

Nevirapine XR APOTEX

Contains the active ingredient Nevirapine anhydrous

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about nevirapine. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

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

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is Nevirapine XR APOTEX modified release tablets. It contains the active ingredient nevirapine anhydrous.

It is used to treat infection by the Human Immunodeficiency Virus (HIV-1). HIV-1 is the main virus responsible for the development of Acquired Immunodeficiency Syndrome (AIDS).

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

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

How it works

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.

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

Nevirapine is prescribed in combination with other antiretroviral medicines which hinder the growth of HIV-1 in other ways. When these medicines are taken with nevirapine

the growth of HIV-1 is hindered more effectively.

Nevirapine 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 does NOT reduce or prevent transmission of HIV-1 to others through sexual contact or blood contamination.

Use in children

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.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- **You have or have had any of the following:**
 - severe liver dysfunction
 - previously experienced serious liver or skin reactions while on nevirapine treatment.
- **You are hypersensitive to, or have had an allergic reaction to, nevirapine or any of the ingredients listed at the end of**

this leaflet.

Symptoms of an allergic reaction may include: shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin;

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

- **The expiry date (EXP) printed on the pack has passed.**
- The packaging is torn, shows signs of tampering or it does not look quite right.

Before you start to take it

It is essential that your doctor knows your medical history before prescribing Nevirapine XR APOTEX.

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - liver problem/disease or hepatitis
 - severe kidney disease undergoing dialysis treatment.
3. You are currently pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.
4. You are currently breastfeeding or you plan to breastfeed. Do not take this medicine whilst breastfeeding because:
 - nevirapine 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.

5. You are planning to have surgery.
6. You are currently receiving or are planning to receive dental treatment.
7. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

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

Taking other medicines

Some medicines may interact with nevirapine. Therefore, tell your doctor if you are taking any of the following:

- other anti-HIV medicines
 - anti-Hepatitis B and C medicines
 - cimetidine
 - clarithromycin
 - fluconazole, itraconazole, ketoconazole
 - methadone
 - corticosteroids (e.g. prednisone)
 - oral contraceptives
- As nevirapine may reduce the effectiveness of oral contraceptives, talk to your doctor about alternative methods of contraception.**
- 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 nevirapine, 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.

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with nevirapine.

How to take this medicine

Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

How much to take

Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

Follow the dosing instructions carefully, especially the once daily dosage during the first 14 days ('lead-in' period) using nevirapine immediate release tablets or oral solution (available from alternative brands).

Adults 16 years and older:

First 14 days: 200 mg immediate-release nevirapine taken once daily (an alternative brand is required for the first 14 days).

After the first 14 days: one Nevirapine XR APOTEX 400 mg modified release tablet once daily (taken at about the same time each day).

Children (aged 3 years or older) and adolescents to 15 years:

Nevirapine modified release tablets

can be taken by children aged 3 years or older able to tolerate tablets. Your child's doctor will decide the most appropriate nevirapine formulation for your child and will calculate the dose they need. The calculation will include your child's age and body weight, or body surface area.

Ask your doctor 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 immediate-release tablets or oral suspension to modified-release tablets:

If you are already taking 200 mg immediate-release tablets or oral suspension twice daily in combination with other antiretroviral agents you can switch to Nevirapine XR APOTEX 400 mg modified-release tablets once daily without the 14 day 'lead-in' period.

Take your immediate-release tablets or oral suspension as normal the day before you switch. Then take your Nevirapine XR APOTEX 400 mg modified-release tablet the next morning and do not take any more of the immediate-release tablets or oral suspension.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

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 this medicine at the same time each day. Taking it at the same time each day will have the best effect and will also help you remember when to take it.

It does not matter if you take it before, with or after food.

How long to take it for

Continue taking your medicine for as long as your doctor tells you.

Make sure you have enough of this medicine to last over weekends and holidays.

If you forget to take it

If it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time. 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 missed doses.

This may increase the chance of you experiencing side effects.

If you have missed taking Nevirapine XR APOTEX 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 to help you remember.

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident and Emergency department at your nearest hospital.

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 this medicine

Things you must do

Tell your doctor that you are taking this medicine 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.

- 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 XR APOTEX.

Liver function tests should be performed at regular intervals, especially during the first 18 weeks of treatment with Nevirapine XR APOTEX. 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 XR APOTEX altogether (in more severe cases).

In rare instances, temporary weakness or pain of muscles has been seen in Nevirapine XR

APOTEX patients experiencing skin and/or liver problems.

- if you experience any symptoms of an overactive thyroid gland, such as rapid heart rate, tremors and increased sweating.
- you are about to be started on any new medicine
- you are pregnant, become pregnant, or are planning to become pregnant while taking Nevirapine XR APOTEX
- you are breastfeeding or are planning to breastfeed
- you are about to have any blood tests
- you are going to have surgery or are going into hospital.
- are taking oral contraceptives (to prevent pregnancy) you should use additional or different type of contraception.

Nevirapine XR Apotex may reduce the effectiveness of oral contraceptives.

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

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects. Go to your doctor regularly for a check-up.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours.

- Take your medicine to treat any other condition unless your doctor tells you to.
- Stop taking your medicine, or change the dosage, without first checking with your doctor.

Things to be careful of

Be careful when driving or operating machinery until you know how this medicine affects you.

Nevirapine may cause sleepiness or drowsiness in some people. Make sure you know how you react to Nevirapine before you drive or operate machinery.

Possible side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking nevirapine or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. It may be difficult to tell whether side effects are the result of taking Nevirapine XR APOTEX, 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 XR APOTEX. All medicines can have side effects. Sometimes they are serious but most of the time they are not. You may need medical treatment if you get some of the side effects.

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 nevirapine 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 nevirapine. 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.

Tell your doctor if you notice any of the following most frequently reported side effects:

- fever
- nausea
- headache
- fatigue
- somnolence
- vomiting
- diarrhoea
- abdominal pain
- aching muscles, muscle tenderness or weakness, not caused by exercise.
- abnormal liver function tests

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

These may be serious side effects and you may need medical attention:

- 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).

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

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 nevirapine, so that these may be properly treated.

If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

These are very serious side effects and you may need urgent medical attention or hospitalisation:

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

- anaphylaxis (sudden life-threatening allergic reaction)
- rash accompanied by other side effects such as fever, blisters, mouth sores, conjunctivitis, facial swelling, muscle or joint aches, swollen lymph glands, or tiredness.

Other side effects not listed above may occur in some patients. You should tell your doctor or pharmacist if you notice anything unusual, during or after taking Nevirapine XR APOTEX.

Allergic reactions

If you think you are having an allergic reaction to nevirapine, do

not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin
- fainting
- hay fever-like symptoms.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 30°C.

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

Keep this medicine 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 it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What Nevirapine XR APOTEX modified release tablets looks like

400 mg modified release tablets

Yellow coloured, oval-shaped, biconvex tablets engraved with "APO" on one side and "NV400" on the other side.

Available in Blister Pack of 30

* Not all strengths, pack types and/or pack sizes may be available.

Ingredients

Each modified release tablet contains 400 mg of nevirapine anhydrous as the active ingredient.

It also contains the following inactive ingredients:

- Methylcellulose
- Hypromellose
- Iron Oxide Yellow
- Magnesium Stearate Vegetable Source

This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

Nevirapine XR APOTEX modified release tablets (Blister pack): AUST R 272979.

Sponsor

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