

NEVIRAPINE TABLET 200MG

Nevirapine (200mg)

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What Nevirapine Tablet 200mg is used for

Nevirapine tablets belong to a group of medicines called antiretrovirals, used in the treatment of Human Immunodeficiency Virus (HIV-1) infection.

Nevirapine tablets are indicated for the treatment of HIV-1 infected adults, adolescents, and children. You must take Nevirapine tablets together with other antiretroviral medicines. Your doctor will recommend the best medicines for you.

How Nevirapine Tablet 200mg works

The active substance of your medicine is called nevirapine. Nevirapine reduces the amount of viruses in the blood thus improving your medical condition.

Nevirapine belongs to a class of anti-HIV medicines called non-nucleoside reverse transcriptase inhibitors (NNRTIs). Reverse transcriptase is an enzyme that HIV needs in order to multiply. Nevirapine stops reverse transcriptase from working. By stopping reverse transcriptase from working, Nevirapine tablets helps control HIV-1 infection.

Before you use Nevirapine Tablet 200mg

-When you must not use it

Do not take Nevirapine Tablet if:

- if you are allergic to nevirapine or any of the other ingredients of this medicine

-Before you start to use it

During the first 18 weeks of treatment with Nevirapine tablets it is very important that you and your doctor watch out for signs of liver or skin reactions. These can become severe and even life threatening. You are at greatest risk of such a reaction during the first 6 weeks of treatment.

YOU SHOULD DISCONTINUE TAKING NEVIRAPINE TABLETS AND YOU MUST CONTACT your doctor IMMEDIATELY as such reactions can be potentially life-threatening or lead to death. If you ever have only mild rash symptoms without any other reaction please inform your doctor immediately, who will advise you whether you should stop taking Nevirapine tablets.

Talk to your doctor or pharmacist before taking Nevirapine Tablets, especially:

- If you have taken Nevirapine tablets before and had to stop the treatment because you suffered from:

- *severe skin rash
- *skin rash with other symptoms for example; fever, blistering, mouth sores, inflammation of the eye, swelling of the face, general swelling, shortness of breath, muscle or joint pain, general feelings of illness, abdominal pain
- *hypersensitivity (allergic) reactions
- *inflammation of the liver (hepatitis)
- *if you have severe liver disease

-if you have had to stop Nevirapine tablets treatment in the past because of changes in your liver function

- if you are taking a medicine containing the herbal substance St. John's Wort (*Hypericum perforatum*). This herbal substance may stop Nevirapine tablets from working properly.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

You should stop breast-feeding if you are taking Nevirapine tablets. It is in general recommended that you do not breast-feed if you have HIV infection because it is possible that your baby can become infected with HIV through your breast milk.

Driving and using machines

You may experience fatigue when taking Nevirapine tablets. Use caution when engaging in activities such as driving, using any tools or machines. If you experience fatigue you should avoid potentially hazardous tasks such as driving or using any tools or machines.

Nevirapine tablets contains lactose

Nevirapine tablets contain lactose (milk sugar).

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Nevirapine tablets.

-Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Inform your doctor about all other medicines you are taking before you start taking Nevirapine tablets. Your doctor might need to monitor whether your other medicines

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are still working and adjust doses.

It is particularly important that you tell your doctor if you are taking or have recently taken:

-St. John's Wort (Hypericum perforatum, medicine to treat depression)

-rifampicin (medicine to treat tuberculosis)

-ketoconazole (medicine to treat fungal infections)

-hormonal contraceptives (e.g. the "pill")

-atazanavir (another medicine to treat HIV-infection)

-fosamprenavir (another medicine to treat HIV-infection)

-efavirenz (another medicine to treat HIV-infection)

Your doctor will carefully monitor the effect of Nevirapine tablets and any of these medicines if you are taking them together.

If you are undergoing kidney dialysis, your doctor may consider a dose adjustment of Nevirapine tablets. This is because Nevirapine tablets can be partly washed out of your blood by dialysis.

How to take Nevirapine Tablet 200mg

-How much to take

You should not use Nevirapine tablets on its own. You must take it with at least two other antiretroviral medicines. Your doctor will recommend the best medicines for you.

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

Dose:

The dose for adult is one 200 mg tablet per day for the first 14 days of treatment ("lead-in" period). After 14 days, the usual dose is one 200 mg tablet twice a day.

The dose for adolescent and children is based on the patient's body weight. Your doctor will

decide the correct dose for you or your child.

-When to take it

As Nevirapine tablets must always be taken together with other HIV antiretroviral medicines, you should follow the instructions for your other medicines carefully.

Only take Nevirapine tablets by mouth. Do not chew your tablets. You may take Nevirapine tablets with or without food.

-How long to take it

You should continue to take Nevirapine tablets for as long as instructed by your doctor.

-If you forget to take it

Try not to miss a dose. If you are not sure what to do, please consult your doctor or pharmacist. Do not take a double dose to replace the missed dose.

-If you take too much (overdose)

Do not take more Nevirapine tablets than prescribed by your doctor and described in this leaflet. There is at present little information on the effects of Nevirapine tablets overdose.

Consult your doctor if you have taken more Nevirapine tablets than you should.

While you are taking Nevirapine Tablet 200mg

-Things you must do

It is very important that you take only one Nevirapine tablet a day for the first 14 days ("lead-in" period). If you have any rash during this period, do not increase the dose but consult your doctor.

If you experience symptoms suggesting damage of the liver, such as:

- loss of appetite,
- feeling sick (nausea),
- vomiting,
- yellow skin (jaundice),
- abdominal pain

you should discontinue taking Nevirapine tablets and must

contact your doctor immediately.

If you develop severe liver, skin or hypersensitivity reactions whilst taking Nevirapine tablets, NEVER TAKE NEVIRAPINE TABLETS again and visit your doctor immediately.

-Things you must not do

Do not change the dose on your own. Continue to take this medicine until your doctor tells you otherwise.

-Things to be careful of

In some patients with advanced HIV infection (AIDS) and a history of opportunistic infection (AIDS defining illness), signs and symptoms of inflammation from previous infections may occur soon after anti-HIV treatment is started.

If you notice any symptoms of infection, please inform your doctor immediately.

Changes of body fat may occur in patients receiving combination antiretroviral therapy. Contact your doctor if you notice changes in body fat.

Side Effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The most important side effects of Nevirapine tablets are severe and life threatening skin reactions and serious liver damage.

These reactions occur mainly in the first 18 weeks of treatment with Nevirapine tablets. This is therefore an important period which requires close monitoring by your doctor.

The side effects described below have been experienced by patients given Nevirapine tablets:

- rash
- decreased numbers of white blood cells (granulocytopenia)
- allergic reactions (hypersensitivity)
- headache

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- feeling sick (nausea)
- vomiting
- abdominal pain
- loose stools (diarrhoea)
- inflammation of the liver (hepatitis)
- feeling tired (fatigue)
- fever
- abnormal liver function tests

This is not a complete list of possible side effects. If you encounter any other side effects, please contact your doctor or pharmacist at the soonest.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting).

Storage and Disposal of Nevirapine Tablet 200mg

-Storage

Store below 25°C. Protect from light.

-Disposal

Do not use after the expiry date stated on the label.

Return any unused tablets to your pharmacist to be disposed of. Only keep the tablets if your doctor tells you to. Do not throw them away in your normal household drainage or waste. This will help to protect the environment.

Product Description

-What it looks like

Nevirapine Tablet 200mg are white to off white oval shaped tablets with bisect on both sides.

-Ingredients

Active ingredient
Each tablet contains Nevirapine 200mg.

Inactive ingredients

Microcrystalline cellulose,
Lactose monohydrate,
croscarmellose sodium, talc,
povidone (K-30), Colloidal
silicon dioxide, Magnesium
Stearate and Purified Water.

-MAL Number

MAL11030013AZ

Manufacturer

Strides Arcolab Limited
36/7, Suragajakkanahalli,
Indlavadi Cross, Anekal Taluk,
Bangalore-562 106, INDIA.

Product Registration Holder

Actavis Sdn Bhd
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