

# STAVUDINE CAPSULES 30MG

Stavudine (30mg)

## What is in this leaflet

1. What Stavudine Capsules 30mg are used for
2. How Stavudine Capsules 30mg work
3. Before you use Stavudine Capsules 30mg
4. How to take Stavudine Capsules 30mg
5. While you are using Stavudine Capsules 30mg
6. Side Effects
7. Storage and Disposal of Stavudine Capsules 30mg
8. Product description
9. Manufacturer and Product Registration Holder
10. Date of Revision

## What Stavudine Capsules 30mg are used for

Stavudine Capsules belongs to a particular group of antiviral medicines, also known as antiretrovirals, called nucleoside reverse transcriptase inhibitors (NRTIs).

These are used to treat Human Immunodeficiency Virus (HIV) infection.

## How Stavudine Capsules 30mg work

This medicinal product, in combination with other antiretrovirals, reduces the HIV viral load and keeps it at a low level. It also increases CD4 cell counts. These CD4 cells play an important role in maintaining a healthy immune system to help fight infection. Response to treatment with Stavudine Capsules varies between patients. Your doctor will therefore be monitoring the effectiveness of your treatment.

Stavudine Capsules may improve your condition, but it is not a cure for your HIV infection. Treatment with Stavudine Capsules has not been shown to reduce the risk of passing HIV infection on to others by sexual contact or by blood transfer. Therefore, you must continue to take appropriate precautions to avoid giving the virus to others.

During treatment, other infections linked to a weakened immunity (opportunistic infections) may arise. These will require specific and sometimes preventive treatment.

## Before you use Stavudine Capsules 30mg

### -When you must not use it

Do not take Stavudine Capsules if:

If you are allergic (hypersensitive) to stavudine or any of the other ingredients of Stavudine Capsules. Contact your doctor or pharmacist for advice.

### -Before you start to use it

Take special care with Stavudine Capsules

- if you suffer from kidney disease or liver disease (such as hepatitis),
- if you have had peripheral neuropathy (persistent numbness, tingling, or pain in the feet and/or hands), or
- if you have suffered from pancreatitis (inflammation of the pancreas).

The class of medicines to which Stavudine Capsules belongs (NRTIs) can cause a sometimes fatal condition called lactic acidosis, together with an enlarged liver. This condition usually does not occur until a few months after onset of treatment. In addition, rare cases of liver failure/renal failure or fatal hepatitis have been reported.

Patients with chronic hepatitis B or C and treated with antiretroviral agents are at increased risk for severe and potentially fatal liver side effects and may require blood tests for control of liver function.

If you develop one of the following, contact your doctor:

- persistent numbness, tingling or pain in feet and/or hands (this may indicate the beginning of peripheral

neuropathy, an adverse effect on the nerves), muscular weakness or

- abdominal pain, nausea or vomiting, or
- rapid deep breathing, drowsiness (which may indicate pancreatitis, liver disturbance such as hepatitis, or lactic acidosis).

## Pregnancy and breast-feeding:

### Pregnancy

If you become pregnant, or are planning to become pregnant, you must contact your doctor to discuss the potential side effects and the benefits and risks of your antiretroviral therapy to you and your child. Lactic acidosis (sometimes fatal) has been reported in pregnant women who received Stavudine Capsules in combination with other antiretroviral treatment.

If you have taken Stavudine Capsules during your pregnancy, your doctor may request regular visits to monitor the development of your child. Such visits may include blood tests and other diagnostic tests.

### Breast-feeding

Tell your doctor if you are breast-feeding. It is recommended that HIV-infected women should not breast-feed under any circumstances in order to avoid transmission of HIV to the baby.

## Important information about some of the ingredients of Stavudine Capsules:

These capsules contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

### -Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Always check with your doctor or pharmacist before you want

# STAVUDINE CAPSULES 30MG

Stavudine (30mg)

to start with any medicine or health supplement as they will have a more complete and detail list of medicines that may interact with Stavudine if taken together.

## How to take Stavudine Capsules 30mg

### -How much to take

#### Adults

The recommended dose is based on body weight:-

> 60kgs : 40mg twice daily

< 60kgs : 30mg twice daily

#### Children

Children weighing 30kg or more should receive the recommended adult dosages.

### -When to take it

Your doctor has defined your daily dose based on your weight and individual characteristics.

Please take this medicine according to your doctor's advice.

### -How long to take it

Always take Stavudine Capsules exactly as your doctor has told you. You should check with your doctor if you are not sure.

### -If you forget to take it

If you accidentally miss a dose, please take it as soon as you remember but if it is near to the next dosing time, then simply take your normal dose at the next dosing time. Do not take a double dose to make up for a forgotten dose.

### -If you take too much (overdose)

If you have taken too many capsules or if someone accidentally swallows some, you should contact your doctor or the nearest hospital for advice.

## While you are taking Stavudine Capsules 30mg

### -Things you must do

Please follow your dosage recommendations closely as they will give you the best

chance to delay development of a resistance to the medicinal product.

### -Things you must not do

Do not change the dose on your own. Continue to take this medicine until your doctor tells you otherwise.

Stavudine Capsules may cause dizziness and drowsiness. If you are affected, do not drive and do not use any tools or machines.

### -Things to be careful of

**Bone problems:** some patients taking Stavudine Capsules may develop a bone disease called osteonecrosis (death of bone tissue caused by loss of blood supply to the bone). The length of combination antiretroviral therapy, corticosteroid use, alcohol consumption, severe immunosuppression, higher body mass index, among others, may be some of the many risk factors for developing this disease. Signs of osteonecrosis are joint stiffness, aches and pains (especially of the hip, knee and shoulder) and difficulty in movement. If you notice any of these symptoms please inform your doctor.

### **Side Effects**

Like all medicines, Stavudine Capsules can cause side effects, although not everybody gets them.

When treating HIV infection, it is not always possible to differentiate between unwanted effects caused by Stavudine Capsules, or those caused by any other medicines you may be taking at the same time, or by the complications of the infection. For this reason, it is important that you inform your doctor of any change in your health.

Therapy for HIV including stavudine often causes changes in body shape due to changes in fat distribution. These may include loss of fat from legs, arms and face (lipoatrophy), and

development of fatty lumps on the back of the neck ("buffalo hump"). Your doctor should monitor for clinical signs and symptoms of changes in your body shape. Tell your doctor if you notice any changes in your body shape or loss of fat from your legs, arms, and face. When these signs occur, consideration should be given to discontinuing Stavudine Capsules treatment.

Patients treated with Stavudine Capsules have reported the following side effects:

### **Common:**

- depression
- peripheral neurologic symptoms including peripheral neuropathy, paresthesia, and peripheral neuritis (numbness, weakness, tingling or pain in the arms and legs)
- dizziness, abnormal dreams, headache
- insomnia (difficulty sleeping), somnolence (sleepiness), abnormal thinking
- diarrhoea, abdominal pain (stomach pain of discomfort),
- nausea, dyspepsia (indigestion)
- rash, pruritus (itching)
- fatigue (extreme tiredness)

### **Uncommon**

- symptomatic hyperlactatemia (build-up of lactic acid in your blood)

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website [portal.bpfk.gov.my](http://portal.bpfk.gov.my) (Consumers → Reporting).

## Storage and Disposal of Stavudine Capsules 30mg

### -Storage

Store below 25°C. Protect from light. Keep in a well-closed container.

# STAVUDINE CAPSULES 30MG

Stavudine (30mg)

---

## -Disposal

Do not use after the expiry date stated on the label.

Return any unused capsules to your pharmacist to be disposed of. Only keep the tablets if your doctor tells you to. Do not throw them away in your normal household drainage or waste. This will help to protect the environment.

## **Product Description**

### -What it looks like

Stavudine Capsules 30mg are White to off-white colored free flowing powder filled in size '2' hard gelatin capsules with Blue cap white body printed S30 on cap and body.

### -Ingredients

Active ingredient

The active ingredient is stavudine. Each capsule contains Stavudine 30mg.

Inactive ingredients

The tablets also contain the following other ingredients:

Microcrystalline cellulose, Anhydrous lactose, Sodium starch glycolate, Colloidal anhydrous silica, Magnesium Stearate.

### -MAL Number

MAL11030015AZ

## **Manufacturer**

Strides Arcolab Limited  
36/7, Suragajakkanahalli,  
Indlavadi Cross, Anekal Taluk,  
Bangalore-562 106, INDIA.

## **Product Registration Holder**

Actavis Sdn Bhd  
C/o Allergan Malaysia Sdn Bhd  
Level 5-02, Block A, PJ 8,  
No. 23, Jalan Barat Section 8,  
46050 Petaling Jaya,  
Selangor, Malaysia

## **Date of Revision**

09-09-2015

## **Serial Number**

BPFK(R4/1)080915/00308