

# RETROVIR IV

## Patient Information Leaflet

### SCHEDULING STATUS:

S4

### PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

**RETROVIR IV** Infusion

Zidovudine 10 mg/1 ml

### 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 ask your doctor or pharmacist.
- RETROVIR IV has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

### 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 IS USED FOR:

RETROVIR IV belongs to a group of antiviral medicines, also known as anti-retrovirals, 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.

**BEFORE YOU RECEIVE RETROVIR IV:**

• **You should not receive RETROVIR IV**

- if you are hypersensitive (allergic) to zidovudine or to any of the ingredients of RETROVIR IV
- 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.

**Take special care with RETROVIR IV:**

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.

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 develop other conditions, which can be serious. Refer to POSSIBLE SIDE EFFECTS – Conditions to look out for.

**Pregnancy and Breastfeeding:**

If you are pregnant, or planning to become pregnant soon, or if you are breastfeeding, please inform your doctor before taking any medicines. 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 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.

**Driving and Using Machinery:**

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.

**Taking other medicines with RETROVIR IV:**

Always tell your healthcare professional 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.

Check with your doctor if you are taking this medicine.

**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
- dapson, 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
- methadone, used as a heroine substitute
- vincristine, vinblastine or doxorubicin, used to treat cancer.

Tell your doctor if you're taking any of the above medicines.

**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.

## **HOW RETROVIR IV IS ADMINISTERED:**

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

You will never be expected to give yourself this medicine. 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.

## **POSSIBLE SIDE EFFECTS:**

RETROVIR IV can have side effects.

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

### **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:***

People taking combination therapy for HIV may find that their body shape changes, because of changes in fat distribution (*lipodystrophy*):

- fat may be lost** from the legs, arms or face
- extra fat may build up** around the tummy (abdomen), or on the breasts or internal organs
- fatty lumps** (sometimes called buffalo hump) may appear on the back of the neck
- increased blood levels of sugar, fatty acids (*triglycerides*) and cholesterol may show up in blood tests.

If you notice changes in your body shape, **tell your doctor**.

***Lactic acidosis is a serious side effect:***

Some people receiving RETROVIR, 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**.

**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 get any side effects, tell your doctor or pharmacist if any of these side effects gets severe or troublesome, or if you notice any side effects not listed in this leaflet.

#### **STORAGE AND DISPOSING OF RETROVIR IV:**

Store all medicines out of reach of children.

Store at or below 30 °C.

Protect from light.

#### **PRESENTATION OF RETROVIR IV:**

An amber glass vial containing 200 mg zidovudine in 20 ml

#### **IDENTIFICATION OF RETROVIR IV:**

A clear, colourless or pale-yellow, sterile aqueous solution.

**REGISTRATION NUMBER:**

29/20.2.8/0483

**NAME AND ADDRESS OF REGISTRATION HOLDER:**

GlaxoSmithKline South Africa (Pty) Ltd

39 Hawkins Avenue

Epping Industria 1, 7460

**DATE OF PUBLICATION:**

Date of registration: 19 August 1995

Date of last revision: 29 June 2018