**Stavudine Capsules, USP**

(Patient Information Leaflet included)

**Warning**

Stavudine is a nucleoside reverse transcriptase inhibitor (NRTI), which is a class of antiretroviral medications that interfere with the production of HIV by preventing the viral enzyme reverse transcriptase from converting HIV RNA to DNA (see section 18). Stavudine may cause bone marrow suppression, including decreases in white blood cell count and platelet count, and may cause pancreatitis and peripheral neuropathy.

**Description**

Stavudine capsules, USP (NRTI) is a white or off-white, oval, capsule-shaped, hard gelatin capsule containing stavudine dihydrogen phosphate (HPLC-purity ≥ 90%). Each capsule contains 0.5 mg, 1 mg, 2 mg, and 4 mg of stavudine. The capsules are available in packages of 100 capsules (0.5 mg, 1 mg, 2 mg, 4 mg).

**Indications**

Stavudine is indicated for the treatment of HIV-1 infection in adults and pediatric patients aged 12 years and older. Stavudine is an component of combination antiretroviral therapy (ART) regimens and is usually used in conjunction with other antiretroviral drugs and possibly non-nucleoside reverse transcriptase inhibitors (NNRTI) or protease inhibitors (PI).

**Contraindications**

Stavudine is contraindicated in the following situations:

- Hypersensitivity to stavudine, other NRTIs, or any component of Stavudine Capsules
- Severe bone marrow suppression (WBC count < 300 cells/mm³, platelet count < 10,000 cells/mm³)
- Severe pancreatitis

**Warnings**

- Severe bone marrow suppression: Patients with a history of bone marrow suppression or a low WBC count (< 3000 cells/mm³) may have an increased risk of developing severe bone marrow suppression.
- Severe pancreatitis: Patients with a history of pancreatitis may have an increased risk of developing severe pancreatitis.

**Adverse Reactions**

Stavudine may cause bone marrow suppression, including decreases in white blood cell count and platelet count. Other adverse reactions may include:

- Nervous system: Peripheral neuropathy, paresthesia, sensory neuropathy
- GI: Diarrhea, nausea, vomiting, abdominal pain
- Skin: Rash, pruritus

**Labs**

- WBC count: Monitor weekly or biweekly during the first 12 weeks of treatment and periodically thereafter
- Platelet count: Monitor weekly or biweekly during the first 8 weeks of treatment and periodically thereafter

**Interactions**

Stavudine may interact with other medications, including amiodarone, cyclosporine, voriconazole, and others. Patients should inform their healthcare provider of all medications they are taking.

**Dosage and Administration**

Stavudine should be administered under the supervision of a healthcare provider who is experienced in the treatment of HIV-1 infection. The recommended dosage for adults and pediatric patients aged 12 years and older is 1 mg, 2 mg, or 4 mg once daily.

**Precautions**

Stavudine should be used with caution in patients with a history of bone marrow suppression or a low WBC count (< 3000 cells/mm³) and in patients with a history of pancreatitis.

**Storage**

Stavudine capsules should be stored at room temperature (15° to 30°C) and protected from light.

**Legal Information**

This information is not intended to replace the advice of a healthcare provider. All patients should be advised to consult their healthcare provider for information regarding the proper use of Stavudine Capsules, USP.
null
This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Chan Park
12/24/2008 10:23:41 AM
LABELING REVIEWER

Lillie Golson
12/24/2008 02:24:43 PM
LABELING REVIEWER