

NEVIRAPINE VIATRIS

Nevirapine Tablets 200 mg



What is in this leaflet

This leaflet answers some common questions about Nevirapine Viatriis.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

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

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

Keep this leaflet with the medicine. You may need to read it again.

What Nevirapine Viatriis is used for

Nevirapine Viatriis is used in combination with other antiretroviral medicines to slow down the progression of Human Immunodeficiency Virus (HIV) infection. HIV can lead to Acquired Immunodeficiency Syndrome (AIDS) and other related illnesses.

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

Nevirapine Viatriis does not cure or prevent HIV infection or AIDS, but it does hinder the growth of HIV. In this way it stops ongoing damage to

the body's immune system, which fights infection.

Nevirapine Viatriis is prescribed in combination with other antiretroviral medicines which hinder the growth of HIV in other ways. When these medicines are taken with Nevirapine Viatriis, the growth of HIV is hindered more effectively.

Nevirapine Viatriis does not prevent or reduce your risk of passing HIV infection to others. You will still be able to pass on the HIV virus by sexual activity or by passing on blood or bodily secretions which carry the HIV virus. You should continue to take all appropriate precautions.

While taking Nevirapine Viatriis and any other therapy for HIV, you may continue to develop other infections and other complications of HIV infection. You should keep in regular contact with your doctor.

The long-term risks and benefits of taking Nevirapine Viatriis are not known.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

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

Before you take Nevirapine Viatriis

When you must not take it:

Do not take Nevirapine Viatriis if you have an allergy to:

- any medicine containing nevirapine

- any of the ingredients listed at the end of this leaflet.

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 Nevirapine Viatriis if you have:

- severe liver problems
- hepatitis B or C infection
- previously experienced serious liver or skin reactions while taking nevirapine.

Nevirapine Viatriis contains lactose.

Do not take it if you have a rare hereditary condition of galactose intolerance such as galactosaemia, Lapp lactase deficiency or glucose-galactose malabsorption. Ask your doctor if you are unsure if you have a condition like this.

Do not take this medicine if you are pregnant or trying to become pregnant without first talking to your doctor.

Your doctor can discuss with you the risks and benefits of taking this medicine if you are pregnant.

Breastfeeding is not recommended while you are taking Nevirapine Viatriis because:

- Nevirapine Viatriis enters the breast milk and there is a possibility your baby may be affected
- there is a risk of passing the HIV infection to your baby.

Talk to your doctor if you have any questions about pregnancy or breastfeeding.

Do not take preparations containing St John's Wort (*hypericum perforatum*) while taking Nevirapine Viatris.

St John's Wort may reduce the effect of Nevirapine Viatris.

Do not take this medicine after the expiry date printed on the pack 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.

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

- liver problems, liver disease or hepatitis
- abnormal liver function tests
- severe kidney disease undergoing dialysis treatment

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

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.

Some medicines and Nevirapine Viatris may interfere with each other. These include:

- other anti-HIV medicines
- some antiviral medicines for Hepatitis B and C
- cimetidine, an antacid
- some antibiotic medicines such as clarithromycin, rifampicin or rifabutin

- some antifungal medicines such as fluconazole, itraconazole, ketoconazole
- methadone for opioid addiction or severe pain
- oral contraceptives
- corticosteroids such as prednisone and cortisone, which reduce the activity of your immune system
- herbal medicines derived from St John's Wort (*Hypericum perforatum*)
- warfarin and medicines used to thin the blood.

Tell your doctor if you are taking any medicine used to treat:

- allergies, such as hayfever
- bacterial/fungal infections
- cancer, such as cyclophosphamide monohydrate
- depression
- epilepsy
- gastrointestinal motility disorder, such as cisapride
- hypertension or heart conditions, such as calcium channel blockers
- irregular heartbeats, such as antiarrhythmics
- immune disorders or to prevent rejection of transplanted organs (immunosuppressants)
- migraine (ergot derivatives)
- severe pain, such as fentanyl.

These medicines may be affected by Nevirapine Viatris or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

If you are taking oral contraceptives (to prevent pregnancy) you should also use additional contraception.

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

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

How to take Nevirapine Viatris

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

They may differ from the information contained in this leaflet.

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

How much to take

Follow the dosing instructions carefully.

It is important to follow the dosing instructions carefully, especially the once daily dosage during the first 14 days ('lead-in' period).

Adults aged 16 years and older:

First 14 days: Take one Nevirapine Viatris 200 mg tablet daily.

After the first 14 days: Take one Nevirapine Viatris 200 mg tablet twice daily.

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

Nevirapine Viatris is usually used together with at least two other antiretroviral medicines. Follow your doctor's instructions for taking the other medicines.

How to take it

Swallow the tablets whole (not chewed) with a full glass of water.

Nevirapine Viatris tablets can be taken with or without food.

When to take it

Take your medicine at about the same time(s) each day.

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

When you are taking Nevirapine Viatris twice daily, try to take it in the morning and at night, approximately every 12 hours.

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

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

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

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

This may increase the chance of you getting an unwanted side effect.

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

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

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

While you are taking Nevirapine Viatris

Things you must do

Contact your doctor if you notice a 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 Nevirapine Viatris.

Liver function tests should be performed at regular intervals, especially during the first 18 weeks of treatment with Nevirapine Viatris.

If the results are abnormal, your doctor may consider performing more frequent tests, or in more severe cases, stopping treatment with Nevirapine Viatris altogether. Women and patients with higher CD4 counts seem to be at increased risk for developing liver problems while taking Nevirapine Viatris.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Nevirapine Viatris.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

If you are taking oral contraceptive (to prevent pregnancy) you should use additional or different type of contraception. Nevirapine Viatris may reduce effectiveness of oral contraceptives.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you have had a previous opportunistic infection, and you notice symptoms of inflammation occurring when you first start taking Nevirapine Viatris, 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.

If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects. These tests may include blood tests to check levels of HIV virus in the blood, check blood cells and your liver and kidney function.

Things you must not do

Do not take Nevirapine Viatris to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking Nevirapine Viatris or change the dosage without checking with your doctor.

This medicine helps control your HIV infection but does not cure it. Therefore, Nevirapine Viatris 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 Nevirapine Viatris affects you.

This medicine may cause fatigue or drowsiness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) for advice or go to Accident and Emergency at the nearest hospital if you think that you or anyone else may have taken too much Nevirapine Viatris. Do this even if there are no signs of discomfort or poisoning. Take the medicine bottle with you if you can. You may need urgent medical attention.

Symptoms of an overdose may include swelling, erythema nodosum (a condition causing red-purple swellings on the shins, thighs and less commonly, the arms, joint and muscle pains and fever), fatigue, fever, headache, difficulty sleeping, lung problems, dizziness, nausea, vomiting and spinning sensation.

Side effects

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

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

Like all medicines, this medicine may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Many of the possible side effects are more likely to occur within the first 18 weeks of treatment, and for major side effects like skin rash and liver problems, the highest risk is during the first 6 weeks of treatment. Women and patients with higher CD4 counts seem to be at increased risk of liver problems with this medicine.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- fever
- nausea
- vomiting
- fatigue
- headache
- diarrhoea
- stomach or abdominal pain
- sleepiness
- muscle aches, tenderness or weakness, not caused by exercise
- joint pain.

The above lists include the less serious side effects of your medicine.

Tell your doctor as soon as possible if you notice any of the following:

- unusual bleeding or bruising
- signs of infection or inflammation such as fever, redness, swelling, heat and pain
- signs of anaemia such as tiredness, headaches, being short of breath while exercising, dizziness and looking pale.

The above list includes serious side effects that may require medical attention.

The major side effect of Nevirapine Viatris is rash. Rashes are usually mild to moderate, located on the trunk, face, arms and/or legs.

Severe and/or potentially life-threatening rashes including Stevens-Johnson Syndrome (SJS) and toxic epidermal necrolysis (TEN) have also been reported with the use of nevirapine, appearing initially as reddish target-like spots or circular patches often with central blisters on the trunk. Additional signs to look for include ulcers in the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes). These potentially life-threatening skin rashes are often accompanied by flu-like symptoms such as fever, swelling of the face or lymph glands, muscle or joint pains and tiredness. The rash may progress to widespread blistering or peeling of the skin. The highest risk for occurrence of serious skin reactions is within the first six weeks of treatment.

If you develop a rash or these skin and accompanying symptoms, seek immediate advice from a doctor and tell him or her that you are taking this medicine.

If you have developed Stevens-Johnson syndrome or toxic epidermal necrolysis with the use of nevirapine, you must not be re-started on nevirapine at any time.

Cases of liver problems including 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 nevirapine.

Symptoms of liver problems may include jaundice (yellowing of the skin or eyes), dark coloured urine, light coloured stools, nausea, vomiting, pain or sensitivity to touch in the right abdominal area (below the ribs), loss of appetite or feeling generally unwell.

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), seek immediate advice from a doctor and tell him or her that you are taking this medicine. This could be signs of serious liver dysfunction which your doctor will monitor these closely and may require stopping treatment with Nevirapine Viatris.

In rare instances, temporary weakness or pain of muscles has been seen in Viramune patients experiencing skin and/or liver problems.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you develop any symptoms of anaphylaxis (sudden life-threatening allergic reaction).

Symptoms 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.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell. Other side effects not listed above may also occur in some people.

Some side effects (for example anaemia, changes in numbers of blood cells, abnormal liver function tests and increased blood pressure) can only be found when your doctor does tests from time to time to check your progress.

Do not be alarmed by this list of side effects. You may not experience any of them.

After taking Nevirapine Viatris

Storage

Keep your tablets in the bottle until it is time to take them.

If you take the tablets out of the bottle they may not keep well.

Keep your tablets in a cool dry place where the temperature stays at or below 25°C.

Heat and damp conditions can destroy some medicines. Do not store Nevirapine Viatris or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

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

Nevirapine Viatris tablets are white to off-white, oval shaped, biconvex uncoated tablets. They are marked with "NE 200" with a score-line separating the "NE" and "200" on one side, and "M" and score-line on the other side.

Nevirapine Viatris tablets are supplied in bottles containing 60 tablets.

Ingredients

Active ingredient:

Nevirapine Viatris contains 200 mg of nevirapine as the active ingredient.

Inactive ingredients:

Nevirapine Viatris also contains:

- lactose monohydrate
- microcrystalline cellulose
- sodium starch glycolate
- povidone
- colloidal silicon dioxide
- magnesium stearate.

Contains sugars as lactose.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

Nevirapine Viatris is supplied in New Zealand by:

Viatris Ltd,
PO Box 11-183,
Ellerslie,
AUCKLAND
www.viatris.co.nz
Telephone 0800 168 169

Date of Preparation

24 July 2023 (Based on datasheet dated 24 July 2023).