PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

LEGRAM 150 mg TABLETS

Lamivudine.

Read all of this leaflet carefully before you start taking LEGRAM 150 mg TABLETS

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **LEGRAM 150 mg TABLETS** 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 150 mg TABLETS CONTAINS

- The active substance is Lamivudine. Each film-coated tablet contains Lamivudine 150 mg.
- The other ingredients are: hypromellose, magnesium stearate, microcrystalline cellulose, polysorbate 80, polyethylene glycol 400, sodium starch glycolate, titanium dioxide (CI no. 77891).

2. WHAT LEGRAM 150 mg TABLETS IS USED FOR

Lamivudine tablets are indicated as part of antiretroviral combination therapy for treatment of HIV infected adults and children.

3. BEFORE TAKING LEGRAM 150 mg TABLETS

Do not take LEGRAM 150 mg TABLETS:

Do not take **LEGRAM 150 mg TABLETS** if you are hypersensitive to Lamivudine or to any of the excipients.

Take special care with LEGRAM 150 mg TABLETS:

- You may develop a potentially fatal condition known as lactic acidosis while taking **LEGRAM 150 mg TABLETS**. 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 150 mg TABLETS** 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 150 mg TABLETS**. Inform your doctor or other healthcare professional immediately if you develop abdominal pain, nausea or vomiting. Your doctor will discontinue treatment with **LEGRAM 150 mg TABLETS** 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 150 mg TABLETS**.
- You may develop liver problems when taking **LEGRAM 150 mg TABLETS**. Inform your doctor or healthcare professional if you have any pre-existing liver disease including Hepatitis B or C.
  Do not stop taking **LEGRAM 150 mg TABLETS** 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 150 mg TABLETS**. 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 150 mg TABLETS** 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 150 mg TABLETS**. Your doctor will treat the infections appropriately.
- You may develop a condition known as osteonecrosis while taking **LEGRAM 150 mg TABLETS**. 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 150 mg TABLETS**. 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 150 mg TABLETS**. Appropriate precautions should continue to be employed.

Pregnancy and Breastfeeding:

The safety of lamivudine in human pregnancy 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 150 mg TABLETS**.

Important information about some of the ingredients of LEGRAM 150 mg TABLETS:

LEGRAM 150 mg TABLETS is sugar free.

Taking other medicines with LEGRAM 150 mg TABLETS:

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

Zidovudine plasma levels are not significantly altered when co-administered with Lamivudine Tablets 150 mg. Zidovudine has no effect on the pharmacokinetics of lamivudine.

Administration of Trimethoprim, a constituent of co-trimoxazole causes an increase in lamivudine plasma levels. However, unless the patient has renal impairment, no dosage adjustment is necessary.

LEGRAM 150 mg TABLETS is not recommended to be used in combination with Zalcitabine.

4. HOW TO TAKE LEGRAM 150 mg TABLETS

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

Always take **LEGRAM 150 mg TABLETS** 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 150 mg TABLETS** is too strong or too weak, talk to your doctor or pharmacist.

The usual dose is:

- ***Adults and adolescents over 12 years of age****:*

The recommended dose is 300 mg daily which is administered as either 150 mg orally twice daily or 300 mg orally once daily in combination with other antiretroviral agents.

- ***Children (Three months to 12 years of age):***

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

Renal impairment:

Lamivudine plasma concentrations are increased in patients with moderate -severe renal impairment due to decreased clearance.

Dosing Recommendations for adults and adolescents over 12 years:

Creatinine Clearance (ml/min)	Recommended dose of **LEGRAM 150 mg TABLETS**
≥ 50	150 mg twice daily
30-49	150 mg once daily
15-29	150 mg first dose, then 100 mg once daily
5-14	150 mg first dose, then 50 mg once daily
< 5	50 mg first dose, then 25 mg once daily

Children > 3 months to 12 years:

Creatinine Clearance (ml/min)	Recommended dose of **LEGRAM 150 MG TABLETS**
≥ 50	4 mg/kg first dose, then 4 mg/kg twice daily
30-49	4 mg/kg first dose; then 4 mg/kg once daily
15-29	4 mg/kg first dose. then 2,6 mg/kg once daily
5-14	4 mg/kg first dose, then 1,3 mg/kg once daily
< 5	1,3 mg/kg first dose, then 0,7 mg/kg once daily

If you take more LEGRAM 150 mg TABLETS than you should:

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 150 mg TABLETS:

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

5. POSSIBILE SIDE EFFECTS

LEGRAM 150 mg TABLETS can have side effects.

The following side effects have been reported during therapy of HIV disease with **LEGRAM 150 mg TABLETS** 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 150 mg TABLETS** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **LEGRAM 150 mg TABLETS**, please consult your doctor, pharmacist or other healthcare 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 150 mg TABLETS

Store at or below 30°C in the original package. Protect from moisture.

STORE ALL MEDICINES OUT OF 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 150 mg TABLETS

1. 60 tablets are packed in white round 70 ml HDPE containers with screw type polypropylene closure with induction sealing wad. The void in the container is filled with absorbent cotton.

2. 60 tablets are packed in white round 40 ml HDPE containers with child resistant polypropylene closure with induction sealing wad. The void in the container is filled with absorbent cotton.

8. IDENTIFICATION OF LEGRAM 150 mg TABLETS

White to off white, film-coated, oval shaped, tablets debossed with “C” on one side and “63” on other side.

9. REGISTRATION NUMBER/REFERENCE NUMBER

A40/20.2.8/0376

10. NAME AND ADDRESS OF REGISTRATION HOLDER

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