

# NEVIRAPINE VIATRIS

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## 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.

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### 1. Why am I using NEVIRAPINE VIATRIS?

NEVIRAPINE VIATRIS contains the active ingredient nevirapine. NEVIRAPINE VIATRIS 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 NEVIRAPINE VIATRIS?](#) in the full CMI.

### 2. What should I know before I use NEVIRAPINE VIATRIS?

Do not use if you have ever had an allergic reaction to nevirapine or any of the ingredients listed at the end of the CMI.

**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 NEVIRAPINE VIATRIS?](#) in the full CMI.

### **3. What if I am taking other medicines?**

Some medicines may interfere with NEVIRAPINE VIATRIS 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 use NEVIRAPINE VIATRIS?**

Adults 16 years and older:

- First 14 days: Take one NEVIRAPINE VIATRIS tablet once daily.
- After the first 14 days: Take one NEVIRAPINE VIATRIS tablet twice daily.

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

### **5. What should I know while using NEVIRAPINE VIATRIS?**

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor or pharmacist you visit</li></ul>
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	<p>that you are using NEVIRAPINE VIATRIS.</p> <ul style="list-style-type: none"> <li>● 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 or swollen lymph glands.</li> </ul>
<p><b>Things you should not do</b></p>	<ul style="list-style-type: none"> <li>● Do not take NEVIRAPINE VIATRIS to treat any other complaints unless your doctor tells you to.</li> <li>● Do not stop taking your medicine or change the dosage without first checking with your doctor.</li> </ul>
<p><b>Driving or using machines</b></p>	<ul style="list-style-type: none"> <li>● NEVIRAPINE VIATRIS may cause sleepiness or drowsiness in some people. If you have these symptoms, do not drive, operate machinery or do anything else that could be dangerous.</li> </ul>

<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>● Store below 25°C in a cool and dry place.</li><li>● Keep medicines where children cannot reach them.</li></ul>
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For more information, see Section [5. What should I know while taking NEVIRAPINE VIATRIS?](#) in the full CMI.

## **6. Are there any side effects?**

**Tell your doctor or pharmacist if you notice any of the following and they worry you:** mild to moderate rash on the trunk, face, arms and/or legs, fever, nausea, headache, fatigue, sleepiness or drowsiness, abnormal liver function tests, vomiting, diarrhoea, stomach pain, myalgia (aching muscles, muscle tenderness or weakness, not caused by exercise).

**If any of the following happens, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:** signs of an allergic reaction, such as 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; yellowing of the skin and/or eyes, also called jaundice, 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.



# NEVIRAPINE VIATRIS

Active ingredient(s): *nevirapine*

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using NEVIRAPINE VIATRIS. **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 NEVIRAPINE VIATRIS.**

**Where to find information in this leaflet:**

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

## 1. Why am I taking NEVIRAPINE VIATRIS?

**NEVIRAPINE VIATRIS contains the active ingredient nevirapine.** Nevirapine belongs to a group of medicines called antiretroviral medicines called non-nucleoside reverse transcriptase inhibitors (NNRTIs). It works

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by inhibiting or interrupting with the enzyme reverse transcriptase that the HIV virus needs to multiply.

**NEVIRAPINE VIATRIS 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).

NEVIRAPINE VIATRIS does not cure or prevent HIV-1 infection or AIDS, but it does hinder the growth of HIV-1.

NEVIRAPINE VIATRIS is used in combination with other antiretroviral medicines which hinder the growth of HIV-1 in other ways. When these medicines are taken with NEVIRAPINE VIATRIS, the growth of HIV-1 is hindered more effectively.

**NEVIRAPINE VIATRIS 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.**

**NEVIRAPINE VIATRIS does not reduce the risk of or prevent transmission of HIV-1 to others through sexual contact or blood contamination.**

**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.

## 2. What should I know before I take NEVIRAPINE VIATRIS?

### Warnings

#### Do not take NEVIRAPINE VIATRIS if:

- you have an allergy to Nevirapine or 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

Always check the ingredients to make sure you can use this medicine.

- you have any rare inherited conditions of galactose and fructose intolerance.
- you use any herbal medicines containing St John's Wort (*Hypericum perforatum*).
- you have or have had any of the following:
  - severe liver dysfunction
  - serious liver or skin reactions while on any Nevirapine treatments
- **the expiry date (EXP) printed on the pack has passed or 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.**

**Check with your doctor if you:**

- **are allergic to any other medicines, foods, dyes or preservatives**
- **have or have had hepatitis, liver problems or liver disease.**
- **are having or have ever had 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 your medical history before taking NEVIRAPINE VIATRIS.**

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

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

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 plan to become pregnant.**

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

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

**Tell your doctor if you are planning to breastfeed during your use of NEVIRAPINE VIATRIS.**

Breastfeeding is not recommended during your use of NEVIRAPINE VIATRIS because:

- NEVIRAPINE VIATRIS 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.

### **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.**

Some medicines and NEVIRAPINE VIATRIS may interfere with each other.

**Tell your doctor if you are taking any of the following medicines:**

- any other anti-HIV medicines
- anti-Hepatitis B & C medicines
- cimetidine, a medicine used to treat reflux and ulcers
- clarithromycin, an antibiotic medicine used to treat bacterial infections
- fluconazole, itraconazole or ketoconazole, medicines used to treat fungal infections
- methadone, a medicine used to treat people with opioid drug dependency
- oral contraceptives, a medicine used to prevent pregnancy
- corticosteroids (e.g. prednisone), medicines such as prednisone and cortisone, which reduce the activity of your immune system
- rifampicin or rifabutin, antibiotic medicines most commonly used to treat tuberculosis (TB)
- herbal medicines derived from St John's Wort (*Hypericum perforatum*)
- warfarin, a medicine used to prevent blood clots

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

- allergies, such as antihistamines
- 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 organ (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.

**Tell your doctor if you are taking oral contraceptives.**

As NEVIRAPINE VIATRIS may reduce the effectiveness of oral contraceptives, 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.

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

## **4. How do I take NEVIRAPINE VIATRIS?**

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

They may differ from the information contained in this leaflet.

**If you do not understand the instructions on the bottle, 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 16 years and older:**

- **First 14 days:** Take one NEVIRAPINE VIATRIS tablet once daily.
- **After the first 14 days:** Take one NEVIRAPINE VIATRIS tablet twice daily.

**Take each dose at regular 12-hour intervals, 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.

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

## **When to take NEVIRAPINE VIATRIS**

- NEVIRAPINE VIATRIS should be used at about the same time each day.

- It does not matter if you take this medicine before or after food.

## **How to take NEVIRAPINE VIATRIS**

- Swallow the tablets whole with a full glass of water.
- Do not crush or chew the tablets.

## **How long to take NEVIRAPINE VIATRIS**

- **Continue taking your medicine for as long as your doctor tells you to.**
- 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 use NEVIRAPINE VIATRIS**

**If it is almost 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 you missed.**

**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 using the 14 days (lead-in) once daily dosing procedure.

**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.**

## **If you take too much NEVIRAPINE VIATRIS**

If you think that you have used too much NEVIRAPINE VIATRIS, you may need urgent medical attention.

### **You should immediately:**

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, 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.**

You may need urgent medical attention.

### **Symptoms of an overdose may include:**

oedema (an abnormal accumulation of fluid beneath the skin or in one or more cavities of the body), fatigue, fever, headache, insomnia, lung problems, rash, dizziness, nausea, vomiting, weight loss or 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 NEVIRAPINE VIATRIS?**

### **Things you should do**

- **Contact your doctor if you experience a rash on any part 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.

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

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 will consider either

performing more frequent liver function tests (in less severe cases) or stopping treatment with NEVIRAPINE VIATRIS altogether (in more severe cases).

Women and patients with higher CD4 cell counts seem to be at increased risk for developing liver problems while taking NEVIRAPINE VIATRIS.

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

- **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 taking oral contraceptives (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 NEVIRAPINE VIATRIS, tell your doctor immediately.**
- **If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking NEVIRAPINE VIATRIS.**

## **Things you should 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 your medicine or change the dosage without first checking with your doctor.**

## **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how NEVIRAPINE VIATRIS affects you.**

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

## **Looking after your medicine**

**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 below 25°C.**

Store it 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.**

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

## **Getting rid of any unwanted medicine**

**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.**

## **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 NEVIRAPINE VIATRIS.**

This medicine helps most people with HIV-1, but it may have unwanted side effects in some people.

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

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 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.

**Do not be alarmed by the following list of side effects.**

You may not experience any of them.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### **Less serious side effects**

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"><li>● fever</li><li>● nausea</li><li>● headache</li><li>● fatigue</li><li>● sleepiness or drowsiness</li><li>● abnormal liver function tests</li><li>● vomiting</li><li>● diarrhoea</li></ul>	<b>Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.</b>

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● stomach pain</li> <li>● myalgia (aching muscles, muscle tenderness or weakness, not caused by exercise)</li> <li>● joint pain.</li> </ul> <p>Combination antiretroviral therapy may cause changes in body shape, due to changes in fat distribution, in some patients. These may include:</p> <ul style="list-style-type: none"> <li>● loss of fat from legs, arms and face</li> <li>● increased fat in the abdomen and other internal organs</li> <li>● breast enlargement</li> <li>● fatty lumps on the back of the neck.</li> </ul> <p>The above list includes the more common side effects of your medicine.</p>	

## Serious side effects

Serious side effects	What to do
<p><b>Skin reactions:</b></p> <ul style="list-style-type: none"><li>● 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.</li></ul> <p><b>Hypersensitivity (allergic) reactions:</b></p> <ul style="list-style-type: none"><li>● 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</li><li>● Rash accompanied by other side effects such as fever, blisters, mouth</li></ul>	<p><b>Tell your doctor as soon as possible, go straight to the Emergency Department at your nearest hospital if you notice any of these side effects.</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<p>sores, conjunctivitis, facial swelling, muscle or joint aches, swollen lymph glands, or tiredness.</p> <p><b>Symptoms of a liver problem, such as:</b></p> <ul style="list-style-type: none"> <li>● Loss of appetite</li> <li>● Nausea, vomiting</li> <li>● Jaundice (yellowing of the skin and/or eyes)</li> <li>● Dark coloured urine</li> <li>● Pale coloured stools</li> <li>● Pain/ache or sensitivity to touch in your right abdominal area (below your ribs).</li> </ul> <p>The above list includes serious side effects that may require medical attention.</p>	

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

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](http://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 NEVIRAPINE VIATRIS contains

<b>Active ingredient (main ingredient)</b>	nevirapine
<b>Other ingredients (inactive ingredients)</b>	lactose monohydrate microcrystalline cellulose povidone sodium starch glycollate A colloidal anhydrous silica

	magnesium stearate
<b>Potential allergens</b>	sugars as lactose.

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

## **What NEVIRAPINE VIATRIS looks like**

NEVIRAPINE VIATRIS 200 mg tablets are white to off white, oval shaped, biconvex uncoated tablets, debossed with "NE" scoreline "200" on one side and "M" scoreline on the other side. (AUST R 167307).

NEVIRAPINE VIATRIS is available in bottles of 60 tablets.

## **Who distributes NEVIRAPINE VIATRIS**

### **Alphapharm Pty Ltd trading as Viatris**

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

[www.viatris.com.au](http://www.viatris.com.au)

Phone: 1800 274 276

This leaflet was prepared in July 2023.

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