PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

VIROPON 200 mg TABLETS (Nevirapine)

Read all of this leaflet carefully before you start taking VIROPON 200 mg TABLETS.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **VIROPON 200 mg TABLETS** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT VIROPON 200 mg TABLETS CONTAINS

- The active substance is Nevirapine. Each uncoated tablet contains Nevirapine 200 mg.
- The other ingredients are: Colloidal silicon dioxide, Lactose Monohydrate, Magnesium Stearate, Microcrystalline Cellulose, Povidone, Sodium Starch Glycolate.
- Contains Lactose

2. WHAT VIROPON 200 mg TABLETS IS 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 infection 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.

3. BEFORE YOU TAKE VIROPON 200 mg TABLETS

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of VIROPON TABLETS with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

Do not take VIROPON 200 mg TABLETS

- If you are hypersensitive (allergic) to Nevirapine or any of the other ingredients of nevirapine tablets.
- If you previously experienced hepatitis, severe skin rash, or liver injury while on nevirapine tablet treatment.
- If you are currently taking Rifampicin. (used to treat Tuberculosis).
- If you are 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 VIROPON 200 mg TABLETS

- **Patients taking VIROPON 200 mg TABLETS may develop severe liver disease or severe skin reactions that can cause death.** Your doctor will want to check you during the first 18 weeks of therapy. The greatest risk of liver disease and skin reactions occurs in the first 6 weeks of therapy. These reactions can also occur later.
- If you develop a severe rash or a rash with any of the following symptoms stop using VIROPON 200 mg TABLETS and call your doctor right away: fever, muscle or joint aches, blisters, mouth sores, conjunctivitis (red or inflamed eyes), swelling of your face, general ill feeling.
- Women and patients with higher CD4 counts (blood counts) seem to have a greater chance of developing liver damage, often accompanied by a rash, while taking nevirapine.

- Patients with higher liver function tests and patients with hepatitis B or C have a greater chance of developing liver damage while taking nevirapine.
- If you develop any of the following symptoms of liver problems call your doctor right away: anorexia (lack of appetite), nausea (queasiness, feeling that one is about to vomit), yellowing of your skin or whites of your eyes, dark urine, pale stools; pain, ache, or sensitivity to touch on your right side below your ribs.
- If you have evidence of lipodystrophy you should have a thorough cardiovascular risk assessment.
- If you experience joint aches and pain, joint stiffness or difficulty in movement.
- If you have been told by your doctor that you have an intolerance to some sugars.
- If you have diabetes mellitus (high blood sugar).

Taking VIROPON 200 mg TABLETS with food or drink:

VIROPON 200 mg TABLETS can be taken before or after meals. The absorption of nevirapine is not affected by food.

Pregnancy: The safety of nevirapine in human pregnancy has not been established.

If you are pregnant or breast feeding your baby while taking VIROPON 200 mg TABLETS, please consult your doctor, pharmacist or other health care professional for advice.

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

Driving and using machinery:

If somnolence (sleepiness) occurs while taking **VIROPON 200 mg TABLETS**, then it is advisable not to drive or use machinery.

Taking other medicines with VIROPON 200 mg TABLETS

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

When you are taking **VIROPON 200 mg TABLETS**, it is especially important that your health care professional knows if you are taking any of the following:

- Cimetidine
- Clarithromycin
- Fluconazole
- Ketoconazole – Ketoconazole and nevirapine should not be given together.
- Warfarin – Your doctor will want to monitor your blood levels more frequently when you are taking VIROPON 200 mg TABLETS at the same time as nevirapine.
- Methadone
- Rifampicin
- Rifabutin
- Oral contraceptives (birth control) – Nevirapine may decrease the amount of these medicines in the body and cause them to be less effective. Talk with your doctor about other types of birth control (e.g. condoms) that you can use.
- St. John's Wort or St. John's Wort containing products – These medicines may decrease the amount of nevirapine in the body.

4. HOW TO TAKE VIROPON 200 mg TABLETS

Do not share medicines prescribed for you with any other person.

Always take VIROPON 200 mg TABLETS exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of VIROPON 200 mg TABLETS is too strong or too weak, talk to your doctor or pharmacist.

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. Nevirapine tablets will always be taken in

combination with other HIV anti-retrovirals, 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.

Do not exceed the dose prescribed by your doctor.

If you take more VIROPON 200 mg TABLETS than you should:

There is at present little information on the effects of nevirapine tablets overdose.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

If you forget to take VIROPON 200 mg TABLETS:

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

5. POSSIBILE SIDE EFFECTS

VIROPON 200 mg 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 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.

Not all side effects reported for VIROPON 200 mg TABLETS are included in this leaflet. Should your general health worsen while taking VIROPON 200 mg TABLETS, please consult your doctor, pharmacist or other health care professional for advice.

6. STORING AND DISPOSING OF VIROPON 200 mg TABLETS

Store at or below 30°C in the original package. Protect from light.

KEEP ALL MEDICINES OUT OF THE REACH AND SIGHT OF CHILDREN.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF VIROPON 200 mg TABLETS

1. 60 tablets are packed in white round 140 ml HDPE containers with screw type polypropylene closure with induction sealing wad. The void in the container is filled with absorbent cotton.

2. 60 tablets are packed in white round 100 ml HDPE containers with stock ribbed polypropylene closure with induction sealing wad. The void in the container is filled with absorbent cotton

8. IDENTIFICATION OF VIROPON 200 mg TABLETS

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 single bisect.

9. REGISTRATION NUMBER / REFERENCE NUMBER

A40/20.2.8/0382

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Novagen Pharma (Pty) Ltd.

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11. DATE OF PUBLICATION

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