PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

VIROPON 50 mg/5 ml ORAL SUSPENSION

Nevirapine

Read all of this leaflet carefully before you start taking VIROPON 50 mg/5 ml ORAL SUSPENSION.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **VIROPON 50 mg/5 ml ORAL SUSPENSION** 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 50 mg/5 ml ORAL SUSPENSION CONTAINS:

- The active substance is nevirapine. Each 5 ml of suspension contains nevirapine 50 mg (as nevirapine hemihydrate).
- The other ingredients are carbopol, non-crystallizing sorbitol solution, polysorbate 80, propylene glycol, purified water, sodium hydroxide, sucrose. (Contains sugar)
- The solution contains 1156 mg sorbitol solution and 750 mg sucrose per 5 ml dosage.
- Preservatives: methylparaben (0.18 % m/v) and propylparaben (0.024 % m/v).

2. WHAT VIROPON 50 mg/5 ml ORAL SUSPENSION IS USED FOR:

VIROPON 50 mg/5 ml ORAL SUSPENSION belongs to a group of medicines called antiretrovirals.

VIROPON 50 mg/5 ml ORAL SUSPENSION is used, with other medicines, for the treatment of the infection caused by human immunodeficiency virus (HIV). HIV is the virus that causes AIDS (Acquired Immune Deficiency Syndrome). This medicine works by lowering the amount of HIV in the blood and appears to slow down destruction of the immune system.

VIROPON 50 mg/5 ml ORAL SUSPENSION will not cure HIV infection or AIDS, and you may still get infections common in people with HIV. Therefore, you should stay under the care of your doctor.

This medicine will not keep you from spreading HIV to other people.

3. BEFORE YOU TAKE VIROPON 50 mg/5 ml ORAL SUSPENSION:

Do not take VIROPON 50 mg/5 ml ORAL SUSPENSION:

- If you are hypersensitive (allergic) to nevirapine or any of the other ingredients of the product.
- If you suffer from severe liver disease.
- If you are in end-stage kidney failure and are not on haemodialysis.
- After you have recovered from serious liver or skin reactions that happened when you previously took **VIROPON 50 mg/5 ml ORAL SUSPENSION.**
- If you are pregnant or are breastfeeding.

Take special care with VIROPON 50 mg/5 ml ORAL SUSPENSION:

- **Patients taking VIROPON 50 mg/5 ml ORAL SUSPENSION 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 **50 mg/5 ml ORAL SUSPENSION** 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 50 mg/5 ml ORAL SUSPENSION with food or drink:

VIROPON 50 mg/5 ml ORAL SUSPENSION can be taken before or after meals. The absorption of nevirapine is not affected by food.

Pregnancy and Breast-feeding:

The safety of nevirapine in pregnancy and breast-feeding has not been established. To avoid unwanted pregnancy, it is a good idea to use additional contraceptive measures while being treated with nevirapine.

If you are pregnant or breast feeding your baby while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

Driving and using machinery:

If somnolence (sleepiness) occurs while taking **VIROPON 50 mg/5 ml ORAL SUSPENSION**, then it is advisable not to drive or use machinery.

Taking other medicines with VIROPON 50 mg/5 ml ORAL SUSPENSION:

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

When you are taking **VIROPON 50 mg/5 ml ORAL SUSPENSION**, 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 this medicine 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 <u>50 mg/5 ml</u> ORAL SUSPENSION:

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

Always take VIROPON 50 mg/5 ml ORAL SUSPENSION 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 ORAL SUSPENSION is too strong or too weak, talk to your doctor

- The usual dose for adults is 20 ml (4 medicine measures) orally, once a day for two weeks, followed by 20 ml (4 medicine measures) twice daily, in combination with other medicines.
- Children 8 years of age and older – Dose is based on body weight and must be determined by your doctor. The usual dose is 4 mg per kilogram (kg) of body weight once a day for two weeks, followed by 4 mg per kg of body weight two times a day.
- Infants 2 months old and children up to 8 years of age – Dose is based on body weight and must be determined by your doctor. The usual dose is 4 mg per kilogram (kg) of body weight once a day for two weeks, followed by 7 mg per kg of body weight two times a day.
- **VIROPON 50 mg/5 ml ORAL SUSPENSION** should be shaken gently prior to use. Use an oral dosing syringe or dosing cup to measure the right dose. After drinking the medicine, rinse the dosing cup with water and drink the rinse to make sure you get all of the medicine. If your dose is less than 5 ml (one teaspoon) use the syringe.
- You should continue to take this medicine every day as instructed by your doctor.
- Your doctor may stop treatment if you experience a severe rash.
- Your doctor will monitor you by performing liver function tests before starting treatment with **VIROPON 50 mg/5 ml ORAL SUSPENSION**, and during therapy. Depending on the outcome, your doctor may decide to interrupt or stop your treatment. Your doctor may then decide to restart you on a lower dose.
- If you stop taking **VIROPON 50 mg/5 ml ORAL SUSPENSION** for more than 7 days, ask your doctor how much to take before you start taking it again. You may need to start with once-a-day dosing.

If you take more VIROPON 50 mg/5 ml ORAL SUSPENSION than you should:

You may experience the following: swelling due to retained fluid, fatigue, fever, headache, inability to sleep, nausea, rash, dizziness, vomiting and weight loss.

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 50 mg/5 ml ORAL SUSPENSION:

- If you forget to take **VIROPON 50 mg/5 ml ORAL SUSPENSION**, take the missed dose right away. If it is almost time for your next dose, do not take the missed dose. Instead, follow your regular dosing schedule by taking the next dose at its regular time.

5. POSSIBILE SIDE EFFECTS:

VIROPON 50 mg/5 ml ORAL SUSPENSION can have side effects.

VIROPON 50 mg/5 ml ORAL SUSPENSION can cause serious liver damage and skin reactions / rashes that can cause death.

If any of the following happens, stop taking **VIROPON 50 mg/5 ml ORAL SUSPENSION and tell your doctor immediately or go the casualty department at the nearest hospital:**

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- Rash or itching,
- Fainting,
- Yellowing of the skin and eyes, also called jaundice.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **VIROPON 50 mg/5 ml ORAL SUSPENSION.** You may need urgent medical attention or hospitalisation.

Other side-effects include: anaemia, allergic reactions, headache, nausea, vomiting, abdominal pain, diarrhoea, yellow eyes and skin, blistering, peeling, loosening of skin, hives, red skin lesions, muscle pain, joint pain, fever and fatigue.

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

6. STORING AND DISPOSING OF VIROPON 50 mg/5 ml ORAL SUSPENSION:

Store at or below 30 °C. Do not refrigerate. Shake the bottle gently before use.

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 50 mg/5 ml ORAL SUSPENSION:

1. White opaque high-density polyethylene bottle, containing 240 ml of oral solution, with a plastic cap and polyethylene wad.
2. White, opaque 250 ml HDPE bottle, containing 240 ml of oral solution, with a polypropylene child resistant cap and polyethylene wad. A syringe is included in the pack.

8. IDENTIFICATION OF VIROPON 50 mg/5 ml ORAL SUSPENSION:

White to off-white homogenous suspension.

9. REGISTRATION NUMBER/REFERENCE NUMBER:

A40/20.2.8/0490

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

Novagen Pharma (Pty) Ltd.

Office 2, 100 Sovereign Drive

Route 21 Corporate Park Nellmapius Drive

Irene – Pretoria

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