viramune XR 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.

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 XR is the brand name of your medicine.

Viramune XR extended-release tablets 400 mg are yellow, oval, biconvex tablets. The tablets are embossed 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.

* Not currently distributed in Australia.

Ingredients

Active ingredients:

Viramune XR 400 mg contains 400 mg nevirapine per tablet

Inactive ingredients:

- lactose monohydrate
- hypromellose
- iron oxide yellow (CI 77492)
- magnesium stearate.

Supplier

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

This Consumer Medicine Information was updated in September 2018.

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