

ZERIT® Capsules

(Zer-it)

Stavudine (d4T) (Stav-u-deen)

Consumer Medicine Information

What is in this leaflet

Read this leaflet carefully before taking Zerit. This leaflet answers some common questions about Zerit.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Zerit against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Zerit is used for

Zerit is a trade name (manufacturer's name) for the medicine, stavudine. Zerit belongs to a group of medicines called nucleoside (NUKE-lee-O-side) analogues. You may also know stavudine as "d4T".

Zerit is used to treat adults and children infected with Human Immunodeficiency Virus (HIV).

What is HIV:

HIV is a virus that kills important cells in the immune system over time (e.g. CD4 cells). When enough of the immune cells have been killed by HIV, your body becomes prone to certain types of infections. Some infections are the cause of

"AIDS-defining" illnesses. This is when someone is said to have developed the Acquired Immunodeficiency Syndrome or AIDS. AIDS is a serious condition and can lead to death.

How Zerit Works

When HIV infects cells in the immune system, it takes over part of the cell's internal workings and uses building blocks in the cells to produce new viruses.

Zerit is a "pretend" building block called a nucleoside analogue. When HIV infects a healthy cell it can pick up Zerit instead of the cell's real building block, stopping HIV from producing more viruses. Interfering with the production of new viruses helps to reduce the total amount of HIV in the body and slows down the damage to the immune system.

Zerit is not a cure for HIV infection. Taking it will not necessarily prevent the illnesses that commonly occur in people with HIV infection or AIDS. You can still infect other people with HIV while you are taking this medicine.

It is not known how safe Zerit is when it is used for long periods.

Your doctor may have prescribed Zerit for another reason. Ask your doctor if you have any questions about why Zerit has been prescribed for you.

Zerit is not addictive. This medicine is available only with a doctor's prescription.

Before you take Zerit

It is important that you check the information below before you take Zerit.

When you must not take Zerit

Do not take Zerit if you have an allergy to it or to any ingredients in the formulation listed at the end of this leaflet.

Do not take Zerit if you are currently taking zidovudine (AZT) as the medicines may interact with each other. Your doctor will discuss this with you.

Do not take Zerit in combination with hydroxyurea and didanosine as this combination can severely affect your liver.

Do not take Zerit with another nucleoside medicine called Videx EC.

Do not use Zerit after the expiry date printed on the back of the pack. If this medicine is taken after the expiry date has passed, it may not work as well.

Do not take Zerit if the packaging is torn or shows signs of tampering.

Before you start to take Zerit

Tell your doctor if you:

1. have allergies to:
 - other medicines from the nucleoside analogue group such as zidovudine (AZT)
 - any other medicines you have been given or purchased
 - substances such as foods, preservatives or dyes.
- Symptoms of an allergic

reaction may include:
swelling of the face, lips, tongue or throat which may cause difficulty in swallowing or breathing, or severe and sudden onset of pinkish, itchy swellings on the skin, also called hives;

2. are pregnant or intend to become pregnant.

Experience is limited with the use of Zerit in pregnant women. Therefore, it should not be used during pregnancy unless it is clearly needed. If there is an urgent need to consider Zerit during pregnancy, your doctor will discuss with you the benefits and risks of taking it;

3. are breast feeding or planning to breast-feed.

It is not known whether Zerit passes into breast milk. Therefore to avoid possible side effects in the nursing infant, mothers should stop breast-feeding if they are taking Zerit (breast-feeding can also transfer HIV to babies);

4. currently experience or have experienced any medical conditions especially:

- peripheral neuropathy, a condition with tingling, burning pain, or numbness of the hands or feet
- pancreatitis, inflammation of the pancreas which may cause severe upper stomach pain, often with nausea and vomiting
- liver problems including hepatitis, yellowing of the skin or eyes (jaundice) or prior use of medicines toxic to the liver. Liver problems may cause higher levels of Zerit in the blood, increasing the chance of side effects. The safety and effectiveness of Zerit in patients with liver problems has not been established.
- skin rashes or other allergic reactions to products related to Zerit (ie other types of nucleoside analogues)
- kidney problems.

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

It is not known how safe Zerit is when used over long periods.

Your doctor may stop Zerit if you develop:

- peripheral neuropathy, a condition that causes numbness, burning pain, motor weakness, tingling or weakness in the hands or feet
- unstable liver disease, increasing liver enzyme levels in the blood
- increasing lactic acid levels in the blood, this may be indicated by digestive symptoms such as nausea, vomiting and pain in the abdomen; by difficulty breathing, shortness of breath or faster or irregular breathing; or by weakness in muscles or difficulty moving.

There may be other reasons why your doctor may decide to stop Zerit. Speak to your doctor if you have any concerns.

Taking other medicines

Tell your doctor if you are taking other medicines, including vitamin supplements, herbal preparations or any medicines you buy without a prescription from your pharmacy, supermarket or health food shop.

Tell your doctor if you are taking zidovudine (AZT). AZT and Zerit may interfere with each other.

Tell your doctor if you are taking hydroxyurea and didanosine together before you take Zerit. Taking these three medicines together (Zerit, hydroxyurea and didanosine) can severely affect your liver. These medicines should not be taken together.

Tell your doctor if you are taking doxorubicin or ribavirin.

There is little information available about how other medicines might affect the way Zerit works. Nevertheless, some medicines or treatments may be affected by Zerit, or may affect how well it works.

Tell both your doctor and pharmacist about any other medicines that you take, even if you have bought the medicines without a doctor's prescription. You may need different amounts of your medicine, or you may need to take different medicines.

It is very important that you do not take other medicines which might cause or worsen peripheral nerve disease (peripheral neuropathy) while taking Zerit.

Your doctor and pharmacist may have more information on medicines to be careful with, or to avoid while taking Zerit.

How to take Zerit

Zerit should be given only when prescribed by your doctor. Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

How much to take

The recommended starting dose of Zerit is determined by your body weight as follows:

For Adults:

Adults weighing equal to or greater than 60 kg: take 40 mg Zerit every 12 hours

Adults weighing less than 60 kg: take 30 mg every 12 hours

For Children:

Children weighing equal to or greater than 60 kg: take 40 mg Zerit every 12 hours.

Children weighing between 30-60 kg: take 30 mg Zerit every 12 hours

Children weighing less than 30 kg: take 1 mg of Zerit per kg of body weight, every 12 hours. (Zerit powder for Oral Solution is available)

For People with Peripheral Neuropathy or Liver Problems:

Your doctor may advise you to

immediately stop taking Zerit if you experience symptoms of peripheral neuropathy such as tingling, burning pain or numbness in the hands or feet. Symptoms may improve after you stop taking Zerit. You may have a temporary worsening of symptoms after stopping Zerit therapy.

If your symptoms of peripheral neuropathy improve satisfactorily, then your doctor may restart you on half the recommended dose.

Tell your doctor if you already have a liver problem.

People with liver problems should be treated with Zerit in the same way as people with peripheral neuropathy.

The safety and effectiveness of Zerit in patients with liver disease has not been established. In addition, the use of Zerit with other antiviral medication called hydroxyurea and didanosine should be avoided. Your doctor will be able to discuss the most suitable treatment option for you if you have a medical problem with your liver.

For People with Kidney Problems:

Read this section if you have a kidney complaint, otherwise you can proceed to the next section.

You can take Zerit if you have kidney problems. Under these circumstances, your dosage and how often you take Zerit depends on how well your kidneys are functioning. Your kidney function is assessed by blood and urine tests which measure the level of a substance called creatinine. The test of kidney function is termed a "creatinine clearance" test, this test and your body weight has to be taken into consideration when your doctor decides on the dose of Zerit for you.

People with kidney problems may need to take a reduced dose and/or increase the time between doses.

It is very important that you follow your doctors instructions about how

much, how often and for how long to take Zerit.

How to take it

Swallow the capsules whole with a drink such as a glass of water or fruit juice.

Zerit may be taken with or without food.

When to take Zerit

You may take Zerit Capsules at any time. It is recommended, however, that you take your medicine at about the same time each day. Taking Zerit at the same time each day will have the best effect. It will also help you remember when to take the capsules.

For people with kidney failure being treated with haemodialysis, take Zerit after your haemodialysis session has finished.

On days when you do not receive dialysis, Zerit should be taken at the same time of day as it is on days when you receive dialysis.

Talk to your doctor or pharmacist to work out when it is best for you to take your doses of Zerit.

How long to take it

Zerit helps control your condition but does not cure it. Therefore you must take Zerit every day as directed by your doctor. Continue taking Zerit for as long as your doctor tells you to.

Do not stop taking Zerit unless your doctor tells you to - even if you feel better.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take the next dose when you are meant to.

Otherwise take it as soon as you remember, and then go back to taking it as you would normally.

Do not take a double dose to make up for the dose you missed. This may increase the chance of you

getting an unwanted side effect. If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints and inform your doctor that you have missed a dose. It is very important not to miss your doses of Zerit. If you miss doses the virus may become resistant to your HIV medicines.

If you take too much (overdose)

Immediately call your doctor or the Poisons Information Centre on 131126 in Australia or go to the Accident and Emergency Centre at your nearest hospital if you or anyone else takes too much Zerit.

Do this even if there are no signs of discomfort or poisoning.

While you are using Zerit

Things you must do

- If you become pregnant while taking Zerit, tell your doctor immediately. Pregnant women have experienced serious side effects when taking stavudine (the active ingredient in Zerit) in combination with Videx®(didanosine).
- If you are about to start taking any new medicines, tell your doctor and pharmacist that you are taking Zerit. Zerit may interfere with the medicine you are taking.
- If you are about to have any medical tests, tell your doctor that you are taking Zerit. Zerit may interfere with the results of these tests.
- If you plan to have surgery, tell your doctor or dentist that you are taking Zerit. You may wish to discuss disclosure issues with

your doctor about who should know you are taking Zerit.

- You should have your kidney and liver functions and blood tested when your doctor advises on a regular basis to ensure that your body chemistry is functioning normally and that Zerit is working.

Things you must not do

- Do not give Zerit to anyone else, even if they have the same condition as you.
- Do not use Zerit to treat any other complaints unless your doctor tells you to.
- Do not stop taking Zerit or lower the dosage without checking with your doctor. Your doctor may gradually want to reduce the amount of Zerit you are taking before stopping completely.

Things to be careful of

- Be careful driving or operating machinery until you know how Zerit affects you. Some patients taking Zerit have experienced dizziness. It is not known if this was caused by Zerit. Make sure you know how you react to Zerit before you drive a car, operate machinery or do anything else that could be dangerous if you are dizzy.
- Make sure that you visit your doctor regularly throughout your entire course of treatment with Zerit.

Things that may help your condition

Things that may help your general health are suggested below:

- exercise
- healthy eating
- stress reduction
- counseling
- regular visits to your doctor to monitor your health
- good oral hygiene

- support groups

Talk with your doctor about all of the above suggestions. You can also access further information about HIV and services for people with HIV by contacting your local AIDS Council, Positive Living Centre or PLWHA organisation.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Zerit. Zerit helps most people with HIV infection but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects

Ask your doctor or pharmacist to answer any questions you may have.

If any of the following happen, stop taking Zerit and tell your doctor immediately, or go to the Accident and Emergency Centre at your nearest hospital:

- swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing
- hives
- fainting
- liver problems including yellowing of the skin or eyes, also called jaundice
- lactic acidosis - symptoms include nausea, vomiting, unusual or unexpected stomach discomfort, feeling very weak and tired, short of breath, or weakness in arms and legs.

These are very serious side effects. If you have them, you may have had a serious reaction to Zerit. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the Accident and Emergency

Centre at your nearest hospital if you experience any of the following:

- inflammation of the pancreas (pancreatitis) which may cause severe upper stomach pain, often with nausea and vomiting
- peripheral neuropathy which causes tingling, burning pain or numbness in the hands and/or feet
- feeling generally unwell with faster or irregular breathing or shortness of breath, nausea, vomiting and/or abdominal pain
- enlarged liver which is tender to the touch (hepatomegaly)
- weakness, or pain and weakness when you try to move

Tell your doctor if you notice any of the following:

- sleeplessness (insomnia)
- headache, chills or fever
- rash
- soreness in the joints (arthralgia)
- diarrhoea, nausea or vomiting
- flu-like symptoms
- back pain
- swollen glands in the neck, armpit and groin (lymphadenopathy)
- unusual tiredness, weakness or muscle aches
- bruising easily, tendency to get infections, tired and/or breathless
- Redistribution or accumulation of body fat, central obesity, peripheral wasting, buffalo hump or facial wasting, breast enlargement

Other side effects not listed above may also occur in some patients.

Tell your doctor if you notice anything that is making you feel unwell. Do not be alarmed by this list of possible side effects. You may not experience any of them or only some of them.

After using Zerit

Storage

Store Zerit capsules in a cool dry place where the temperature stays below 30°C.

Keep your capsules in the bottle until it is time to take them. If you take the capsules out of the bottle they may not keep as well.

Do not store Zerit or any other medicine in the bathroom or near the kitchen sink. Do not leave it in the car. Heat and dampness can destroy some medicines.

Keep Zerit capsules where children cannot reach them. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking Zerit capsules, or the capsules have passed their expiry date, ask your pharmacist what to do with any that are left over.

- Zerit 20 mg capsules - 20 mg of stavudine per capsule
- Zerit 30 mg capsules - 30 mg of stavudine per capsule
- Zerit 40 mg capsules - 40 mg of stavudine per capsule

Other ingredients:

microcrystalline cellulose, sodium starch glycolate, lactose and magnesium stearate.

The capsule shell is made from gelatin, methyl and propyl hydroxy benzoates, titanium dioxide and iron oxides.

Sponsored by

Bristol-Myers Squibb Australia Pty Ltd,
4 Nexus Court, Mulgrave,
Victoria 3170, Australia

Date of Preparation: April 2017

®Zerit is a registered trademark of a Bristol-Myers Squibb Company.

This information in no way replaces the advice of your doctor or pharmacist.

AU_CMI_Zerit
Cap_V10_Apr17.docx

Product description

What it looks like

Zerit Capsules come in three types of capsules:

- Zerit 20 mg capsules - light brown capsules, marked BMS 1965 20 in black ink (AUST R 54299)
- Zerit 30 mg capsules - light and dark orange capsules, marked BMS 1966 30 in black ink (AUST R 54300)
- Zerit 40 mg capsules - dark orange capsules, marked BMS 1967 40 in black ink (AUST R 54301)

Ingredients

Each capsule contains:

Active ingredients: