SCHEDULING STATUS: S4

ZOVILAM film-coated tablets

Lamivudine/Zidovudine

Sugar free

Read all of this leaflet carefully before you start taking ZOVILAM

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- ZOVILAM has been prescribed for you personally and you should not share your medicine with other people. It may harm then, even if their symptoms are the same as yours.

What is in this leaflet

1. What ZOVILAM is and what it is used for
2. What you need to know before you take ZOVILAM
3. How to take ZOVILAM
4. Possible side effects
5. How to store ZOVILAM
6. Contents of the pack and other information

1. What ZOVILAM is and what it is used for

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

ZOVILAM does not completely cure HIV infection; it reduces the amount of virus in your body and keeps it at a low level. It also increases the CD4 cell count in your blood. CD4 cells are a type of white blood cells that are important in helping your body to fight infection.

ZOVILAM is also used as a prophylaxis against occupation exposure, such as disposal of sharp objects

(for instance needles and scalpels).

2. What you need to know before you take ZOVILAM

Do not take ZOVILAM

- If you are hypersensitive (allergic) to lamivudine or zidovudine or any of the other ingredients of ZOVILAM tablets (listed in section 6).
- If you have a very low red blood cell count (anaemia) or a very low white blood cell count (neutropenia).
- If you are taking ZOVILAM tablets, you must not take it with stavudine, zalcitabine or ribavirin.
- ZOVILAM should not be given to children of younger than 12 years.
- ZOVILAM should not be taken with any other medicines containing lamivudine or medicines containing emtricitabine.

Warnings and precautions

Take special care with ZOVILAM:

- Not everyone responds to treatment with ZOVILAM in the same way. The doctor will monitor the effectiveness of your treatment and if necessary separate preparations of lamivudine and zidovudine will be given where dosage adjustment is needed.
- You may develop very low red blood cell count, or a very low white blood cell count, especially if you have advanced HIV infection (AIDS), and because of this experience fever or chills when taking zidovudine and therefore, ZOVILAM.
- Inflammation of the pancreas have occurred in patients treated with lamivudine and zidovudine, and therefore, ZOVILAM, and because of this experience stomach pain, nausea and vomiting when taking zidovudine and therefore, ZOVILAM.
- ZOVILAM can cause a condition called lactic acidosis, together with an enlarged liver. This rare but serious side effect occurs more often in women. If you have liver disease you may also be more at risk of getting this condition while being treated with ZOVILAM. The doctor will monitor you for any signs of developing lactic acidosis. Possible signs of lactic acidosis are:
  - Deep, rapid breathing.
  - Drowsiness.

- Numbness or weakness in the limbs.
- Nausea, vomiting and stomach pain.
- Loss of appetite or weight loss.

- Your body shape may change. If you are taking combination antiretroviral therapy for HIV you may find that your body shape changes, because of changes in fat distribution:
  - Fat may be lost from your legs, arms or face.
  - Extra fat may build up around your tummy (abdomen), or on the breasts or internal organs.
  - Fatty lumps (sometimes called buffalo hump) may appear on the back of your neck.
  - If you notice changes in your body shape, tell your doctor.
- With HIV infection (AIDS) your immune system is weakened, and you are more likely to develop serious infections (opportunistic infections). When starting treatment, you may find that old, hidden infections flare up, causing signs and symptoms of inflammation, usually within the first three months of starting treatment. These symptoms are probably caused by the body's immune system becoming stronger, so that the body starts to fight these infections.
- If you have ever had liver disease, including hepatitis B or C (if you have hepatitis infection), you are at an increased risk of severe and potentially fatal liver effects and may require blood tests to monitor your liver function. Do not stop ZOVILAM without the doctor's advice, as the hepatitis may come back. If liver function abnormalities recur, ZOVILAM should be stopped permanently. Contact your doctor IMMEDIATELY if you experience any symptoms of liver problems, such as loss of appetite, nausea, vomiting, jaundice (yellowing of the skin and/or eyes), dark coloured urine, pale coloured stools, pain/ache or sensitivity to touch in your right abdominal area (below your ribs). These could be signs of serious liver dysfunction which your doctor will need to monitor closely.
- You must contact the medical practitioner if you experience joint aches and pain, joint stiffness or difficulty in movement. You may have bone problems. Some patients taking combination therapy for HIV develops a condition called osteonecrosis. With this condition, parts of the bone tissue die because of reduced blood supply to the bone.

  People may be more likely to get this condition:
  - If they have advanced HIV disease and/or have been taking combination therapy for a long time.
  - If they are also taking anti-inflammatory medicines called corticosteroids.

- If they drink alcohol.
- If their immune systems are very weak.
- If they are overweight.

- You may continue to develop other infections and other illnesses associated with HIV disease. You should therefore keep in regular contact with the medical practitioner while taking ZOVILAM.
- ZOVILAM helps to control HIV infection but is not a cure. You will need to take it every day. You must not stop taking ZOVILAM without first talking to the doctor. If you are concerned that you may be developing symptoms of a hypersensitivity reaction, call the doctor immediately who will advise whether you must stop taking ZOVILAM.

It must be realised that the use of ZOVILAM tablets do not reduce the risk of transmitting the HIV infection to others through sexual contact or by blood transfer. If you are sexually active, you should continue to use appropriate precautions to prevent this.

To protect other people from becoming infected with HIV:

- **A condom must be used** when someone has oral or penetrative sex.
- **Blood transfer should be avoided** – for example, needles must not be shared.

Children and adolescents

ZOVILAM must not be given to children younger than 12 years.

Other medicines and ZOVILAM

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

If you are taking the following medicines, your doctor may want to adjust the dosage of these medicines or change your ZOVILAM treatment:

- Sorbitol-containing medicines (usually liquids) which are used regularly.
- Amphotericin or co-trimoxazole (trimethoprim and sulfamethoxazole) (to treat fungal and bacterial infections).
- Zalcitabine (antiviral medicine).
- Ganciclovir (to treat viral infections).
- Foscarnet (this belongs to a group of medicines called antiviral medicines. It works by stopping viruses from multiplying in number and is used to treat different infections caused by viruses).

- Ciprofloxacin (an antibiotic).
- Emtricitabine (antiviral medicine).
- Cladribine (used to treat multiple sclerosis).
- Atovaquone (an antibiotic).
- Clarithromycin (an antibiotic which decreases the way your medicine works).
- Rifampicin (used to treat tuberculosis and other infections).
- Phenytoin (to treat epilepsy).
- Probenecid (to treat gout).
- Ribavirin (antiretroviral medicine).
- Stavudine (antiretroviral medicine).
- Paracetamol (to treat pain and inflammation).
- Aspirin (for relief of pain and reducing of inflammation, high temperature and fever.
- Codeine (used to relief pain, suppress coughs and treat diarrhoea).
- Morphine (for relief of severe pain).
- Methadone (for treating substance addiction and to treat moderate to severe pain).
- Indomethacin, ketoprofen and naproxen (relief of pain, to reduce swelling and ease inflammation).
- Oxazepam and lorazepam (treatment of anxiety).
- Cimetidine (decrease the natural production of acid in the stomach).
- Clofibrate (type of medicine called lipid-regulating medicine, which lower high levels of cholesterol and other fats in the blood.
- Dapsone (antibacterial medicine).
- Inosine pranobex (used in viral infections).
- Pentamidine (to treat parasitic infections).
- Pyrimethamine (to treat malaria and other parasitic infections).
- Aciclovir (antiviral medicine which works by stopping viruses from spreading).
- Valproic acid (to treat epilepsy).
- Flucytosine (to treat fungal infections).
- Interferon (to treat viral infections).
- Vincristine, vinblastine, adriamycin and doxorubicin (to treat cancer – these medicines may increase

the risk of toxicity with zidovudine, such as in ZOVILAM).

ZOVILAM with food and drink

You can take ZOVILAM with or without food.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or health care provider for advice before taking this medicine.

Pregnancy

The safe use of ZOVILAM in human pregnancy has not been established.

ZOVILAM and similar medicines may cause side effects in unborn babies. If you have taken ZOVILAM during your pregnancy, your doctor may request regular blood tests and other diagnostic tests to monitor the development of your child.

Breastfeeding

You must not take ZOVILAM because the active ingredients lamivudine and zidovudine and HIV pass into breast milk.

You should discontinue breastfeeding if you are taking ZOVILAM. It is recommended that HIV infected women must not breastfeed their infants under any circumstances in order to avoid the transmission of HIV.

Driving and using machines

It is not always possible to predict to what extent ZOVILAM may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which ZOVILAM affects them.

ZOVILAM can make you dizzy, and you may have other side effects that make you less alert. Do not drive or operate machines unless you are feeling well.

ZOVILAM contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

3. How to take ZOVILAM

Do not share medicines prescribed for you with any other person.

Always take ZOVILAM exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your will be stabilised on the separate preparations of lamivudine and zidovudine before your doctor will switch you over to ZOVILAM.

Adults and children over the age of 12 years

The recommended dose of ZOVILAM is one tablet twice a day. ZOVILAM can be taken with or without food.

If you must discontinue treatment with one of the active ingredients of ZOVILAM or the dosage must be reduced, separate preparations of lamivudine and zidovudine are available.

Take the tablets at regular times, leaving approximately 12 hours between each tablet.

Treatment following exposure

Treatment will start after exposure occurred and should be preferably within 1 to 2 hours. The HIV status of the source must be confirmed. If the source is infected with HIV, it is recommended that the prophylactic course be continued for a period of 4 weeks.

Recommended dose

Duration: ZOVILAM dosage

Days 1 – 3: One (1) ZOVILAM tablet taken twice a day.

Days 4 – 28: One (1) ZOVILAM tablet taken twice a day.

Treatment should be stopped as soon as the source material is confirmed not be infected with HIV.

Special populations

Kidney disease

Your doctor may decide to adjust your dosage and recommend that you receive separate preparations.

Liver disease

Your doctor may decide to adjust your dosage and recommend that you receive separate preparations.

Your doctor will tell you how long your treatment with ZOVILAM will last. Do not stop treatment early because you are feeling better.

Blood disorders

If you have a very low red blood cell count (anaemia) or a very low white blood cell count (neutropenia),

your doctor may decide to adjust your dosage and recommend that you receive separate preparations. If you have the impression that the effect of ZOVILAM is too strong or too weak, tell your doctor or pharmacist.

If you take more ZOVILAM than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

If you forget take ZOVILAM

If you forget to take a dose of ZOVILAM, take it as soon as you remember and then continue as before. Do not take a double dose to make up for forgotten individual doses.

If you stop taking ZOVILAM

Do not stop taking the tablets unless the doctor instructs you to. When the ZOVILAM supply starts to run low, get more from a healthcare provider or pharmacy. This is very important because the amount of virus in your blood may increase if ZOVILAM is stopped for even a short time. The virus may develop resistance to ZOVILAM and become harder to treat.

4. Possible side effects

ZOVILAM tablets can have side effects.

Not all side effects reported for ZOVILAM are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ZOVILAM, please consult your health care provider for advice.

If any of the following happens, stop taking ZOVILAM and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Lactic acidosis (signs include deep, rapid, difficult breathing, drowsiness, numbness or weakness in the limbs, nausea, vomiting, abdominal (stomach) pain.
- Shortness of breath and difficulty breathing.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Decreased number of red blood cells, too few white blood cells.
- Ear, nose and throat infections.
- Too much lactate in the blood.
- Loss of appetite.
- Headache.
- Difficulty to sleep.
- Feeling dizzy.
- Cough, irritated or runny nose.
- Nausea, vomiting, abdominal pain or cramps, diarrhoea.
- Rash.
- Loss of hair.
- Redness of the skin.
- Pain.
- Pain in joint.
- Muscle disorders including musculoskeletal pain.
- Tiredness.
- Feeling of bodily discomfort.
- Fever.
- An increase in certain liver enzymes and an increased amount in the blood of bilirubin (a substance produced in the liver) which may make your skin appear yellow.

Less frequent side effects:

- A decrease in the number of cells involved in blood clotting or in all kinds of blood cells.
- A failure of the bone marrow to produce new red or white blood cells.
- Changes in body or face shape due to changes in fat distribution (these changes may include an increase amount of fat in the upper back and neck (“buffalo hump”), in the breasts and around the trunk, as well as loss of fat from the legs, arms and face).
- Unpleasant tingling feeling in arms or legs, numbness, tingling, a burning sensation or weakness of hands and feet.
- Sleepiness, loss of mental sharpness, fits (seizures).

- Disease of the heart muscle.
- Shortness of breath and/or difficulty breathing.
- Wind, changes in the colour of the inside of the mouth, changes in taste, heartburn, inflammation of pancreas, enlargement of the spleen, inflammation of the mouth, an increase in an enzyme called serum amylase.
- Inflammation of the liver, liver disorders such as enlargement of the liver with fatty degeneration.
- Sudden swelling of the skin or mucous membranes (e.g. throat or tongue) with difficulty breathing.
- Itching, changes in the colour of your nails and skin, allergic skin reaction/nettle-rash.
- Muscle disease.
- Passing urine more often.
- Growth of breasts in men.
- Generalised pain, lack of energy, chills, chest pain, flu-like symptoms (chills and sweating).
- Anxiety, depression.
- Breakdown of muscle tissue/tenderness or weakness.

Frequency not known:

- If you are taking combination therapy for HIV you may develop a condition called osteonecrosis. With this condition, parts of the bone tissue die because of reduced blood supply to the bone. Signs of this condition include stiffness in the joints, aches and pains (especially in the hip, knee or shoulder) and difficulty moving.
- Too much sugar in the blood.
- Abnormal breathing**,** sore throat.
- Weakness.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of ZOVILAM.

5. How to store ZOVILAM

Store all medicines out of reach of children.

- Store at or below 30 °C.
- Store in the original container.
- Do not remove from the carton until required for use.
- Keep the bottles tightly closed.
- Protect from light/moisture.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the label.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What ZOVILAM contains

The active substances are lamivudine and zidovudine.

Each ZOVILAM film-coated tablet contains:

Lamivudine 150 mg

Zidovudine 300 mg

The other ingredients of the tablet are cellulose microcrystalline, colloidal anhydrous silica, magnesium stearate and sodium starch glycolate.

The film-coating consists of hypromellose, propylene glycol and titanium dioxide.

What ZOVILAM like and content of the pack

A white to off-white, film-coated, capsule shaped, biconvex tablet debossed with M on the left of the score and 2 on the right of the score on one side of the tablet and L on the left of the score and Z on the right of the score on the other side.

ZOVILAM is packed in an HDPE bottle pack (marketable pack) comprised of round wide-mouth white high-density polyethylene bottle and 33 mm white opaque screw cap with induction sealing liner packed in an outer carton in pack sizes of 60’s and 100’s.

ZOVILAM is packed in an HDPE bottle pack (marketable pack) comprised of white opaque

polypropylene screw cap with aluminium induction sealing liner wad in an outer carton in a pack size of 56’s.

ZOVILAM is packed in an HDPE bottle pack (marketable pack) comprised of blue opaque HDPE bottle with blue opaque polypropylene screw closure with wad containing aluminium induction sealing liner packed in an outer carton in pack sizes of 56’s and 60’s.

ZOVILAM is packed in a polybag LDPE plain 150 micron 330 mm x 485 mm IND-DMF (non-marketable pack) in a 50’s pack size with a 10 g silica gel bag desiccant or a canister/sachet desiccant.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Viatris Healthcare (Pty) Ltd

4 Brewery Street

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