

Package leaflet: Information for the user

Nevirapine 200 mg Tablets

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

The name of this medicine is Nevirapine 200 mg Tablets. In the rest of this leaflet it will be called Nevirapine Tablets.

What is in this leaflet:

1. What Nevirapine Tablets are and what they are used for
2. What you need to know before you take Nevirapine Tablets
3. How to take Nevirapine Tablets
4. Possible side effects
5. How to store Nevirapine Tablets
6. Contents of the pack and other information

1. What Nevirapine Tablets are and what they are used for

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

The active ingredient of your medicine is called nevirapine. The active ingredient is the substance in this medicine that 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.

You must take Nevirapine Tablets together with other antiretroviral medicines. Your doctor will recommend the best medicines for you.

If Nevirapine Tablets have been prescribed for your child, please note that all information in this leaflet is addressed to your child (in this case please read “your child” instead of “you”).

2. What you need to know before you take Nevirapine Tablets

Do not take Nevirapine Tablets

- if you are allergic (hypersensitive) to nevirapine or any of the other ingredients of Nevirapine Tablets. (listed in section 6 “Contents of the pack and other information”).
- 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.

Warnings and precautions

Talk to your doctor or pharmacist before taking Nevirapine Tablets. 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.

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,
- or abdominal pain

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.

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 without referring to your doctor. You must take the dose of Nevirapine Tablets as prescribed by your doctor. This is especially important within the first 14 days of treatment (see more information in “How to take Nevirapine Tablets”).

The following patients are at increased risk of developing liver problems:

- women
- infected with hepatitis B or C
- abnormal liver function tests
- treatment-naïve patients with higher CD4 cell counts at the start of Nevirapine Tablets therapy (women more than 250 cells/mm³, men more than 400 cells/mm³)
- pre-treated patients with detectable HIV-1 plasma viral load and higher CD4 cells counts at the start of Nevirapine Tablets therapy (women more than 250 cells/mm³, men more than 400 cells/mm³)

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. It is believed that these symptoms are due to an improvement in the body's immune response, enabling the body to fight infections that may have been present with no obvious symptoms. If you notice any symptoms of infection, please inform your doctor immediately.

In addition to the opportunistic infections, autoimmune disorders (a condition that occurs when the immune system attacks healthy body tissue) may also occur after you start taking medicines for the treatment of your HIV infection. Autoimmune disorders may occur many months after the start of treatment. If you notice any symptoms of infection or other symptoms such as muscle weakness, weakness beginning in the hands and feet and moving up towards the trunk of the body, palpitations, tremor or hyperactivity, please inform your doctor immediately to seek necessary treatment. Changes of body fat may occur in patients receiving combination antiretroviral therapy. Contact your doctor if you notice changes in body fat (see section 4, possible side effects).

Some patients taking combination antiretroviral therapy may develop a bone disease called osteonecrosis (death of bone tissue caused by loss of blood supply to the bone). The length of combination antiretroviral therapy, corticosteroid use, alcohol consumption, severe weakness of the immune system and higher body mass index may be some of the many risk factors for developing this disease. Signs of osteonecrosis are joint stiffness, aches and pains (especially of the hip, knee and shoulder) and difficulty in movement. If you notice any of these symptoms please inform your doctor.

If you are taking nevirapine and zidovudine concomitantly please inform your doctor since they might need to check your white blood cells.

Do not take Nevirapine Tablets after an exposure to HIV unless you have been diagnosed with HIV and instructed to do so by your doctor.

Prednisone should not be used to treat a rash related to Nevirapine Tablets.

If you are taking oral contraceptives (e.g. pill) or other hormonal methods of birth control during treatment with Nevirapine Tablets, you should use a barrier contraception (e.g. condoms) in addition to prevent pregnancy and further HIV transmission.

If you are receiving post-menopausal hormone therapy, ask your doctor for advice before taking this medicine.

If you are taking or are prescribed rifampicin to treat tuberculosis please inform your doctor before taking this medicine with Nevirapine Tablets.

Children and adolescents Nevirapine Tablets can be taken by:

- children 16 years of age or older
- children under 16 years of age who:
 - weigh 50 kg or more
 - or have a body surface area above 1.25 square meters.

For smaller children an oral suspension liquid form is available in the market.

Other medicines and Nevirapine

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines, including medicines obtained without a prescription. 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 are still working and adjust doses.

Carefully read the package leaflet of all other HIV medicinal products you are taking in combination with Nevirapine Tablets.

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)
- fluconazole (medicine to treat fungal infections)
- ketoconazole (medicine to treat fungal infections)
- itraconazole (medicine to treat fungal infections)
- methadone (medicine used for treatment of opiate addicts)
- warfarin (medicine to reduce blood clotting)
- hormonal contraceptives (e.g. the "pill")
- atazanavir (another medicine to treat HIV-infection)
- lopinavir/ritonavir (another medicine to treat HIV-infection)
- fosamprenavir (another medicine to treat HIV-infection)
- efavirenz (another medicine to treat HIV-infection)
- etravirine (another medicine to treat HIV infection)
- rilpivirine (another medicine to treat HIV infection)
- zidovudine (another medicine to treat HIV infection)
- elvitegravir/cobicistat (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.

Nevirapine Tablets with food and drink

There are no restrictions on taking Nevirapine Tablets with food and drink.

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

Breast-feeding **is not recommended** in women living with HIV because HIV infection can be passed on to the baby in breast milk.

If you are breast-feeding, or thinking about breast-feeding, you **should discuss it with your doctor as soon as possible.**

Driving and using machines

You may experience fatigue when taking Nevirapine Tablets. Use with 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.

Information on sodium content

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

3. How to take Nevirapine Tablets

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

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

Dose:

The dose 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.

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.

The 14-day “lead-in” period has been shown to lower the risk of skin rash.

As Nevirapine Tablets must always be taken together with other HIV antiretroviral medicines, you should follow the instructions for your other medicines carefully. These are supplied in the package leaflets for those medicines.

Nevirapine Tablets is also available in the market in liquid form as an oral suspension. This is particularly suitable if:

- you have problems swallowing tablets
- or you are a child weighing less than 50 kg,
- or you are a child having a body surface area less than 1.25 square metres (your doctor will work out your surface area).

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

As explained in ‘*Warnings and precautions*’, above, your doctor will monitor you with liver tests or for undesirable effects such as rash. Depending on the outcome your doctor may decide to interrupt or stop your Nevirapine Tablets treatment. Your doctor might then decide to restart you on a lower dose.

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

If you take more Nevirapine Tablets than you should

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.

If you forget to take Nevirapine Tablets

Try not to miss a dose. If you notice that you have missed a dose within 8 hours of when it was due, take missed dose as soon as possible. If it has been more than 8 hours since the dose was due only take the next dose at the usual time.

Do not take a double dose to make up for a forgotten dose.

If you stop taking Nevirapine Tablets

Taking all doses at the appropriate times:

- greatly increases the effectiveness of your combination antiretroviral medicines.
- reduces the chances of your HIV infection becoming resistant to your antiretroviral medicines.

It is important that you continue taking Nevirapine Tablets correctly, as described above, unless your doctor instructs you to stop.

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 have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

During HIV therapy there may be an increase in weight and in levels of blood lipids and glucose.

This is partly linked to restored health and life style, and in the case of blood lipids sometimes to the HIV medicines themselves. Your doctor will test for these changes.

Like all medicines, Nevirapine Tablets can cause side effects, although not everybody gets them.

As mentioned in 'Warnings and precautions', above, 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.

If you ever observe any rash symptoms, inform your doctor immediately.

When rash occurs it is normally mild to moderate. However, in some patients a rash, which appears as a blistering skin reaction, can be severe or life-threatening (Stevens-Johnson syndrome and toxic epidermal necrolysis) and deaths have been recorded. Most of the cases of both severe rash and mild/moderate rash occur in the first six weeks of treatment.

If rash occurs and you also feel sick, you must stop treatment and visit your doctor immediately.

Hypersensitivity (allergic) reactions can occur. Such reactions may appear in the form of anaphylaxis (a severe form of allergic reaction) with symptoms such as:

- rash
- swelling of the face
- difficulty breathing (bronchial spasm)

- anaphylactic shock

Hypersensitivity reactions can also occur as rash with other side effects such as:

- fever
- blistering of your skin
- mouth sores
- inflammation of the eye
- swelling of the face
- general swelling
- shortness of breath
- muscle or joint pain
- a reduction in the numbers of your white blood cells (granulocytopenia)
- general feelings of illness
- severe problems with liver or kidneys (liver or kidney failure)

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 Tablets. 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.

Tell your doctor if you experience any of the following clinical symptoms of liver damage:

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

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

Very common (may affect more than 1 in 10 people):

- rash

Common (may affect up to 1 in 10 people):

- headache
- loose stools (diarrhoea)
- feeling tired (fatigue)
- abnormal liver function test
- decreased numbers of white blood cells (granulocytopenia)
- allergic reactions (hypersensitivity)
- feeling sick (nausea)
- vomiting
- abdominal pain
- inflammation of the liver (hepatitis)
- fever

Uncommon (may affect up to 1 in 100 people):

- allergic reaction characterized by rash, swelling of the face, difficulty breathing (bronchial spasm) or anaphylactic shock
- decreased numbers of red blood cells (anaemia)

- decreased blood phosphorus
- increased blood pressure
- yellow skin (jaundice)
- severe and life-threatening skin rashes (Stevens Johnson Syndrome/toxic epidermal necrolysis)
- hives (urticaria)
- fluid under the skin (angioedema)
- joint pain (arthralgia)
- muscle pain (myalgia)

Rare (may affect up to 1 in 1000 people):

- sudden and intense inflammation of the liver (fulminant hepatitis)
- drug reaction with systemic symptoms (drug reaction with eosinophilia and systemic symptoms)

The following events have also been reported when Nevirapine Tablets has been used in combination with other antiretroviral agents:

- decreased numbers of red blood cells or platelets
- inflammation of the pancreas
- decrease in or abnormal skin sensations

These events are commonly associated with other antiretroviral agents and may be expected to occur when Nevirapine Tablets is used in combination with other agents; however, it is unlikely that these events are due to treatment with Nevirapine Tablets.

Additional side effects in children and adolescents

A reduction in white blood cells (granulocytopenia) can occur, which is more common in children. A reduction in red blood cells (anaemia), which may be related to nevirapine therapy, is also more commonly observed in children. As with rash symptoms, please inform your doctor of any side effects.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Nevirapine Tablets

Keep this medicine out of the sight and reach of children.

Do not use Nevirapine Tablets after the expiry date which is stated on the carton and on the blister after "EXP". The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Nevirapine Tablets contain

- The active substance is nevirapine. Each tablet contains 200 mg nevirapine.
- The other ingredients are:
- microcrystalline cellulose
- croscarmellose Sodium
- maize starch
- povidone (K30)
- sodium starch glycolate
- silica, colloidal anhydrous
- magnesium stearate

What Nevirapine Tablets looks like and contents of pack

Off-white to pale yellow coloured, capsule shaped, biconvex tablets, embossed with 'H' on one side and '7' on the other side, with break-line on both sides. The tablets should not be divided.

Nevirapine Tablets are supplied in blisters, with 14, 60 or 120 tablets per carton. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Morningside Healthcare Ltd
115 Narborough Road
Leicester, LE3 0PA
UK

Manufacturer

Pharmadox Healthcare Ltd.
KW20A Corradino Industrial Estate,
Paola PLA3000,
MALTA.

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