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BINDOPIN SUSPENSION 50 mg/5 ml (suspension)

Nevirapine

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

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

The active substance is nevirapine.

BINDOPIN SUSPENSION 50 mg/5 ml:

Each 5 mL of suspension contains nevirapine 50 mg (as nevirapine hemihydrate). Contains sugar: 750 mg sucrose per 5 mL.

Preservatives: methylparaben (0.18 % m/v) and propylparaben (0.024 % m/v).

The other ingredients are carbopol, non-crystallising sorbitol solution, polysorbate 80, propylene glycol, purified water and sodium hydroxide.

2. WHAT BINDOPIN SUSPENSION 50 mg/5 ml IS USED FOR

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

BINDOPIN SUSPENSION 50 mg/5 ml is used, with other medicines, for the treatment of the infection caused by human immunodeficiency virus (HIV).

BINDOPIN SUSPENSION 50 mg/5 ml 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.

BINDOPIN SUSPENSION 50 mg/5 ml will not keep you from spreading HIV to other people.

3. BEFORE YOU TAKE BINDOPIN SUSPENSION 50 mg/5 ml

Do not take BINDOPIN SUSPENSION 50 mg/5 ml:

- If you are hypersensitive (allergic) to nevirapine or any of the other ingredients of **BINDOPIN SUSPENSION 50 mg/5 ml.**
- 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 **BINDOPIN SUSPENSION 50 mg/5 ml**, or product containing nevirapine.
- If you are pregnant or are breastfeeding.

Take special care with BINDOPIN SUSPENSION 50 mg/5 ml:

- **Patients taking BINDOPIN SUSPENSION 50 mg/5 ml 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 **BINDOPIN SUSPENSION 50 mg/5 ml** 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, such as in **BINDOPIN SUSPENSION 50 mg/5 ml**.
- Patients with higher liver function tests and patients with hepatitis B or C have a greater chance of developing liver damage while taking nevirapine, such as in **BINDOPIN SUSPENSION 50 mg/5 ml**.
- 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.

Taking other medicines with BINDOPIN SUSPENSION 50 mg/5 ml:

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

When you are taking **BINDOPIN SUSPENSION 50 mg/5 ml**, it is especially important that your healthcare professional knows if you are taking any of the following:

- Cimetidine
- Clarithromycin
- Fluconazole
- Ketoconazole – Ketoconazole and **BINDOPIN SUSPENSION 50 mg/5 ml** 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 **BINDOPIN SUSPENSION 50 mg/5 ml**.
- Methadone
- Rifampicin
- Rifabutin
- Saquinavir
- Indinavir
- Oral contraceptives (birth control) – **BINDOPIN SUSPENSION 50 mg/5 ml** 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 (the active substance of **BINDOPIN SUSPENSION 50 mg/5 ml**) in the body.

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **BINDOPIN SUSPENSION 50 mg/5 ml** with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

Pregnancy and Breastfeeding:

The safety of **BINDOPIN SUSPENSION 50 mg/5 ml** in pregnancy and breastfeeding has not been established. To avoid unwanted pregnancy, barrier contraceptive measures should be used while being treated with **BINDOPIN SUSPENSION 50 mg/5 ml**.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **BINDOPIN SUSPENSION 50 mg/5 ml**.

Driving and using machinery:

Do not drive or use machinery if somnolence (sleepiness) occurs while taking **BINDOPIN SUSPENSION 50 mg/5 ml**.

Important information about some of the ingredients of BINDOPIN SUSPENSION 50 mg/5 ml:

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking **BINDOPIN SUSPENSION 50 mg/5 ml.**

4. HOW TO TAKE BINDOPIN SUSPENSION 50 mg/5 ml

Always take **BINDOPIN SUSPENSION 50 mg/5 ml** 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 **BINDOPIN SUSPENSION 50 mg/5 ml** is too strong or too weak, talk to your doctor or pharmacist.

- The absorption of **BINDOPIN SUSPENSION 50 mg/5 ml** is not affected by food.
- The usual dose for adults is 200 mg, i.e. 20 mL (4 medicine measures) once a day for two weeks (this lead-in period has been shown to lower the incidence of skin rash), followed by 200 mg, i.e. 20 mL (4 medicine measures) twice daily.
- **BINDOPIN SUSPENSION 50 mg/5 ml** will always be taken in combination with other HIV antiretrovirals, for which you should follow the recommended dosage given by your doctor.
- 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.
- For any patient, the total daily dose should not exceed 400 mg.
- **BINDOPIN SUSPENSION 50 mg/5 ml** is also available in tablet form. For adults and children weighing 50 kg or more, **BINDOPIN TABLETS 200 mg** can be taken instead of **BINDOPIN SUSPENSION 50 mg/5 ml**.

- Shake **BINDOPIN SUSPENSION 50 mg/5 ml** gently before use. Use an oral dosing syringe or dosing cup to measure the right dose. After drinking **BINDOPIN SUSPENSION 50 mg/5 ml**, 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 **BINDOPIN SUSPENSION 50 mg/5 ml** every day as instructed by your doctor.
- If you have any rash within the two week lead-in period, see your doctor before increasing the dose.
- 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 **BINDOPIN SUSPENSION 50 mg/5 ml**, 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 **BINDOPIN SUSPENSION 50 mg/5 ml** 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 BINDOPIN SUSPENSION 50 mg/5 ml than you should:

- You may experience the following: swelling due to retained fluid; red, tender lumps on the shins; 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, contact the nearest hospital or poison centre.

If you forget to take BINDOPIN SUSPENSION 50 mg/5 ml:

- 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

BINDOPIN SUSPENSION 50 mg/5 ml can have side effects.

Get emergency medical help if you have any of these **signs of an allergic reaction:**

- Skin rash; hives; difficulty breathing; swelling of your face, lips, tongue, or throat; or shock (anaphylaxis).

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

Call your doctor at once if you have any of these serious side effects:

- If you develop a severe rash (including severe blistering, peeling, loosening of skin and red skin lesions), or a rash accompanied by: fever, muscle or joint aches, blisters, mouth sores, conjunctivitis (red or inflamed eyes), swelling of your face, general ill feeling. Stop using **BINDOPIN SUSPENSION 50 mg/5 ml**.
- If you develop any of the following symptoms of liver problems: anorexia (lack of appetite); nausea (queasiness, feeling that one is about to vomit); yellowing of your skin or whites of your eyes (jaundice); dark urine; pale stools; pain, ache, or sensitivity to touch on your right side below your ribs. Inflammation of the liver (hepatitis) and sudden and intense inflammation of the liver (fulminant hepatitis) can occur.
- Any other signs of a new infection.

Other side effects include:

- Reduction in white blood cells, reduction in red blood cells (anaemia), headache, feeling sick (nausea), vomiting, abdominal pain, loose stools (diarrhoea), liver function tests abnormal, skin rash, muscle pain, joint pain, fever and fatigue.

Tell your doctor if you notice any of the above side effects and they worry you or if any of **these symptoms are severe or do not go away.**

The following side effects have also been reported when **BINDOPIN SUSPENSION**

50 mg/5 ml has been used in combination with other antiretroviral agents:

- A reduction in red blood cells or in platelets, inflammation of the pancreas, changes in body shape due to changes in fat distribution and nerve disease affecting the extremities of the body.

Not all side effects reported for **BINDOPIN SUSPENSION 50 mg/5 ml** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **BINDOPIN SUSPENSION 50 mg/5 ml**, please consult your doctor, pharmacist or other healthcare professional for advice.

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

Store at or below 30 °C. After first opening, the suspension may be stored for a period of 2 months below 30 °C. Do not refrigerate. Keep the bottle well closed. Shake the bottle gently before use.

Store 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 BINDOPIN SUSPENSION 50 mg/5 ml:

240 mL solution

1. White opaque high-density polyethylene bottle, containing 240 mL of oral solution, with a plastic cap and polyethylene wad.

2. White opaque HDPE bottle, containing 240 mL of oral solution, with a polypropylene child resistant cap with an induction sealing wad.

3. White, opaque 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 BINDOPIN SUSPENSION 50 mg/5 ml:

White to off-white homogenous suspension.

9. REGISTRATION NUMBER/REFERENCE NUMBER

43/20.2.8/0287

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

Aurobindo Pharma (Pty) Ltd

Woodhill Office Park, Building 1, 53 Phillip Engelbrecht Avenue

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11. DATE OF PUBLICATION:

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