

NEVIRAPINE RBX

Nevirapine Tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about NEVIRAPINE RBX. It does not contain all the available information. It does not take the place of talking to 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 <https://www.ebs.tga.gov.au/> and may contain important information about the medicine and its use of which you should be aware.

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

Ask your doctor or pharmacist if you have any questions about your medicine or if you have any trouble before, during or after using NEVIRAPINE RBX.

Keep this leaflet with your NEVIRAPINE RBX.

You may need to read it again later.

What NEVIRAPINE RBX is used for

NEVIRAPINE RBX 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 RBX 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.

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

NEVIRAPINE RBX 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 RBX, the growth of HIV-1 is hindered more effectively.

NEVIRAPINE RBX has not been shown to reduce the incidence or frequency of the illnesses caused by AIDS. It is important for you to continue seeing your doctor regularly.

NEVIRAPINE RBX 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.

NEVIRAPINE RBX is not addictive. It is available only with a doctor's prescription.

Before you take NEVIRAPINE RBX

When you must not take it

Do not take NEVIRAPINE RBX tablets if you are allergic to nevirapine or any of the other ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty in breathing, swelling of the face, lips, tongue or other parts of the body, rash, itching or hives on the skin.

NEVIRAPINE RBX contains lactose. If you have an intolerance to some sugars, contact your doctor before taking this medicine.

If you are not sure if you have these allergies, you should raise those concerns with your doctor.

Do not take NEVIRAPINE RBX if you have:

- severe liver dysfunction
- previously experienced serious liver or skin reactions while on nevirapine treatment.

If you are not sure whether you should start taking NEVIRAPINE RBX, talk to your doctor.

Do not take NEVIRAPINE RBX after the expiry date 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.

Before you start to take NEVIRAPINE RBX

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

Before taking NEVIRAPINE RBX, you must tell your doctor if you have, or have had, any of the following conditions:

- liver problem/disease or hepatitis
- 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.

Taking other medicines

Before using NEVIRAPINE RBX, it is important to tell your doctor 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, you should tell your doctor if you are taking:

- herbal medicines derived from St John's Wort (*Hypericum perforatum*)
- other anti-HIV medicines
- cimetidine
- clarithromycin
- fluconazole, itraconazole, ketoconazole
- methadone
- oral contraceptives
- corticosteroids (e.g. prednisone)
- rifampicin, rifabutin
- 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 heart beats (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 or pharmacist will advise you.

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

Pregnancy

Ask for your doctor's advice if you are pregnant, or likely to become pregnant during your course of medication.

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

Breastfeeding

You should ask for your doctor's advice if you wish to breastfeed during your use of NEVIRAPINE RBX.

Breastfeeding is not recommended during your use of NEVIRAPINE RBX 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.

Children

NEVIRAPINE RBX can be given to children aged 16 years or older.

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

How to take NEVIRAPINE RBX

Always take NEVIRAPINE RBX exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

How much to take

Follow the dosing instructions carefully, especially the once daily dosage during the first 14 days ('lead-in' period).

- **First 14 days:** one NEVIRAPINE RBX tablet once daily.
- **After the first 14 days:** one NEVIRAPINE RBX tablet twice daily (i.e. at regular 12-hour intervals at about the same time each day: morning and night).

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.

How to take it

NEVIRAPINE RBX tablets should be swallowed whole (not chewed) with water. The tablets can be taken with or without food.

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 a dose

It is important to take NEVIRAPINE RBX 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 NEVIRAPINE RBX 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 have taken too much (overdose)

Immediately telephone your doctor, pharmacist or Poisons Information Centre (in Australia telephone 13 11 26; in New Zealand telephone 0800 764 766) for advice, or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much NEVIRAPINE RBX. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

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) may occur.

While you are taking NEVIRAPINE RBX

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 nevirapine.

Liver function tests should be performed at regular intervals, especially during the first 18 weeks of treatment with nevirapine. 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 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 RBX. In rare instances, temporary weakness or pain of muscles has been seen in nevirapine 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 NEVIRAPINE RBX.

If you are taking oral contraceptives (to prevent pregnancy) you should use additional or different type of contraception.

NEVIRAPINE RBX may reduce effectiveness of oral contraceptives.

If you become pregnant while taking NEVIRAPINE RBX 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 RBX, 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.

Things you must not do

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

Do not stop taking NEVIRAPINE RBX or change the dose without first checking with your doctor.

Nevirapine helps control your HIV infection but does not cure it. Therefore, NEVIRAPINE RBX 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 RBX affects you. NEVIRAPINE RBX may cause sleepiness or drowsiness in some people.

Side effects

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

It may be difficult to tell whether side effects are the result of taking NEVIRAPINE RBX, 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 for any change in your condition. Your doctor may need to change your dose or advise you to stop taking NEVIRAPINE RBX.

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 NEVIRAPINE RBX.

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 RBX 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 RBX. 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, tiredness or kidney problems.

Contact your doctor immediately if you experience rash and/or any signs of hypersensitivity reactions.

The other most frequently reported side effects of NEVIRAPINE RBX 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), frequent infections such as fever, severe chills, sore throat or mouth ulcers due to lack of white blood cells, and increase in some white blood cells.

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 nevirapine.

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 NEVIRAPINE RBX, 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 NEVIRAPINE RBX.

After taking NEVIRAPINE RBX

Storage

Keep NEVIRAPINE RBX in the pack/bottle until it is time to take them. If you take the tablets out of the bottle/pack they may not keep well.

Keep NEVIRAPINE RBX in a cool dry place where the temperature stays below 25°C.

Do not store NEVIRAPINE RBX in the bathroom or near a sink.

Do not store in direct sunlight or heat.

For example, do not leave it in the car on hot days. Heat and dampness can destroy some medicines.

Keep NEVIRAPINE RBX 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

Any unused medicine should be returned to your pharmacist so that it can be disposed of safely.

Product description

What NEVIRAPINE RBX looks like

The tablets are white to off-white, oval-shaped, uncoated tablets with a break line on both sides. One side is marked with 'RX921'.

The tablets are supplied in plastic bottles containing 60 tablets.

Ingredients

Each NEVIRAPINE RBX tablet contains 200 mg of nevirapine as the active ingredient.

It also contains:

- lactose

- microcrystalline cellulose
- povidone
- sodium starch glycollate type A
- colloidal anhydrous silica
- magnesium stearate

NEVIRAPINE RBX tablets do not contain gluten, sucrose, glucose or colouring agents.

Sponsor

Ranbaxy Australia Pty Ltd

9-13 Waterloo Road
Macquarie Park NSW 2113
Australia

NEVIRAPINE RBX is supplied in New Zealand by:

Douglas Pharmaceuticals Ltd
Central Park Drive, Lincoln
Auckland 0610
New Zealand

Australian Register Numbers

AUST R 195526 (bottle)

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