Patient Information

Nevirapine Tablets USP 200 mg

Rx Only

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet since you may need to read it again
- If you have further questions, please ask your doctor
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

In this leaflet:

Nevirapine Tablets USP 200 mg

Nevirapine tablets each contain 200 mg of active pharmaceutical ingredient nevirapine, used in the treatment of HIV infection.

The other ingredients are lactose monohydrate, microcrystalline cellulose, sodium starch glycolate, povidone, colloidal silicon dioxide, magnesium stearate.

Nevirapine tablets are white to off-white, oval shaped, biconvex tablets, one side debossed with “C” and “35” with a single bisect separating the “C” and “35”. The other side has a single bisect.

The Marketing Authorisation Holder for Nevirapine tablets is:

M/s Aurobindo Pharma Ltd

Plot No.: 2, Maitrivihar

Ameerpet, Hyderabad-500 038

India.

Nevirapine tablets are manufactured by:

M/s Aurobindo Pharma Limited,

Unit III, Survey No. 313 & 314,

Bachupally, Bachupally Mandal,

Medchal-Malkajgiri District,

Telangana State, India

ZIP Code – 500 090

1. What are Nevirapine tablets and what are they used for ?

Nevirapine tablets belong to a group of medicines called antiretroviral. They are used in combination with other antiretroviral agents to delay the progression of Human Immunodeficiency Virus (HIV) in both adults and children with HIV infection and those who have gone on to develop the symptoms of AIDS.

It is important to realise that nevirapine tablets are not a cure for HIV infection and that you may continue to develop infections or other illnesses associated with HIV infection. It is also important to realise that nevirapine tablets have not been shown to reduce the risk of transmission of HIV to others through sexual contact or blood contamination.

2. Questions you should ask yourself before taking Nevirapine tablets

- Are you hypersensitive (allergic) to nevirapine or any of the other ingredients of nevirapine tablets.
- Have you previously experienced hepatitis, severe skin rash, or liver injury while on nevirapine tablets treatment.
- Are you currently taking rifampicin (used to treat tuberculosis)
- Are you taking products containing Hypericum perforatum (St. John's Wort) as this may stop nevirapine tablets from working properly.

If the answer is "YES" to any of these questions, and if you have not already discussed them with your doctor, go back to him BEFORE starting treatment.

Take special care with NEVIRAPINE Tablets:

The first 8 weeks of treatment with NEVIRAPINE are an important period which require a close surveillance to discover the occurrence of severe and life threatening cutaneous reactions and serious hepatic injuries. During this period the dosage of NEVIRAPINE prescribed by your doctor must be strictly adhered to, especially during the first 14 days of treatment, so called "lead-in"period (see more information in *How to take NEVIRAPINE tablets*).

Please be sure to inform your doctor if you are suffering from, or have ever suffered from, kidney or liver disease. Also, because nevirapine tablets have been shown to cause variations in liver

function, your doctor will monitor the function of your liver by blood tests before and during nevirapine tablets treatment, especially during the first weeks of treatment. If your doctor is worried about the effects of nevirapine tablets on your liver function he or she may decide to perform additional blood tests to monitor the functions of your liver and according to the results he or she may decide to discontinue your treatment. It is important to realise that nevirapine tablets can result in liver toxicity, which in the worst cases can be serious and life-threatening and which has resulted in fatalities. (See more information in "Possible side effects", below)

If you experience clinical symptoms suggesting an injury of the liver such as loss of appetite, Nausea, vomiting, jaundice you should promptly inform your doctor.

Because nevirapine tablets may interact with other medicinal products, please inform your doctor of any other medicinal products you are taking. If you normally take oral contraceptives then it will be necessary to change your form of contraception upon starting treatment with nevirapine tablets.

You should carefully read the package leaflet of the other HIV medicinal products which you will be taking in combination with nevirapine tablets.

It is important to realize that nevirapine tablets can result in skin reactions and hypersensitivity reactions, which in the worst cases can be serious and life-threatening and which have resulted in fatalities (see more detailed information in "Possible side effects", below).

Hypersensitivity (allergic) reactions can occur. Such reactions may appear in the form of rash accompanied by other side effects such as fever blistering mouth sores eye inflammation facial swelling general swelling, muscle or joint aches a reduction in white blood cells (granulocytopaenia) general feelings of illness or severe problems with liver or kidneys.

If you experience rash and any other side effects of a hypersensitivity reaction, YOU MUST CONTACT your doctor IMMEDIEATELY as such reactions can be potentially life – threatening.

If you ever have any rash symptoms please inform your doctor immediately who will advise you whether you should stop taking nevirapine tablets.

If you develop a severe rash whilst taking nevirapine tablets, NEVER TAKE nevirapine tablets again without referring to your doctor. `

The following events have also been reported when nevirapine tablets have been used in combination with other antiretroviral agents: a reduction in red blood cells or in platelets, changes in body shape due to changes in fat distribution, inflammation of pancreas and decrease in or abnormal skin sensations. These events are commonly associated with other antiretroviral agents and may be expected to occur when nevirapine tablets are used in combination with other agents; however, it is unlikely that these events are due to a treatment with nevirapine tablets. Nevirapine tablets are suitable for older children and adolescents under 16 years of age who weigh 50 kg or more.

Pregnancy

Ask your doctor or pharmacist for advice before taking any medicine.

Breast feeding

You should discontinue breast-feeding if you are taking nevirapine tablets. Some health experts anyway recommend that you discontinue breast-feeding if you have HIV infection in order to lower the chances of passing the infection on to your baby.

Driving and using machines:

There is evidence that nevirapine tablets can cause sleepiness. Therefore care should be taken if you are driving or operating machinery. If you do feel sleepy then you should stop driving or operating machinery.

Can I take other medication while I am taking nevirapine tablets?

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

You should inform your doctor of all other medicines you are taking before you start taking nevirapine tablets because he or she might need to monitor whether the other medicines are still having their desired effects and make necessary dose-adjustments.

The antibiotics rifabutin and rifampicin have been shown to reduce the blood concentration of nevirapine tablets whilst cimetidine and macrolides (e.g. clarithromycin) have been shown to increase concentrations. Your doctor will carefully monitor the effect of nevirapine tablets and any of these medicines if you are taking nevirapine tablets and any of these medicines together. See Section 2, before you take nevirapine tablets, for further information. Nevirapine tablets can affect oral contraceptives and therefore you should employ an alternative contraceptive method such as barrier contraception (e.g. condoms) if you are taking nevirapine tablets. Nevirapine tablets may

decrease blood concentrations of the HIV protease inhibitors, saquinavir, indinavir, ritonavir, or lopinavir. Your doctor will consider the necessity of appropriate dose adjustments with, indinavir or lopinavir but a dose adjustment is not necessary for combination of nevirapine tablets with ritonavir or with saquinavir soft gel capsules when used with a low dose of ritonavir (100 mg). Nevirapine tablets do not have any important interactions with nelfinavir and therefore no dosage adjustments are necessary for combination of nevirapine tablets with nelfinavir.

Nevirapine tablets do not have any interaction with the HIV nucleoside analogues zidovudine, didanosine, zalcitabine, stavudine or lamivudine and therefore no dose-adjustment of any of these medicinal products is necessary. If you are taking nevirapine tablets together with sustiva (efavirenz) it is possible that your doctor will consider a dose increase of sustiva (efavirenz). If you are undergoing dialysis, your doctor may consider a dose increase of nevirapine tablets. Nevirapine tablets may affect blood concentrations of methadone and therefore if you are undergoing methadone treatment it is possible that your doctor will consider methadone dosage adjustments. Ketoconazole and nevirapine tablets should not be taken at the same time.

3. How to take nevirapine tablets?

Nevirapine tablets should only be taken by mouth. The normal dosage is one 200 mg tablet for the first 14 days of treatment (this "lead in" period has been shown to lower the incidence of skin rash) followed by one 200 mg tablet twice daily. Nevirapinetablets will always be taken in combination with other HIV antiretrovirals, for which you should follow the instructions within the supplied package leaflet.

It is essential to follow strictly the once a day dosage during the 14 day "lead in" period before rising to the twice daily dosage.

You should continue to take nevirapine tablets for as long as instructed by your doctor. As explained in "*Take special care with nevirapine tablets*", above, your doctor will monitor you by liver tests or for undesirable effects such as rash. Depending on the outcome he or she may decide to interrupt or stop your nevirapine tablets treatment. He or she might then decide to restart you on a lower dose. If you stop taking nevirapine tablets for more than 7 days your doctor will instruct you to start the 14 day "lead-in" period (described above) once again before returning to the twice daily dose.

If you take more nevirapine tablets than you should:

Do not exceed the dose 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 take an overdose.

If you forget to take nevirapine tablets:

Try not to miss a dose. If you do miss a dose, take the next dose as soon as possible but do not try to double the next dose.

4. Possible side effects of nevirapine tablets

Like all medicines, nevirapine tablets can have side effects. The major side effects of nevirapine tablets are severe and life threatening cutaneous reactions and serious hepatic injuries. These reactions occur mainly in the first 8 weeks of treatment with nevirapine tablets. This is therefore an important period which requires a close surveillance. When rash does occur it is normally mild to moderate. However, in about 7% of patients a rash, which appears as a blistering skin reaction, can be severe or life-threatening and fatalities have been recorded. Most of the cases of both severe rash and mild/moderate rash occur in the first eight weeks of treatment. If you ever do observe any rash symptoms please inform your doctor immediately. If the symptoms are severe you must stop treatment and visit your doctor immediately.

Hypersensitivity (allergic) reactions can occur. Such reactions may appear in the form of rash accompanied by other side effects such as fever, blistering, mouth sores, eye inflammation, facial swelling, general swelling, muscle or joint aches, a reduction in white blood cells (granulocytopaenia), general feelings of illness or severe problems with liver or kidneys.

If you experience rash and any of the other side effects of a hypersensitivity reaction, please be sure to tell your doctor immediately as such reactions can be potentially life-threatening.

Abnormal liver functioning has been reported with the use of nevirapine tablets, including some cases of hepatitis, which have resulted in recorded fatalities.

If you experience clinical symptoms suggesting an injury of the liver, such as loss of appetite, nausea, vomiting, jaundice, you should inform your doctor.

Other side effects which can occur are fever, nausea, headache, sleepiness, vomiting, diarrhoea, stomach pain, muscle pain and allergic reactions. Many of these side effects can occur together with the rash side effect (hypersensitivity reaction). Joint pain has been reported as a stand-alone event in rare instances in patients receiving nevirapine containing regimens.

In addition, a reduction in white blood cells (granulocytopaenia) can occur, which is more common in children. In very rare instances a reduction in red blood cells or white blood cells (neutropenia) may be related to nevirapine therapy. As with rash symptoms, please inform your doctor of any side effects. If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. Storing nevirapine tablets

Keep out of the reach and sight of children.There are no special storage instructions.

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

6. Further information

If you notice any side effect (s) with the use of this drug, please report it immediately via internet to the following e-mail address:

pharmacovigilance@aurobindo.com

For any information about this medicinal product please contact the local representative of the Marketing Authorization Holder.