

## **PATIENT INFORMATION**

### **Nevirapine Oral Suspension USP 50 mg/5 mL**

**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:**

1. What is Nevirapine Oral Suspension and how does it work?
2. Questions you should ask yourself before taking Nevirapine Oral Suspension
3. How to take Nevirapine Oral Suspension?
4. Possible side effects of Nevirapine Oral Suspension
5. Storing Nevirapine Oral Suspension
6. Further information

#### **Nevirapine Oral Suspension USP 50 mg/5 mL**

Nevirapine Oral Suspension is a white to off-white, homogeneous suspension and contains 50 mg of active pharmaceutical ingredient Nevirapine (as Nevirapine hemihydrate) per 5 mL of the suspension. The other ingredients are carbopol, methyl parahydroxybenzoate, propyl parahydroxybenzoate, sorbitol, sucrose, polysorbate 80, propylene glycol, sodium hydroxide and water.

Nevirapine Oral Suspension comes in bottles of 100 mL and 240mL.

The Marketing Authorisation Holder for Nevirapine Oral Suspension is:

M/s Aurobindo Pharma Ltd

Plot No.: 2, Maitrivihar

Ameerpet, Hyderabad-500 038

Telangana State

India

Nevirapine Oral Suspension is 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 NEVIRAPINE ORAL SUSPENSION IS AND WHAT IT IS USED FOR**

Nevirapine Oral Suspension belongs to a group of medicines called antiretrovirals, which are used for the treatment of human immunodeficiency virus (HIV-1) infection. Nevirapine Oral Suspension is also used to prevent passing HIV-1 infection from mother to baby at birth and during breast-feeding.

The active ingredient of Nevirapine Oral Suspension is called nevirapine. Nevirapine helps to control HIV-1 infection by reducing the multiplication of HIV in the blood. Specifically, nevirapine interferes with the virus enzyme called *reverse transcriptase*, which is needed for making copies of the virus. Because of the way it works, nevirapine is called *non-nucleoside reverse transcriptase inhibitor* (often abbreviated NNRTI).

To prevent the virus becoming resistant to nevirapine, for therapy your child must take Nevirapine Oral Suspension together with other antiretroviral medicines. Your doctor or health care provider will recommend the best medicines for your child. Nevirapine can sometimes be used alone to prevent passing HIV infection from mother to baby but your doctor or health care provider will give advice on exactly how it should be used.

**This medicine is not a cure for HIV infection.** While taking Nevirapine Oral Suspension your child may still develop infections or other illnesses associated with HIV infection.

*This product is intended for use in children. Safety information on use in adults is also provided.*

## **2. BEFORE YOUR CHILD TAKES NEVIRAPINE ORAL SUSPENSION**

### **Your child should not take Nevirapine Oral Suspension:**

- if your child is allergic (hypersensitive) to nevirapine or any of the other ingredients of Nevirapine Oral Suspension (see section 6, ‘What Nevirapine Oral Suspension contains’).
- if your child has taken nevirapine before and had to stop the treatment because of:
  - o severe skin rash
  - o 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 feeling of illness
- abdominal pain
- allergic (hypersensitivity) reactions
- inflammation of the liver (hepatitis)
- if your child has severe liver disease
- if your child has had to stop Nevirapine Oral Suspension treatment in the past because of changes in liver function
- If your child is taking St John's wort (*Hypericum perforatum*, a herbal remedy against depression).
- This herbal substance may stop Nevirapine Oral Suspension from working properly.

### **Take special care with Nevirapine Oral Suspension**

During the first 18 weeks of treatment with Nevirapine Oral Suspension it is very important that your child, you and your child's doctor or health care provider watch out for signs of liver or skin reactions. The reactions can become severe and even life threatening. Your child is at greatest risk of such a reaction during the first 6 weeks of treatment.

If your child develops severe liver, skin or allergic (hypersensitivity) reactions whilst taking Nevirapine Oral Suspension, your child must **never be given** Nevirapine Oral Suspension again without checking with your child's doctor or health care provider. Your child must be given the dosage of Nevirapine Oral Suspension as prescribed. This is especially important in the first 14 days of treatment (see more information in 'How to take Nevirapine Oral Suspension').

Nevirapine is not a cure for HIV infection. Therefore, your child may continue to develop infections and other illnesses associated with HIV infection. Your child should, therefore, remain in regular contact with the doctor or health care provider. Nevirapine does not prevent passing on of HIV to others. Please ask your child's doctor or health care provider for more information.

Skin reactions

If your child has severe rash or develops allergic reactions (hypersensitivity) 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 feeling of illness
- abdominal pain

your child **should stop taking** Nevirapine Oral Suspension and you **must contact** your child's doctor or health care provider **immediately** as such reactions can be potentially life threatening.

If your child gets mild rash without any other reaction please tell your child's doctor or health care provider **immediately**, who will advise whether your child should stop taking Nevirapine Oral Suspension.

Liver disease

If your child has symptoms suggesting damage of the liver, such as

- loss of appetite
- feeling sick (nausea)
- vomiting
- yellow skin and eyes (jaundice)
- dark urine
- discoloured stool
- abdominal pain

your child should stop receiving Nevirapine Oral Suspension and your child's doctor or health care provider must be contacted **immediately**.

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

- women
- those infected with hepatitis B or C

- those with abnormal liver function tests
- those with higher CD4 cell count at the start of nevirapine therapy (women more than 250 cells per cubic millimetre, men more than 400 cells per cubic millimetre)

### Immune reactivation syndrome

In some patients with advanced HIV infection (AIDS) who have had other infections that can occur in AIDS patients (AIDS defining illness), signs and symptoms of previous infections may occur soon after starting antiretroviral treatment ('immune reactivation syndrome'). These symptoms probably result from improvement in the body's immune response, enabling the body to fight infections that may have been present with no obvious symptoms. If you or your child notice any symptoms of infection, please tell your child's doctor or health care provider immediately.

### Bone problems

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). So far, this disease has been reported mainly in adults. The risk of developing this disease may be higher with long-term combination antiretroviral therapy, corticosteroid use, excessive alcohol use, very weak immune system and being overweight. If your child has signs of joint stiffness, aches and pains (especially of the hip, knee and shoulder) and difficulty in movement please tell your doctor or health care provider.

### **Taking other medicines**

Tell your child's doctor, health care provider or pharmacist if your child is taking or has recently taken any other medicines, including medicines obtained without a prescription, before starting to take Nevirapine Oral Suspension. Your child's doctor or health care provider might need to check if the other medicines are still needed and adjust doses. Carefully read the package leaflet of all other HIV medicines your child is taking in combination with Nevirapine Oral Suspension.

It is particularly important that you tell your doctor if your child is taking or has recently taken:

- atazanavir, lopinavir with ritonavir, fosamprenavir, or efavirenz (other antiretroviral medicines)
- rifampicin or rifabutin (medicines to treat tuberculosis)
- clarithromycin (medicine to treat bacterial infections)
- fluconazole, itraconazole or ketoconazole (medicines to treat fungal infections)

- quinine (medicine to treat malaria)
- methadone (medicine for managing opioid addiction)
- warfarin (medicine to reduce blood clotting)
- hormonal contraceptives (e.g. the ‘pill’)
- carbamazepine, phenobarbital or phenytoin (medicines for managing epilepsy)
- St John’s Wort (*Hypericum perforatum*, medicine to treat depression)

### **Taking Nevirapine Oral Suspension with food and drink**

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

### **Pregnancy and breast-feeding**

A woman who is pregnant or contemplating pregnancy should ask her doctor, health care professional or pharmacist for advice before taking any medicine.

In babies born to mothers who have taken antiretroviral medicines comprising nucleoside and nucleotide analogues, the benefit of reduced risk of becoming infected with HIV outweighs the risk of side effects of these medicines.

If a mother wants to breastfeed her baby, she should ask her doctor or healthcare provider for advice on the risks and benefits. Medicines may be needed for the mother or child or both.

It is generally recommended that the infant is not breast-fed if the mother has HIV infection because it is possible that the baby can become infected with HIV through breast milk.

### **Driving and using machines**

There are no specific studies on the ability to drive vehicles and use machinery. If the ability to drive or use machines seems to be affected then one should not drive or use machines.

### **Important information about some of the ingredients of Nevirapine Oral Suspension**

Nevirapine Oral Suspension oral suspension contains sorbitol. This should be taken into account in those with diabetes mellitus. If a doctor or health care provider has told you that your child has an intolerance to some sugars, contact the child’s doctor or health care provider before giving this medicine to your child.

Nevirapine Oral Suspension oral suspension contains methyl parahydroxybenzoate and propyl parahydroxybenzoate. These ingredients can cause allergic reactions over time.

### 3. HOW TO TAKE NEVIRAPINE ORAL SUSPENSION

For the treatment of HIV infection, your child should not be given Nevirapine Oral Suspension on its own. Your child must take it with at least two other antiretroviral medicines. Your child's doctor or health care provider will recommend the best medicines.

Always give Nevirapine Oral Suspension exactly as described by your child's doctor or health care provider. You should check with your child's doctor, health care provider or pharmacist if you are not sure. Your child's doctor or health care provider will watch out for unwanted effects such as signs of liver or skin reactions. In case of problems your child's doctor or health care provider may decide to interrupt or stop Nevirapine Oral Suspension treatment. Your child's doctor or health care provider might then decide to restart nevirapine at a lower dose.

Your child may take Nevirapine Oral Suspension with food or between meals.

Your child's doctor or health care provider will calculate the dose for your child. The calculation will include your child's age and bodyweight. Make sure that your child's doctor or health care provider clearly tells you what dose you must give to your child.

Nevirapine Oral Suspension oral suspension should only be taken by mouth.

Use the oral dosing syringe supplied with the pack to measure your child's dose accurately.

1. Remove the bottle cap. Keep it safely
2. Hold the bottle firmly. Push the plastic adapter into the neck of the bottle.
3. Insert the syringe firmly into the adapter.
4. Turn the bottle upside down.
5. Pull out syringe plunger until the syringe contains the first part of your full dose.
6. Turn the bottle the correct way up. Remove the syringe from the adapter.
7. Put the syringe into your child's mouth, placing the tip of the syringe against the inside of your child's cheek. Slowly push the plunger in, allowing time to swallow. Do not push too hard and squirt the liquid into the back of your child's throat or your child may choke.
8. Take the syringe out of the bottle and wash it thoroughly in clean water. Let it dry completely before you use it again.

Close the bottle tightly with the cap, leaving the adaptor in place

## **Treatment of HIV infection (in combination with other antiretroviral drugs)**

The dose for treating HIV infection in children is given once a day for the first 14 days of treatment ('lead-in period'). Thereafter your child will be switched to a twice-daily dosing schedule and your child's doctor or health care provider will decide the right dose based on your child's weight. Usual doses are shown in the table below

It is very important that your child takes Nevirapine Oral Suspension only once a day for the first 14 days ('lead-in' period). If your child develops any rash during this period, do not increase the dose but see your child's doctor or health care provider. The 14-day 'lead-in' period can lower the risk of skin rash.

<b>Usual doses for treating HIV infection (in combination with other antiretroviral medicines)</b>		
<b>Child's weight</b>	<b>'Lead-in' dose for first 14 days in ml of Nevirapine Oral Suspension oral suspension</b>	<b>Maintenance dose in ml of Nevirapine Oral Suspension oral suspension</b>
3–5.9 kg	5 ml once daily	5 ml twice daily
6–9.9 kg	8 ml once daily	8 ml twice daily
10–13.9 kg	10 ml once daily	10 ml twice daily
14–19.9 kg	13 ml once daily	13 ml twice daily
20–24.9 kg	15 ml once daily	15 ml twice daily

Nevirapine is also available as 200-mg tablets for older children, particularly those weighing more than 25 kg. Your child's doctor or health care provider will inform you of the correct dose for your child. Your child's doctor or health care provider will regularly check your child's weight to ensure that the child receives the correct dose.

For adults

The dose for treating HIV infection in adults is 20 ml (200 mg) once a day for the first 14 days of treatment ('lead-in' period). After 14 days, the usual dose is 20 ml (200 mg) twice a day.

It is very important that you take only 20 ml of Nevirapine Oral Suspension a day for the first 14 days ('lead-in' period). If you have any rash during this period, do not increase the dose but see your doctor or health care provider.

As Nevirapine Oral Suspension must always be taken 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.



You should continue to take Nevirapine Oral Suspension for as long as instructed by your doctor or health care provider.

### **Preventing passing HIV infection from mother to newborn baby**

To prevent passing HIV infection from mother to a newborn baby the mother should take a single dose of 20 ml (200 mg) as soon as labour starts. Your doctor or health care provider will give you advice on the choice of medicines during and after pregnancy.

The dose for preventing infection in a newborn baby is started as soon as possible after birth, preferably within the first 6 hours. The medicine is usually given for 6 weeks but it can be given for longer if the baby is breastfeeding and the mother is not taking antiretroviral medicines. Usual doses for the baby are shown in the table below:

#### **Usual doses for preventing HIV infection in a baby**

<b>Age</b>	<b>Dose in ml of Nevirapine Oral Suspension oral suspension 50</b>
Birth to 6 weeks weighing under 2.5 kg	1 ml daily
Birth to 6 weeks weighing over 2.5 kg	1.5 ml daily
6 weeks–6 months	2 ml daily
6–9 months	3 ml daily
9 months to 1 week after end of breastfeeding	4 ml daily

#### **If your child takes more Nevirapine Oral Suspension than the child should**

Your child must not take more Nevirapine Oral Suspension than prescribed by your child's doctor or health care provider and described in this leaflet. There is very little information on the effects of Nevirapine Oral Suspension overdose. See your doctor or health care provider if your child has taken more Nevirapine Oral Suspension than the child should.

#### **If your child's dose of Nevirapine Oral Suspension is missed**

Try to ensure that your child does not miss a dose. If you notice that your child has missed a dose within 8 hours, your child should receive the next dose as soon as possible. If it is longer than 8 hours since the dose was missed, the child should receive the next dose at the usual time.

#### **If your child stops taking Nevirapine Oral Suspension**

Taking all doses at the right time:

- ensures that the combination of antiretroviral medicines work as well as possible
- reduces the chances of the HIV infection becoming resistant to the antiretroviral medicines your child is taking.

It is important that your child continues taking Nevirapine Oral Suspension correctly unless your child's doctor or health care provider instructs that your child should stop taking it.

If your child stops taking Nevirapine Oral Suspension for more than 7 days your child's doctor or health care provider will instruct starting the 14-day 'lead-in' period (described above) once again, before returning to the twice-daily dose.

If you have any questions about your child's treatment, ask your doctor, health care provider or pharmacist.

#### **4. POSSIBLE SIDE EFFECTS**

Like all medicines, Nevirapine Oral Suspension can cause side effects, but not everybody gets them.

As mentioned in 'Take special care with Nevirapine Oral Suspension', above, the most important side effects of nevirapine are severe and life-threatening skin reactions and serious liver damage.

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

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

- rash
- swelling of the face
- difficulty breathing
- anaphylactic shock

Allergic (hypersensitivity) reactions can also occur as rash with 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
- a reduction in the numbers of white blood cells (granulocytopenia)
- general feeling of illness
- severe problems with liver or kidneys (liver or kidney failure)

Abnormal liver functioning can occur with the use of nevirapine. This includes inflammation of the liver (hepatitis), which can be sudden and intense (fulminant hepatitis), and liver failure, both of which can be fatal. Any of the following symptoms can suggest liver damage:

- loss of appetite
- feeling sick (nausea)
- vomiting
- yellow skin and eyes (jaundice)
- dark urine
- discoloured stool
- abdominal pain

Evaluation of the side effects is based on the following frequencies:

- Very common: in at least 1 out of 10 patients treated
- Common: in at least 1 out of 100 and less than 1 out 10 patients treated
- Uncommon: in at least 1 out of 1000 and less than 1 out 100 patients treated
- Rare: in at least 1 out of 10,000 and less than 1 out 1000 patients treated

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

Very common:

- rash

Common:

- decreased numbers of white blood cells (granulocytopenia)
- allergic reactions (hypersensitivity)
- headache

- feeling sick (nausea)
- vomiting
- abdominal pain
- loose stools
- inflammation of the liver
- muscle pain
- feeling tired (fatigue)
- fever
- abnormal liver function tests

Uncommon:

- decreased numbers of red blood cells (anaemia)
- yellow skin (jaundice)
- severe and life-threatening skin rashes (Stevens-Johnson syndrome/toxic epidermal necrolysis)
- hives (urticaria)
- accumulation of fluid and swelling under the skin (angioedema)
- joint pain

Rare:

- sudden and intense inflammation of the liver (fulminant hepatitis)

Frequency not known:

- drug rash with systemic symptoms (drug rash with eosinophilia and systemic symptoms)
- allergic reaction characterized by rash, swelling of the face, difficulty breathing (bronchial spasm) or anaphylactic shock

Combination antiretroviral therapy may cause changes in body shape due to changes in fat distribution. These may include loss of fat from legs, arms and face, increased fat in the abdomen (belly) and other internal organs, breast enlargement and fatty lumps on the back of the neck ('buffalo hump'). The cause and long-term health effects of these conditions are not known at this time. Combination antiretroviral therapy may also cause raised lactic acid, resistance to insulin, raised sugar in the blood, and increased fats in the blood (hyperlipaemia).

Use in children

Reduction in white blood cells (granulocytopenia) is more common in children. A reduction in red blood cells (anaemia), which may be related to nevirapine therapy, is also more common in children. As with rash, please inform your doctor or health care provider of any side effects.

If any side effect gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, health care provider or pharmacist.

## **5. HOW TO STORE NEVIRAPINE ORAL SUSPENSION**

Do not store above 30°C.

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

Keep out of the reach and sight of children.

Do not use Nevirapine Oral Suspension after the expiry date which is stated on the bottle. The expiry date refers to the last day of that month.

**240 ml:** Use within 7 months after first opening.

**100 ml:** Use within 3 months after first opening.

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. FURTHER INFORMATION**

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

“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](mailto:pharmacovigilance@aurobindo.com)