

# SLN 30 TABLET

Stavudine/Lamivudine/Nevirapine (30mg/150mg/200mg)

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## What SLN 30 Tablet is used for

The name of your medicine is SLN 30. It contains three active ingredients namely stavudine, lamivudine, and nevirapine. These medicines are antiviral medicines, also known as antiretrovirals.

SLN 30 is used as antiretroviral combination therapy for the treatment of HIV infection. It is used to slow down the progression of Human Immunodeficiency Virus (HIV) infection. HIV can lead to Acquired Immunodeficiency Syndrome (AIDS) and other related illnesses.

Treatment with SLN 30 will only be prescribed by your doctor or health care provider when you have been shown to be stable on the three individual medications. SLN 30 reduces the amount of HIV in your body, and keeps it at a low level. It also increases CD4 cell counts. CD4 cells are a type of white blood cells that play an important role in maintaining a healthy immune system to help fight infection.

Response to treatment with SLN 30 varies between patients. Your doctor or health care provider will be monitoring the effectiveness of your treatment.

## How it works

Stavudine and lamivudine are in a class of medications called nucleoside reverse transcriptase inhibitors (NRTIs). Nevirapine is in a class of medications called non-nucleoside reverse transcriptase inhibitors (NNRTIs). They work by inhibiting or interrupting the enzyme reverse transcriptase that the HIV virus uses to multiply.

## Before you take SLN 30

### - When you must not take it

Do not take SLN 30 if you have ever had an allergic reaction to:

- any medicine containing stavudine, lamivudine or nevirapine
- any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body, rash, itching or hives on the skin.

Do not take this medicine if you are pregnant or trying to become pregnant without first talking to your doctor. Your doctor can discuss with you the risks and benefits of taking this medicine if you are pregnant.

Breastfeeding is not recommended while you are taking SLN 30. Talk to your doctor if you have any questions about pregnancy or breastfeeding.

Do not take SLN 30 if you have:

- severe liver problems
- just be given nevirapine because there is a lead-in dose of nevirapine 200mg once a day while this product contains the maintenance dose of Nevirapine 200mg twice a day.
- previously experienced serious liver or skin reactions while taking nevirapine-containing products.

Do not take preparations containing St John's Wort (*hypericum perforatum*) and Rifampicin (anti-tuberculosis medicine) while taking SLN 30.

### - Before you start to take it

Tell your doctor if you are allergic to any other medicines or any foods, dyes or preservatives.

Tell your doctor if you have or have had any of the following medical conditions:

- liver problems, liver disease or hepatitis
- abnormal liver function tests
- undergoing dialysis treatment
- diabetes
- kidney disease
- persistent tingling or numbness or pain in the feet and/or hands (peripheral neuropathy)
- inflammation of the pancreas (pancreatitis)

If you have not told your doctor about any of the above, tell them before you use SLN 30.

### - Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. Some medicines may interfere with SLN 30. These include:

- other anti-HIV medicines
- some antibiotic medicines such as rifampicin or rifabutin
- some antifungal medicines such as fluconazole and ketoconazole
- methadone for severe pain
- oral contraceptives
- warfarin and other medicines used to thin the blood

Consult your doctor or pharmacist if you are not sure as they will have a more detail and complete list of

medicines that will interact with SLN 30 if taken together.

### How to take SLN 30

#### - How much to take

*The recommended dose of SLN 30 in adults:*

One tablet taken twice daily.

SLN 30 is not suitable for patients requiring dosage adjustment. If you have low body weight (<50kg), you may not be suitable to take SLN 30 because appropriate dose reduction cannot be made.

#### *Elderly*

Special care is advised in the elderly due to changes associated with aging, such as decreased kidney function.

#### - When to take it

Swallow the tablets whole (not chewed) with a full glass of water.

The tablets can be taken with or without food.

#### - How long to take it

Continue taking your medicine for as long as your doctor tells you. Because this medicine helps to control your condition, but does not cure it, take SLN 30 every day, as prescribed by your doctor.

#### - If you forget to take it

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

If you are not sure what to do, ask your doctor or pharmacist.

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

Telephone your doctor, or go to Accident and Emergency at your nearest hospital immediately if you think that you or anyone else may have taken too much SLN 30. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

### While you are using SLN 30

#### - Things you must do

SLN 30 may cause serious skin and allergic reactions, which in the worst case can be life-threatening. Fatalities have been reported. Such reactions may appear in form of rash accompanied by other side effects such as fever, blistering, mouth sores, eye inflammation, facial swelling, general swelling, muscle or joint aches, a reduction in white blood cells (granulocytopenia), general feelings of illness or severe problems with liver or kidneys.

If you experience a severe rash or any rash associated with other side effects of an allergic reaction, as described above, you should discontinue taking SLN 30 right away and must contact your doctor immediately.

The first 18 weeks of therapy are a critical period to monitor the potential appearance of severe and life-threatening skin reactions or serious liver failure. The greatest risk occurs in the first 6 weeks of therapy.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking SLN 30. If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

#### - Things you must not do

Do not give SLN 30 to anyone else, even if they have the same condition as you.

Do not use SLN 30 to treat any other complaints unless your doctor tells you to.

Do not stop taking your medicine or change the dosage without checking with your doctor.

#### - Things to be careful of

Be careful driving or operating machinery until you know how SLN 30 affects you.

This medicine may cause fatigue or drowsiness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

### Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking SLN 30.

Short-term adverse reactions to combination antiretroviral therapy are common. After you start taking SLN 30 headache, nausea and vomiting, abdominal pain, diarrhea and fatigue may occur.

The most serious side effects of SLN 30 are severe and life-threatening skin reactions and serious liver injuries.

The *most commonly* reported side effects are headache and nausea.

Other *common* side effects are fatigue, vomiting, stomach pain, dyspepsia (indigestion), diarrhoea, fever, rash (red, raised or itchy), increased blood concentrations of fats, joint pain, muscle pain and other muscle disorders, general aches and pains, dizziness, drowsiness, difficulty sleeping, depression, abnormal thinking, hair loss, anaemia (low red blood cell count), and neutropenia (low white blood cell count).

The following side effects are *uncommon*: loss of appetite, flatulence, inflammation of the pancreas, inflammation of the liver (hepatitis), yellowing of the skin and whites of the eyes, urticaria, cough, feeling anxious, emotional liability, general weakness, and decreased numbers of platelets (blood cells important for blood clotting). If you have a low platelet count you may notice that you bruise more easily.

There are *rare* reports of breakdown of muscle tissue, hyperglycaemia (high sugar levels in the blood), hepatic steatosis (fat in the liver) and breast enlargement in male patients.

*Very rarely* diabetes mellitus, liver failure, motor weakness (most often reported in the setting of symptomatic hyperlactataemia or lactic acidosis syndrome) and a blood disorder called pure red cell aplasia have been reported.

In some patients with advanced HIV infection (AIDS) and a history of opportunistic infection, signs and symptoms of inflammation from previous infections may occur soon after anti-HIV treatment is started.

Cases of liver problems including jaundice (yellowing of the skin and/or eyes), hepatitis, severe and life threatening liver dysfunction (including fulminant hepatitis and liver failure) have been reported in patients being treated with nevirapine. Symptoms of liver problems may include jaundice (yellowing of the skin or eyes), dark coloured urine, light coloured stools, nausea, vomiting, pain or sensitivity to touch in the right abdominal area (below the ribs), loss of appetite or feeling generally unwell.

Women and patients with higher CD4 cell counts are at increased risk of liver adverse events.

Lactic acidosis, usually associated with liver enlargement has been reported. Early symptoms include nausea, vomiting, abdominal pain, non-specific malaise, loss of appetite, and weight loss. Lactic acidosis has a high mortality and may be associated with pancreas inflammation, kidney/liver failure or motor paralysis. If you are co-infected with hepatitis C and treated with alpha interferon and ribavirin, you may constitute a special risk. Stop taking SLN 30 and visit your doctor immediately if you encounter any sign/symptom mentioned above.

Talk to your doctor or pharmacist if you are not sure, as they will have a more detail and complete explanation on the

possible side effects, including those not listed here

**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 SLN 30

#### - Storage

Keep the tablets in a cool dry place where the temperature stays below 25°C.

Keep it where young children cannot reach it.

#### - Disposal

Ask your pharmacist what to do with any tablets you have left over if your doctor tells you to stop taking them, or you find that the expiry date has passed.

### Product description

#### - What SLN 30 looks like

A green colour, 13mm round tablet, with marking of a small and a big 'd' on either side.

#### - **Ingredients**

Active Ingredient:

Each tablet contains Stavudine 30mg; Lamivudine 150mg; Nevirapine 200mg.

Inactive Ingredients:

- *Lactose*
- *Crospovidone*
- *Magnesium Stearate*
- *Aerosil*
- *Avicel*
- *Promigel*
- *Quinoline Yellow*
- *Tween 80*
- *Polyvinylpyrrolodone (PVP)*
- *Brilliant Blue*

- MAL Number :  
MAL05090024AZ

### Manufacturer

**DUOPHARMA (M) SDN. BHD. (42491-M)**  
WHOLLY OWNED BY CCM  
DUOPHARMA BIOTECH BERHAD  
(524271-W)  
Lot. 2599, Jalan Seruling 59, Kawasan 3, Taman Klang Jaya, 41200 Klang, Selangor Darul Ehsan, Malaysia.

### Product Registration Holder

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### Date of Revision

09/12/2015

### Serial Number

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