APPROVED PATIENT INFORMATION LEAFLET

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BINDOLAM ORAL SOLUTION 10 mg/ml (Solution)

Lamivudine

Read all of this leaflet carefully before you start taking BINDOLAM ORAL SOLUTION 10 mg/ml.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **BINDOLAM ORAL SOLUTION 10 mg/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 BINDOLAM ORAL SOLUTION 10 mg/ml CONTAINS

Each ml contains:

Lamivudine 10 mg

Contains 200 mg sucrose.

Preservatives: Methylparaben 0.18 %

Propylparaben 0.02 %

The other ingredients are anhydrous citric acid, liquid banana flavour, liquid strawberry flavour, propylene glycol, purified water and sodium citrate.

2. WHAT BINDOLAM ORAL SOLUTION 10 mg/ml IS USED FOR

BINDOLAM ORAL SOLUTION 10 mg/ml is an antiviral medication that prevents human immunodeficiency virus (HIV) cells from multiplying in your body. HIV is the virus which causes the acquired immunodeficiency syndrome (AIDS). **BINDOLAM ORAL SOLUTION 10 mg/ml** is not a cure for HIV or AIDS.

BINDOLAM ORAL SOLUTION 10 mg/ml is used in combination with other antiviral medications for the treatment of HIV infection in adults and children.

3. BEFORE YOU TAKE BINDOLAM ORAL SOLUTION 10 mg/ml

Do not take BINDOLAM ORAL SOLUTION 10 mg/ml:

- If you are hypersensitive (allergic) to lamivudine or any of the other ingredients found in **BINDOLAM ORAL SOLUTION 10 mg/ml**.

Take special care with BINDOLAM ORAL SOLUTION 10 mg/ml:

- Even while taking **BINDOLAM ORAL SOLUTION 10 mg/ml**, you may continue to have HIV-related illnesses, including infections caused by other disease-producing organisms. Continue to see your doctor regularly and report any medical problems that occur.
- **BINDOLAM ORAL SOLUTION 10 mg/ml** does not prevent a patient infected with HIV from passing the virus to other people. To protect others, you must continue to practice safe sex, safe injection and take precautions to prevent others from coming into contact with your blood and other contaminated body fluids.
- **BINDOLAM ORAL SOLUTION 10 mg/ml**, when used alone or in combination with other antiviral medicines, can cause a sometimes fatal condition called lactic acidosis (excess of lactic acid in the blood), together with an enlarged fatty liver. Call your doctor at once if you have any of the following symptoms: feeling very tired, nausea (queasiness; feeling that one is about to vomit), vomiting, abdominal pain, sudden unexplained weight loss, rapid breathing, shortness of breath, or severe weakness.

  Fatal (causing death) lactic acidosis has occured in pregnant women receiving didanosine and stavudine used in combination with other medicines used to treat HIV.

  The combination of stavudine and didanosine medications used to treat HIV, should be used cautiously during pregnancy, and is recommended only if your doctor decides that the potential benefits of this combination outweigh the potential risks to you and your baby.
- Tell your doctor if you have liver disease (including hepatitis B). If you have a chronic (lasting a long time) hepatitis B infection, there is a small possibility that you may have a recurrence of your hepatitis, when stopping your treatment with **BINDOLAM ORAL SOLUTION 10 mg/ml**.
- **BINDOLAM ORAL SOLUTION 10 mg/ml** can also cause a dangerous inflammation of the pancreas.

  Tell your doctor right away if you develop abdominal pain, nausea or vomiting.

Fatal (causing death) and non-fatal pancreatitis have occurred when stavudine was used in combination with other medicines used to treat HIV, that included didanosine, with or without hydroxyurea.

- Tell your doctor if you have kidney disease. The standard recommended dose of **BINDOLAM ORAL SOLUTION 10 mg/ml** may have to be reduced.

Taking BINDOLAM ORAL SOLUTION 10 mg/ml with food and drink:

BINDOLAM ORAL SOLUTION 10 mg/ml can be taken with or without food.

Pregnancy and Breast feeding:

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

Taking other medicines with BINDOLAM ORAL SOLUTION 10 mg/ml:

Tell your doctor if you are using any of the following medicines:

- Zalcitabine - **BINDOLAM ORAL SOLUTION 10 mg/ml** should not be taken with zalcitabine.
- Trimethoprim
- Co-trimoxazole (trimethoprim/sulfamethoxazole)

If you are taking any of these medicines, your doctor may need to monitor your therapy more closely, adjust your dosage, or you may not be able to use **BINDOLAM ORAL SOLUTION 10 mg/ml**.

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **BINDOLAM ORAL SOLUTION 10 mg/ml** with these medicines may cause undesirable interactions. Please consult your doctor or pharmacist.

4. HOW TO TAKE BINDOLAM ORAL SOLUTION 10 mg/ml

- **BINDOLAM ORAL SOLUTION 10 mg/ml** can be taken with or without food.
- Measure **BINDOLAM ORAL SOLUTION 10 mg/ml** with the special dose-measuring cup included in the pack.

- The usual daily dose of **BINDOLAM ORAL SOLUTION 10 mg/ml** in adults and adolescents over 12 years of age (weighing 50 kg or more) is 300 mg. This can be taken either as 300 mg (30 ml) once a day or 150 mg (15 ml) twice a day.

  For patients weighing less than 50 kg, the usual recommended dose is 2 mg/kg twice a day.
- In children 3 months to 12 years of age, the usual recommended dose is 4 mg/kg twice a day, up to a maximum of 300 mg daily.
- If you have kidney disease, your dose may be reduced. Please follow the instructions of your doctor.
- HIV/AIDS is usually treated with a combination of different medicines. To best treat your condition, use all your medications as directed by your doctor. Do not change your doses or medication schedule without advice from your doctor.

Always take **BINDOLAM ORAL SOLUTION 10 mg/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 **BINDOLAM ORAL SOLUTION 10 mg/ml** is too strong or too weak, talk to your doctor or pharmacist.

If you take more BINDOLAM ORAL SOLUTION 10 mg/ml than you should:

- Seek emergency medical attention if you think you have used too much of **BINDOLAM ORAL SOLUTION 10 mg/ml**.

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

If you forget to take BINDOLAM ORAL SOLUTION 10 mg/ml:

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

5. POSSIBLE SIDE-EFFECTS

BINDOLAM ORAL SOLUTION 10 mg/ml can have side-effects.

The following side-effects may occur:

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

- Hives

- Difficulty breathing
- Swelling of your face, lips, tongue, or throat.

Call your doctor immediately if you have any of these serious side-effects:

- Lactic acidosis (severe increase of lactic acid in the blood) - feeling very tired, nausea (queasiness; feeling that one is about to vomit), vomiting, abdominal pain, sudden unexplained weight loss, rapid breathing, shortness of breath, or severe weakness.
- Liver damage - nausea, stomach pain, low fever, loss of appetite, dark urine, clay-coloured stools, jaundice (yellowing of the skin or eyes)
- Peripheral neuropathy – tingling, numbness, and pain in the hands and feet.
- Pancreatitis (inflammation of the pancreas) - abdominal pain, nausea or vomiting.
- Easy bruising or bleeding, unusual weakness, pale skin.
- Any signs of a new infection.
- Fever
- Muscle problems
- Skin rash

Other side-effects include:

Abdominal (belly) pain, diarrhoea (frequent or loose watery stools), nausea (queasiness, feeling that one is about to vomit), vomiting (being sick), loss of hair, headache, joint pain, general feeling of being unwell, tired feeling.

Tell your doctor if any of the above side-effects are severe, bothersome or do not go away.

Not all side-effects reported for **BINDOLAM ORAL SOLUTION 10 mg/ml** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **BINDOLAM ORAL SOLUTION 10 mg/ml**, please consult your doctor, pharmacist or other health care professional for advice.

6. STORING AND DISPOSING OF BINDOLAM ORAL SOLUTION 10 mg/ml

Store at or below 30 °C (room temperature). Keep the bottle tightly closed.

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 BINDOLAM ORAL SOLUTION 10 mg/ml

1. The solution is packed in a 300 ml round white opaque HDPE bottle closed with a plastic screw cap containing an expanded polyethylene wad and a pilfer proof skirt.

Pack size: 240 ml of oral solution.

2. The solution is packed in a 250 ml round white opaque HDPE bottle closed with a polypropylene child resistant cap containing an expanded polyethylene wad.

Pack size: 240 ml of oral solution.

3. The solution is packed in a 250 ml round white opaque HDPE bottle closed with a polypropylene child resistant closure having induction sealing liner.

Pack size: 240 ml of oral solution

A measuring Syringe is incorporated along with the bottle.

8. IDENTIFICATION OF BINDOLAM ORAL SOLUTION 10 mg/ml

A clear, colourless to pale yellow, strawberry-banana flavoured liquid in 250 ml round white opaque HDPE bottle.

9. REGISTRATION NUMBER/REFERENCE NUMBER

BINDOLAM ORAL SOLUTION 10 mg/ml: 42/20.2.8/1093

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Woodhill Office Park, Building No. 1,

53 Phillip Engelbrecht Avenue,

Meyersdal, Ext. 12, 1448,

Johannesburg,

South Africa

11. DATE OF PUBLICATION

30 April 2010

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