

## NEVIRAPINE ALPHAPHARM

*Nevirapine Tablets 200 mg*



### What is in this leaflet

This leaflet answers some common questions about NEVIRAPINE ALPHAPHARM.

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 ALPHAPHARM 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 ALPHAPHARM is used for

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

NEVIRAPINE ALPHAPHARM 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 ALPHAPHARM 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 ALPHAPHARM 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 ALPHAPHARM

**When you must not take it:**

**Do not take NEVIRAPINE ALPHAPHARM 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.

**NEVIRAPINE ALPHAPHARM 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 ALPHAPHARM because:**

- NEVIRAPINE ALPHAPHARM 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 NEVIRAPINE ALPHAPHARM if you have:**

- severe liver problems
- hepatitis B or C infection
- previously experienced serious liver or skin

reactions while taking nevirapine.

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

St John's Wort may reduce the effect of NEVIRAPINE ALPHAPHARM.

**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
- undergoing dialysis treatment

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

**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 ALPHAPHARM may interfere with each other. These include:

- other anti-HIV medicines
- some antiviral medicines for Hepatitis B and C
- 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
- herbal remedies containing St John's Wort (hypericum perforatum)
- warfarin and medicines used to thin the blood
- medicines used for immune disorders or to prevent rejection of transplanted organs (immunosuppressants).

These medicines may be affected by NEVIRAPINE ALPHAPHARM 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 ALPHAPHARM may reduce the effectiveness of oral contraceptives, so talk to your doctor about methods of contraception.

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

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## How to take NEVIRAPINE ALPHAPHARM

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**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

For adults aged 16 years and older, the usual dose is one NEVIRAPINE ALPHAPHARM 200 mg tablet daily for the first 14 days, followed by one

NEVIRAPINE ALPHAPHARM 200 mg tablet twice daily.

NEVIRAPINE ALPHAPHARM 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 ALPHAPHARM 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 ALPHAPHARM 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.**

Because this medicine helps to control your condition, but does not cure it, take NEVIRAPINE ALPHAPHARM every day, as prescribed by your doctor.

### 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 ALPHAPHARM for more than 7 days, contact your doctor before you start taking it**

**again.**

You may need to restart using the 14 day 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 (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 ALPHAPHARM. 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, red-purple swellings or rash on the skin, fatigue, fever, headache, difficulty sleeping, lung problems, dizziness, nausea, vomiting and spinning sensation.

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## **While you are using NEVIRAPINE ALPHAPHARM**

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### ***Things you must do***

**Contact your doctor if you notice a rash on any part of the body. Side effects are listed in the next section of this leaflet.**

If a rash occurs during the 14 day "lead-in" period, your doctor may tell you not to increase your NEVIRAPINE ALPHAPHARM dose until the rash resolves.

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

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

**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.

**Liver function tests should be performed at regular intervals, especially during the first 18 weeks of treatment with NEVIRAPINE ALPHAPHARM.** If the results are abnormal, your doctor may consider performing more frequent tests, or in more severe cases, stopping treatment with NEVIRAPINE ALPHAPHARM altogether. Women and patients with higher CD4 counts seem to be at increased risk for developing liver problems while taking NEVIRAPINE ALPHAPHARM.

### ***Things you must not do***

**Do not take NEVIRAPINE ALPHAPHARM 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 checking with your doctor.**

### ***Things to be careful of***

**Be careful driving or operating machinery until you know how NEVIRAPINE ALPHAPHARM 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.

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## **Side effects**

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking NEVIRAPINE ALPHAPHARM.**

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

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.

**Do not be alarmed by the following lists of side effects. You may not experience any of them.**

**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:**

- nausea
- vomiting
- fatigue
- headache
- diarrhoea
- stomach or abdominal pain

- muscle or joint pain not caused by exercise.

The above list includes the more common 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 ALPHAPHARM 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, seek immediate advice from a doctor and tell him or her that you are taking this medicine. Your doctor will monitor these closely and may require stopping treatment with NEVIRAPINE ALPHAPHARM.**

**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.

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## After using NEVIRAPINE ALPHAPHARM

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## 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 below 25°C.

Heat and damp conditions can destroy some medicines. Do not store NEVIRAPINE ALPHAPHARM 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.

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## Product description

### What it looks like

NEVIRAPINE ALPHAPHARM 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 ALPHAPHARM tablets are supplied in bottles containing 60 tablets.

### Ingredients

NEVIRAPINE ALPHAPHARM contains 200 mg of nevirapine as the active ingredient.

It also contains:

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

This medicine does not contain gluten.

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## **If you want to know more**

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

### ***Who supplies this medicine***

Distributed in New Zealand by:

Mylan New Zealand Ltd,  
PO Box 11183,  
Ellerslie,  
Auckland.

Telephone: (09) 579 2792

### ***Date of Information***

27 July 2017 (Based on datasheet dated 27 July 2017).