Lamovir-S ®



<u>Lamovir-s</u>

Each tablet contains

Composition	
Stavudine	30 mg
Lamivudine	150 mg

Indications

Lamovir-S is indicated for the treatment of HIV infection as part of combination therapy.

Description

Stavudine is an analog of thymidine. It is phosphorylated by cellular kinases into active triphosphate. Stavudine triphosphate inhibits the HIV reverse transcriptase by competing with natural substrate, thymidine triphosphate. It also causes termination of DNA synthesis by incorporating into it.Simultaneous use of AZT is not recommended, as it can inhibit the intracellular phosphorylation of stavudine. Other anti-HIV drugs do not possess this property.

Adverse events

The main severe adverse effect is peripheral neuropathy, which can be corrected by reducing dosage. Stavudine has been shown in laboratory test to be genotoxic, but with clinical doses its carcinogenic effects are non-existent. It is also one of the most likely antiviral drugs to cause lipodystrophy, and for this reason it is no longer recommended as a component of first line therapy.

CONTRA-INDICATIONS

STAVUDINE is contra-indicated in patients with hypersensitivity to stavudine or to any of the components in the formulation.

Pregnancy and Lactation

Safety in pregnancy has not been established. Studies in animals suggest that stavudine is excreted in milk. Because of both the potential for HIV transmission and the potential for side-effects in breast-feeding infants, Stavudine is not recommended for use by breast-feeding mothers.

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WARNINGS

Less frequent cases of lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogues alone or in combination, including Stavudine and other antiretrovirals. Obesity and prolonged nucleoside exposure may be risk factors. The majority of cases reported have been in women and fatal lactic acidosis has been reported in pregnant women who received

the combination of Stavudine and didanosine with other antiretrovirals. Caution should be exercised when prescribing Stavudine to patients with known risk factors for liver disease.

Patients with risk factors and those being given a combination of Aspen Stavudine, didanosine and hydroxyurea should be closely monitored for liver toxicity.

Peripheral neuropathy is a dose-related clinical toxicity that is characterized by numbness, tingling or pain in the hands and feet. Therapy should be withdrawn immediately. Symptoms may temporarily worsen following discontinuation of Aspen Stavudine. Should symptoms resolve satisfactorily, then a lower dose therapy may be considered.

Patients with either a history of neuropathy, or in the advanced stages of HIV infection or those using combination therapy of Stavudine with didanosine, are at greater risk for peripheral neuropathy and should be monitored closely.

Pancreatitis, either fatal or non-fatal, has been reported in patients on combination therapy with didanosine (with or without hydroxyurea). Combination therapy should be suspended should pancreatitis be suspected and reinstitution of stavudine therapy alone, once diagnosis is confirmed, should be undertaken with particular caution and close patient monitoring.

Dosage

1 tablet twice daily for patients weighing < 60 kg

Presentations

10 tablets Pack 60 tablets Pack

<u>Note</u>: This product information is intended only for residents of the India. Taj Pharmaceuticals Limited, medicines help to treat and prevent a range of conditions—from the most common to the most challenging—for people around the world.

Information for Health Care Professionals

*** Please consult local Prescribing Information for any product before use. This website is an international information resource for healthcare professionals with an interest in disease management.

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