PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

LEGRAM 10 mg/ml ORAL SOLUTION (Solution).

Lamivudine.

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

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

The active substance is Lamivudine. Each ml contains Lamivudine 10 mg.

The other ingredients are: banana flavour, citric acid, propylene glycol, sodium citrate, strawberry flavour, sucrose.

Preservatives: Methylparaben 018 %, Propylparaben 0,02 %.

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

LEGRAM 10 mg/ml ORAL SOLUTION is indicated as part of antiretroviral combination therapy for the treatment of HIV infected adults and children.

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

Do not take LEGRAM 10 mg/ml ORAL SOLUTION:

If you are hypersensitive to any ingredient of the formulation.

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

- You may develop a potentially fatal condition known as lactic acidosis while taking **LEGRAM 10 mg/ml ORAL SOLUTION**. Inform your doctor or other healthcare professional immediately if you develop nausea, vomiting, abdominal pain, dyspnoea, fatigue and weight loss. Your doctor will perform blood tests and treat you accordingly.
- If you became pregnant while taking **LEGRAM 10 mg/ml ORAL SOLUTION** your baby may develop blood and nervous system disorders. Your doctor will monitor your baby's condition.
- Pancreatitis (inflammation of the pancreas) has been observed in some patients receiving **LEGRAM 10 mg/ml ORAL SOLUTION**. Inform your doctor or other healthcare professional immediately if you develop abdominal pain, nausea or vomiting. Your doctor will discontinue treatment with **LEGRAM 10 mg/ml ORAL SOLUTION** until the diagnosis of pancreatitis is excluded.
- If you have kidney problems your doctor or healthcare professional will need to adjust the dosage of **LEGRAM 10 mg/ml ORAL SOLUTION**.
- You may develop liver problems when taking **LEGRAM 10 mg/ml ORAL SOLUTION**. Inform your doctor or healthcare professional if you have any pre-existing liver disease including Hepatitis B or C. Do not stop taking **LEGRAM 10 mg/ml ORAL SOLUTION** if you are co-infected with HIV and Hepatitis as this may cause the Hepatitis to worsen.
- You may develop a condition known as lipodystrophy while taking **LEGRAM 10 mg/ml ORAL SOLUTION**. Inform your doctor or healthcare professional if you notice a change in the distribution of your body fat (e.g. accumulation of fat around the waist/stomach area, on the back of the neck and between the shoulders (buffalo hump), breast enlargement), wasting of the arms, legs and facial muscles, and increased blood glucose and lipid values.
- If you are taking **LEGRAM 10 mg/ml ORAL SOLUTION** for the first time you may develop a condition known as Immune Reconstitution Inflammatory Syndrome (IRIS), within the first few months of treatment. This condition can cause opportunistic infections that are being treated to become worse or opportunistic diseases that were asymptomatic to be unmasked. Tell your doctor or healthcare professional if your general health worsens or if you think you may have an infection. You should not stop taking **LEGRAM 10 mg/ml ORAL SOLUTION**. Your doctor will treat the infections appropriately.
- You may develop a condition known as osteonecrosis while taking **LEGRAM 10 mg/ml ORAL SOLUTION**. Seek medical advice if you experience joint aches and pain, joint stiffness or difficulty in

movement.

- You may continue to develop opportunistic infections and other complications of HIV infection while taking **LEGRAM 10 mg/ml ORAL SOLUTION**. You should remain under close observation by healthcare professionals experienced in the treatment of patients with associated HIV disease. Regular monitoring of viral load and CD4 counts needs to be done.
- You are still at risk of transmitting HIV to others through sexual contact or blood contamination while taking current antiretroviral therapy including **LEGRAM 10 mg/ml ORAL SOLUTION**. Appropriate precautions should continue to be employed.

Pregnancy and Breastfeeding:

Safety in pregnancy and lactation has not been established.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **LEGRAM 10 mg/ml ORAL SOLUTION**.

Important information about some of the ingredients of LEGRAM 10 mg/ml ORAL SOLUTION:

LEGRAM 10 mg/ml ORAL SOLUTION contains sugar (i.e. sucrose).

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

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

Caution must be exercised in the concomitant use of self-administered medicines. Consult your doctor/pharmacist.

Zidovudine plasma levels are not significantly altered when co-administered **LEGRAM 10 mg/ml ORAL SOLUTION**. (See **Pharmacokinetic properties**).

An interaction with trimethoprim, a constituent of co-trimoxazole, causes a 40 % increase in lamivudine plasma concentrations at therapeutic doses. This does not require dose adjustment unless the patient also has renal impairment.

Administration of co-trimoxazole with the **LEGRAM 10 mg/ml ORAL SOLUTION** /zidovudine combination in patients with renal impairment should be carefully assessed. **LEGRAM 10 mg/ml ORAL SOLUTION** may inhibit the intracellular phosphorylation of zalcitabine when the two medicinal products are used concurrently. **LEGRAM 10 mg/ml ORAL SOLUTION** is therefore, not recommended to be used in

combination with zalcitabine.

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

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

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

Recommended dosage in adults:

Adults and adolescents more than 12 years of age:

The recommended dose of **LEGRAM 10 mg/ml ORAL SOLUTION** is 300 mg orally daily. This may be administered as either 300 mg once daily or 150 mg twice daily.

The package insert for lamivudine must be consulted for information on its dosage and administration.

For patients with low body weights (less than 50 kg), the recommended oral dose of **LEGRAM 10 mg/ml ORAL SOLUTION** is 2 mg/kg orally twice daily.

Children ≥ 3 months to 12 years of age:

The recommended dose is 4 mg/kg orally twice daily up to a maximum of 300 mg daily.

Children < 3 months of age:

There is a limited data to propose specific dosage recommendations (see "**Pharmacokinetic properties**").

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

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

TREATMENT IS SYMPTOMATIC AND SUPPORTIVE.

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 LEGRAM 10 mg/ml ORAL SOLUTION:

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

5. POSSIBLE SIDE EFFECTS

LEGRAM 10 mg/ml ORAL SOLUTION can have side effects.

Side Effects:

The following side effects have been reported during therapy of HIV disease with **LEGRAM 10 mg/ml ORAL SOLUTION** alone, and in combination with other antiretrovirals.

Gastro-intestinal disorders:

Pancreatitis, upper abdominal pain, nausea, vomiting and diarrhoea have been reported.

Blood and lymphatic system disorders:

Neutropenia, thrombocytopenia, anaemia have occurred.

Skin and appendages disorders:

Alopecia has been reported.

Central and Peripheral Nervous system disorders:

Peripheral neuropathy, paraesthesia, and headache have been reported.

Musculoskeletal system disorders:

Arthralgia, muscle disorders including less frequently, rhabdomyolysis have been reported.

Body as a whole:

Malaise, fatigue and fever have occurred.

Hypersensitivity reactions:

Skin rash.

Changes in laboratory test parameters:

Transient rises in serum liver enzymes (AST, ALT) and rises in serum amylase have been reported.

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

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

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

Store at or below 30 °C. Keep the bottle tightly closed

STORE ALL MEDICINES OUT OF THE REACH 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 LEGRAM 10 mg/ml ORAL SOLUTION

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

Pack size: 240 ml of oral solution.

A syringe is included in the pack.

3. The solution is packed in a 250 ml round white opaque HDPE bottle closed with closed with a child resistant 28 mm 400 CR closure with Tri-Gard® II – TS PE.

Pack size: 240 ml of oral solution.

A syringe is included in the pack.

4. The solution is packed in a 250 ml round white opaque HDPE Bottle closed with a white opaque 28 mm - 400 CR closure having an induction sealing liner.

Pack size: 240 ml of oral solution.

A syringe is included in the pack.

8. IDENTIFICATION OF LEGRAM 10 mg/ml ORAL SOLUTION

A clear, colourless to pale yellow, strawberry-banana flavoured liquid in a 250 ml or 300 ml white round HDPE bottle.

9. REGISTRATION NUMBER/REFERENCE NUMBER

A40/20.2.8/0561

10. NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE

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11. DATE OF PUBLICATION

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