

NEVIREX 200(NEVIRAPINE TABLETS USP 200MG)

/NEVIREX (NEVIRAPINE ORAL SUSPENSION)

Nevirapine (200mg, 50mg/5ml)

What is in this leaflet

1. What Nevirapine is used for
2. How Nevirapine works
3. Before you use Nevirapine
4. How to use Nevirapine
5. While you are using it
6. Side effects
7. Storage and Disposal of Nevirapine
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What Nevirapine is used for?

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

How Nevirapine works

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

The active substance of your medicine is called nevirapine. 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 helps control HIV-1 infection.

Before you use Nevirapine

- When you must not use it

Do not take Nevirapine if you:

- are allergic to nevirapine or any of the other ingredients of this product.
- have taken Nevirapine 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)

- have severe liver disease
- have had to stop Nevirapine treatment in the past because of changes in your liver function
- are taking a medicine containing the herbal substance St. John's Wort (*Hypericum perforator*). This herbal substance may stop Nevirapine from working properly

Pregnancy and lactation

Do not take Nevirapine if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take Nevirapine if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine

- Before you start use it.

Talk to your doctor or pharmacist before taking Nevirapine. During the first 18 weeks of treatment with Nevirapine 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.

If you experience severe rash or hypersensitivity (allergic reactions that may appear in the form of rash) accompanied by other side effects such as

- 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

You should discontinue taking Nevirapine 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.

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 and must contact your doctor immediately. If you develop severe liver, skin or hypersensitivity reactions whilst taking Nevirapine, never take Nevirapine again without referring to your doctor. You must take the dose of Nevirapine as prescribed by your doctor. This is especially important within the first 14 days of treatment.

- 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. Your doctor might need to monitor whether your other medicines are still working and adjust doses. Carefully read the package leaflet of all other HIV medicinal products you are taking in combination with Nevirapine.

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)
- rifabutin (medicine to treat tuberculosis)
- macrolides e.g., clarithromycin (medicine to treat bacterial infections)
- ketoconazole (medicine to treat fungal infections)
- hormonal contraceptives (e.g., the "pill")

Your doctor will carefully monitor the effect of Nevirapine 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. This is because Nevirapine can be partly washed out of your blood by dialysis

NEVIREX 200(NEVIRAPINE TABLETS USP 200MG)

/NEVIREX (NEVIRAPINE ORAL SUSPENSION)

Nevirapine (200mg, 50mg/5ml)

How to use Nevirapine

- How much to use

For adults

The dose for adults is 20 ml (200 mg) once a day for the first 14 days of treatment ("lead in" period). After 14 days, the usual dose is 20 ml (200 mg) twice a day.

Nevirapine is also available as 200 mg tablets for adults (16 years of age and older).

For children

The dose for children is 4 mg/kg body weight or 150 mg/m² body surface area once a day for the first 14 days of treatment ("lead-in period"). Thereafter your child will be switched to a twice daily dosing schedule and your child's doctor will decide the right dose based either on your child's weight or body surface area.

- It is very important that your child takes Nevirapine only once a day for the first 14 days ("lead-in" period). If your child develops any rash during this period, do not increase the dose but consult your child's doctor.

Nevirapine is also available as 200 mg tablets for older children, particularly adolescents, weighing more than 50 kg or having a body surface of more than 1.25m². Your child's doctor will inform you exactly of the correct dose for your child. Your child's doctor will continually check your child's weight or body surface area to ensure the correct dose. If you are uncertain, please be sure to ask your child's doctor or pharmacist.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking Nevirapine for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your

next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for a forgotten dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there is no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of overdosage include fatigue, fever, headache, difficulty sleeping, nausea, rash, vomiting, decrease in weight.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors and pharmacists treating you that you are taking Nevirapine.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Nevirapine to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

To be sold by Retail on the prescription of a Registered Medical Practitioner

Shake thoroughly before use (for oral suspension)

Side effects

Like all medicines, Nevirapine can cause side effects although not everybody gets them. Tell your doctor immediately if you experience any of the following symptoms after taking this medicine as the symptoms can be severe.

- Hypersensitivity (allergic) reactions can occur. Such reactions may appear in the form of rash accompanied with fever, blistering, mouth sores, eye

inflammation, facial swelling, general swelling and blistering skin reaction,

- muscle or joint aches, a reduction in white blood cells, reduction in red blood cells
- fever, nausea, headache, sleepiness, vomiting, diarrhoea, stomach pain, muscle pain and allergic reaction.

Tell your doctor immediately if you experience rash and any of the other side effects of a hypersensitivity (allergic) reaction. Such reactions can be life-threatening. Abnormal liver functioning has been reported with the use of Nevirapine. This includes some cases of inflammation of the liver (hepatitis), which can be sudden and intense (fulminant hepatitis), and liver failure, which can be both fatal.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Nevirapine

- Storage

Store in a dry place at a temperature not exceeding 30°C

Store in the original package

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

NEVIREX 200 (Nevirapine Tablets USP 200 mg):

White to off-white, oval shaped, biconvex tablets, one side debossed with "C" and "35", with a single bisect separating "C" and "35". The other side has a single bisect.

NEVIREX (Nevirapine oral suspension 50 mg/5ml):

White to off white homogenous suspension.

Ingredients

Nevirapine 200 mg:

NEVIREX 200 (NEVIRAPINE TABLETS USP 200MG) /NEVIREX (NEVIRAPINE ORAL SUSPENSION)

Nevirapine (200mg, 50mg/5ml)

Active ingredient

Nevirapine 200 mg

Inactive ingredients

Microcrystalline cellulose, lactose (as monohydrate), povidone K25, sodium starch glycolate, colloidal silicon dioxide and magnesium stearate.

NEVIREX (Nevirapine oral suspension 50 mg/5ml):

Active ingredient

Nevirapine USP as Nevirapine hemihydrate 50mg/5ml

Inactive ingredients

Methyl paraben, Propylparaben, Propylene glycol, non-Crystallizing sorbitol solution, polysorbate 80, sucrose NF, Carbomer (Carbopol 974P NF), Purified Water, Sodium Hydroxide.

- MAL number(s):

NEVIREX 200 (Nevirapine Tablets USP 200 mg):

MAL08042461AZ

NEVIREX (Nevirapine oral suspension 50mg/5ml):

MAL08010705AZ

Manufacturer

**AUROBINDO PHARMA LIMITED
(UNIT III)**

Sy.No.313 & 314, Bachupally,
Bachupally Mandal, Medchal-Malkajgiri
Dist, Telangana State, India.

Product Registration Holder

UNIMED SDN BHD
53, Jalan Tembaga SD 5/2B,
Bandar Sri Damansara,
52200, Kuala Lumpur, Malaysia.

Date of revision

21/10/2024

Serial number:

NPRA(R4/1)100418/00104