PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

RETROVIR IV

Concentrate for Solution for Infusion

Zidovudine 200 mg/20 mL

Sugar free

Read all of this leaflet carefully before you are given RETROVIR IV.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist, nurse or other healthcare provider.

What is in this leaflet:

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

1. What RETROVIR IV is and what it is used for:

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

RETROVIR IV is used for the short-term management of serious HIV infection in patients who are unable to take zidovudine oral formulations. RETROVIR IV is also used during labour and at the birth to prevent the baby getting infected with HIV.

RETROVIR IV reduces the amount of HIV virus in the body and keeps it at a low level. It also increases CD4 cell counts. CD4 cells are a type of white blood cell, that play an important role in maintaining a healthy immune system to help fight infection.

2. What you need to know before you are given RETROVIR IV:

You should not receive RETROVIR IV:

- if you are hypersensitive (allergic) to zidovudine or to any of the ingredients of RETROVIR IV (listed in section 6)
- if you have a very low white blood cell count (neutropenia) or very low red blood cell count (anaemia)
- if you are also taking antiretroviral medicines containing stavudine.

If you think any of these apply to you, check with your doctor before he administers RETROVIR IV to you.

Warnings and precautions:

Treatment with RETROVIR IV has not been shown to reduce the risk of passing HIV infection on to others by sexual contact or by blood transfer. You should continue to use appropriate precautions to prevent this. You can still pass on HIV when receiving RETROVIR IV, although the risk is lowered by effective antiretroviral therapy. Discuss with your doctor the precautions needed to avoid infecting other people.

RETROVIR IV helps to control your condition and delay disease progression, but it is not a cure for HIV infection. You may continue to develop other infections and other illnesses associated with HIV disease. You should keep in regular contact with your doctor.

Anaemia (low red blood cell count), which may make you feel tired and lack energy, light-headed, short of breath and pale; and neutropenia/leucopenia (low white blood cell count), which causes a weakened immunity and a greater risk of infections, may occur during treatment with RETROVIR IV. These side effects are usually not seen until at least 4-6 weeks of treatment. If severe, your doctor may reduce your dose or stop treatment with RETROVIR IV. Regular blood tests will be arranged to check whether the number of your white and red blood cells are reducing.

Look out for important symptoms:

Some people taking medicines for HIV infection such as RETROVIR IV develop other conditions, which can be serious. Refer to section 4, Possible side effects – Conditions to look out for.

Other medicine and RETROVIR IV:

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

The following medicine is not recommended with RETROVIR IV:

- stavudine, used to treat HIV infection.

Some medicines can make it more likely that you'll have side effects or make side effects worse. These include:

- ganciclovir or interferon, used to treat virus infections
- pyrimethamine, used to treat malaria and other parasitic infections
- dapsone, used to prevent pneumonia and treat skin infections
- flucytosine, used to treat fungal infections such as candida

- atovaquone, used to treat parasitic infections
- amphotericine or co-trimoxaole, used to treat fungal and bacterial infections
- probenecid, used to treat gout and similar conditions and given with some antibiotics to make them more effective
- rifampicin, used to treat tuberculosis (TB) and other infections
- methadone, used as a heroine substitute
- vincristine, vinblastine or doxorubicin, used to treat cancer.

Some medicines interact with RETROVIR IV. These include

- rifampicin and clarithromycin, which are antibiotics
- phenytoin, used for treating epilepsy
- aspirin, codeine or morphine, used for pain relief
- non-steroidal anti-inflammatory drugs (NSAIDs), used for pain relief and inflammation
- oxazepam or lorazepam, used to treat anxiety or to aid sleep
- cimetidine, used to treat ulcers
- clofibrate, used to reduce high cholesterol.

Tell your doctor if you're taking any of these medicines. Your doctor may need to monitor you while you are being given RETROVIR IV.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before receiving RETROVIR IV. RETROVIR IV can be given to HIV-positive pregnant women only after the first 3 months of pregnancy to reduce the risk of transmitting HIV to their unborn child. RETROVIR IV is

given during labour and is stopped after delivery. It may also be given to the newborn baby for the first six weeks of life.

In babies and infants exposed to NRTIs during pregnancy or labour, small increases in blood levels of a substance called lactate have been observed. Additionally, there have been very rare reports of diseases that affect the nervous system such as a delayed development and seizures.

It is recommended that HIV infected women do not breastfeed their infants in order to avoid transmission of HIV. The active substance in RETROVIR IV is found in human breast milk. If formula feeding is not possible, you should get advice from your doctor.

Driving and using machines:

RETROVIR IV can make you dizzy and have other side effects that may make you feel less alert. Do not drive or operate machinery unless you are feeling well.

RETROVIR IV contains sodium:

RETROVIR IV contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially 'sodium-free'.

3. How RETROVIR IV is given:

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

You will never be expected to give yourself RETROVIR IV. It will always be given to you by a person who is qualified to do so. Your doctor will decide on the correct dose to be given to you.

Your doctor will give you RETROVIR IV by infusing it into a vein (a drip). It is diluted before use and is given slowly over a one-hour period.

If you have the impression that the effect of RETROVIR IV is too strong or too weak, tell your doctor.

If you receive more RETROVIR IV than you should:

Since a healthcare provider will administer RETROVIR IV, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to receive RETROVIR IV:

Since a healthcare provider will administer RETROVIR IV, it is unlikely that the dose will be missed.

4. Possible side effects:

RETROVIR IV can have side effects.

Not all side effects reported with RETROVIR IV are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving RETROVIR IV, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, stop receiving RETROVIR IV and tell our doctor immediately:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching.

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

Conditions to look out for:

Other possible side effects of combination therapy for HIV:

Some other conditions may develop during HIV treatment.

Old infections might flare up:

Patients with advanced HIV infection (AIDS) have weak immune systems and are more likely to develop serious infections *(opportunistic infections)*. When these patients start treatment, they may find that old, hidden infections such as tuberculosis flare up, causing signs and symptoms of inflammation. These symptoms are probably caused by the body's immune system becoming stronger, so that the body starts to fight these infections.

If you get any symptoms of infection while you are given RETROVIR IV, **tell your doctor immediately**. Do not take other medicines for the infection without your doctor's advice.

***Your body shape may change*:**

Treatment with RETROVIR IV or other medicines that contain zidovudine may cause a loss of fat from legs, arms and face (lipoatrophy). Your doctor should monitor for signs of lipoatrophy. Tell your doctor if you notice any loss of fat from your legs, arms, and face. When these signs occur,

your doctor will assess if RETROVIR IV should be stopped and your HIV treatment changed. If you stop receiving RETROVIR IV it may take several months to see any lost fat return. You may not regain all of your lost body fat.

Other effects may show up in blood tests:

- Increased blood levels of sugar, fatty acids *(triglycerides)* and cholesterol may show up in blood tests.

Lactic acidosis is a serious side effect:

Some people receiving RETROVIR IV, develop a condition called lactic acidosis, together with an enlarged liver. Lactic acidosis is caused by a build-up of lactic acid in the body. It is rare; if it happens, it usually develops after a few months of treatment. It can be life-threatening, causing failure of internal organs.

Lactic acidosis is more likely to develop in women and people who have liver disease.

Signs of lactic acidosis include:

deep, rapid, difficult breathing

weakness in the limbs

loss of appetite, sudden unexplained weight loss

feeling sick (nausea), **being sick** (vomiting)

stomach pain.

During your treatment, your doctor will monitor you for signs of lactic acidosis. If you have any of the symptoms listed above, or any other symptoms that worry you, **see your doctor as soon as possible**.

Tell your doctor if you notice any of the following:

Frequent side effects:

- headaches
- feeling sick (nausea)
- being sick (vomiting)
- diarrhoea
- stomach pains
- generally feeling unwell (malaise)
- feeling dizzy
- aching muscles.

Frequent side effects that show up in your blood tests are:

- a low red blood cell count (anaemia) or low white blood cell count (neutropenia or leukopenia)
- an increase in the level of liver enzymes
- an increase in lactic acid (see "*Lactic acidosis is a serious side effect*" above)
- an increased amount of bile (a substance produced in the liver).

Less frequent side effects include:

- skin rash (red, raised or itchy skin)
- feeling breathless
- fever (high temperature)
- general aches and pains
- wind (flatulence)
- weakness
- inflammation of the pancreas
- chest pain, disease of the heart muscle
- fits (convulsions)

- feeling depressed or anxious, not being able to sleep (insomnia), not being able to concentrate, feeling drowsy
- indigestion, loss of appetite, taste disturbance
- changes in the colour of the nails, skin, or the skin inside the mouth
- a flu-like feeling – chills, sweating and cough
- tingly feelings in the skin (pins and needles)
- passing urine more often
- enlarged breasts in men.

Less frequent side effects that show up in your blood tests are:

- a decrease in the number of cells involved in blood clotting (thrombocytopenia), or all kinds of blood cells (pancytopenia)
- liver disorders, such as enlarged liver or fatty liver
- lactic acidosis (see "*Lactic acidosis is a serious side effect*" above)
- a reduction in the number of red blood cells (pure red cell aplasia), failure of the bone marrow to produce new blood cells.

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 or 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 RETROVIR IV..

5. How to store RETROVIR IV:

Store all medicines out of reach of children.

Store at or below 30 °C.

Protect from light.

6. Contents of the pack and other information:

What RETROVIR IV contains:

The active substance in RETROVIR IV is zidovudine.

Each vial contains 200 mg of zidovudine in 20 mL solution.

The other ingredients are hydrochloric acid, sodium hydroxide and water for injection.

What RETROVIR IV looks like and contents of the pack:

A clear, colourless or pale-yellow, sterile aqueous solution, practically free from visible particulate matter.

An amber glass (Type 1) vial, sealed with a bromobutyl rubber stopper and aluminium collar with plastic flip-top cover, containing 200 mg zidovudine in 20 mL.

Holder of certificate of registration:

GlaxoSmithKline South Africa (Pty) Ltd

No 1 Bridgeway Road

Bridgeways Precinct

Century City, Cape Town, 7441

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