

RETROVIR ORAL SOLUTION

Zidovudine (50mg/5ml)

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What RETROVIR is used for
RETROVIR is used to treat HIV (human immunodeficiency virus) infection.

RETROVIR is used, in combination with other medicines ('combination therapy'), to treat HIV infection in adults and children.

If you are pregnant, your doctor may want you to take RETROVIR, to help prevent you passing HIV on to your unborn baby. After the birth, your baby may be given RETROVIR to help prevent HIV infection.

How RETROVIR works

The active ingredient in RETROVIR is zidovudine.

RETROVIR is a type of medicine known as an anti-retroviral. It belongs to a group of medicines called *nucleoside analogue reverse transcriptase inhibitors* (NRTIs). RETROVIR does not cure HIV infection; it reduces the amount of virus in your body, and keeps it at a low level. RETROVIR also increases the *CD4 cell count* in your blood. CD4 cells are white blood cells that are important in helping your body to fight infection.

Before you use RETROVIR

- When you must not use it

Do not take RETROVIR:

- if you are allergic (hypersensitive) to zidovudine or

any of the other ingredients of RETROVIR.

- if you have a very low white blood cell count (*neutropenia*) or a very low red blood cell count (*anaemia*).

If you think any of these apply to you, do not take RETROVIR until you have checked with your doctor.

- Before you start to use it

Before you take RETROVIR your doctor needs to know:

- If you have ever had liver disease (including hepatitis B or C)
 - If you have a blood disorder
- Talk to your doctor if any of these apply to you. You may need extra check-ups, including blood tests, while you're taking your medication.

Conditions you need to look out for:

RETROVIR can cause serious side effects. You must look out for certain symptoms while you are taking RETROVIR:

- Old infections flaring up
- Change in body shape
- Lactic acidosis

Pregnancy and breast feeding

If you are pregnant, if you become pregnant, or if you are planning to become pregnant, talk to your doctor about the risks and benefits to you and your baby of taking RETROVIR.

If pregnant women who are HIV-positive take RETROVIR, they are less likely to pass the HIV infection on to their unborn babies. In some cases HIV infection may be passed on to unborn babies even if RETROVIR is used.

RETROVIR and similar medicines may cause side effects in unborn babies; which won't show up until after the baby has been born. However, this does not affect the

recommendation to use RETROVIR to help protect your baby from getting HIV.

Where possible, women who are HIV-positive should not breast feed, because HIV infection can be passed on to the baby in breast milk. If formula feeding is not possible, you should get advice from your doctor.

A small amount of the ingredients in RETROVIR can also pass into your breast milk.

- Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, if you have taken any recently, or if you start taking new ones. This includes herbal medicines or other medicines bought without a prescription.

This medicine is not recommended with RETROVIR:

- stavudine, used to treat HIV infection

Check with your doctor if you're taking this medicine.

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

- ribavirin, used to treat hepatitis C
- ganciclovir or interferon, used to treat viral 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 such as PCP
- amphotericin or co-trimoxazole, 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 heroin substitute
- vincristine, vinblastine or doxorubicin, used to treat cancer

Tell your doctor if you are taking any of these.

Some medicines interact with RETROVIR.

These include:

- rifampicin and clarithromycin, which are antibiotics
- phenytoin, used for treating epilepsy
- aspirin, codeine, or morphine, used for pain relief
- indomethacin, ketoprofen or naproxen, 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
- isoprinosine, used to treat virus infections

Tell your doctor if you are taking any of these medicines. Your doctor may need to monitor you while you are taking RETROVIR.

How to use RETROVIR

- How much to use

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

Adults and adolescents weighing at least 30 kg

The usual dose of RETROVIR is 250 or 300 mg twice a day. Take each dose 12 hours apart.

Children weighing at least 9 kg and less than 30 kg

Your doctor will decide on the correct dose of RETROVIR for your child, depending on the size of the child.

The usual dose of RETROVIR is 9 mg/kg twice a day. Take each dose 12 hours apart.

Children weighing at least 4 kg and less than 9 kg

Your doctor will decide on the correct dose of RETROVIR for your child, depending on the size of the child.

The usual dose of RETROVIR is 12 mg/kg twice a day. Take each dose 12 hours apart.

Prevention of HIV in newborn babies

Your newborn baby may also be given RETROVIR to help prevent your baby from getting infected with HIV.

Your doctor will decide on the correct dose of RETROVIR for your baby, depending on the weight of the baby.

The usual dose of RETROVIR is 0.2 ml/kg (2 mg/kg) from birth and continuing every 6 hours until 6 weeks old (e.g. a 3 kg baby would require 0.6 ml dose of oral solution every 6 hours). The amount of liquid medicine to be given to your baby is very small and an appropriate sized dosing syringe (such as 1 ml) should be used.

If your baby cannot take medicines by mouth, your doctor may decide to give your baby RETROVIR by injection instead.

People with kidney or liver problems

If you have severe kidney or liver problems, you may be given a lower dose of RETROVIR, depending on how well your kidneys or liver are working. Follow your doctor's advice.

- When to use it

Use as directed by your doctor or pharmacist.

1. Remove the plastic wrap from the syringe/adaptor.
2. Remove the adaptor from the syringe.

3. Remove the bottle cap and keep it safely
4. Push the plastic adaptor into the neck of the bottle, while holding the bottle firmly.
5. Insert syringe firmly into adaptor
6. Turn the bottle upside down
7. Pull out syringe plunger until the first portion of your full dose is withdrawn
8. Turn the bottle the right way up and remove the syringe from the adaptor
9. Put the syringe into your mouth. Slowly push the plunger in and repeat above steps until you have taken the whole dose.
10. Take the syringe and the adaptor off and wash them thoroughly in clean water and dry completely before you use them again.
11. Close the bottle tightly with the cap

- How long to use it

Take RETROVIR for as long as your doctor recommends. Do not stop unless your doctor advises you to.

- If you forget to use it

If you forget to take a dose, just take your next dose at the usual time. Do not take a double dose to make up for a missed dose.

- If you use too much (overdose)

If you take too much RETROVIR, contact your doctor or pharmacist for advice. If possible, show them the RETROVIR pack.

While you are using it

- Things you must do

For as long as you are taking RETROVIR, your doctor will arrange regular blood tests to check for side effects.

RETROVIR helps to control your condition, but it is not a cure for HIV infection. You need to keep taking it every day to stop your illness getting worse. Because RETROVIR does not cure HIV

infection, you may still develop other infections and illnesses linked to HIV infection.

Stay in regular contact with your doctor.

HIV infection is spread by sexual contact with someone who has got the infection, or by transfer of infected blood (for example, by sharing needles). You can still pass on HIV when taking this medicine, although the risk is lowered by effective antiretroviral therapy. Discuss with your doctor the precautions needed to avoid infecting other people.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor. This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

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

- Things to be careful of

Some people taking medicines for HIV infection develop other conditions, which can be serious. You need to know about important signs and symptoms to look out for while you are taking RETROVIR.

Read the information under section 'Side effects' in this leaflet. If you have any questions about this information or the advice given, talk to your doctor.

Side Effects

Like all medicines, this medicine can cause side effects, but not everyone gets them. Some side effects may show up in your blood tests, and may not appear until 4 to 6 weeks after you start taking RETROVIR. If you get any of these

effects, and if they are severe, your doctor may advise you to stop taking RETROVIR.

Very common side effects

These may affect **more than 1 in 10** people:

- headaches
- feeling sick (nausea)

Common side effects

These may affect **up to 1 in 10** people:

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

Common side effects that may show up in your blood tests are:

- a low red blood cell count (*anaemia*) or low white blood cell count (*neutropenia* or *leucopenia*)
- an increase in the level of liver enzymes
- an increase in lactic acid
- an increased amount of *bilirubin* (a substance produced in the liver)

Uncommon side effects

These may affect **up to 1 in 100** people:

- skin rash (red, raised or itchy skin)
- feeling breathless
- fever (high temperature)
- general aches and pains
- wind (flatulence)
- weakness

Uncommon side effects that may show up in your blood tests are:

- a decrease in the number of cells involved in blood clotting (*thrombocytopenia*), or in all kinds of blood cells (*pancytopenia*).

Rare side effects

These may affect **up to 1 in 1000** people:

- liver disorders, such as enlarged liver or fatty liver
- lactic acidosis (excess lactic acid in the blood)
- 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

A rare side effect that may show up in your blood tests is:

- reduction in the number of red blood cell (*pure red cell aplasia*)

Very rare side effects

These may affect **up to 1 in 10,000** people:

A very rare side effect that may show up in blood tests is:

- failure of the bone marrow to produce new blood cells (*aplastic anaemia*)

Conditions you need to look out for

Some other conditions may develop during HIV treatment.

Old infections may flare up

People with advanced HIV infection (AIDS) have weak immune system, and are more likely to develop serious infections (*opportunistic infections*). When these people start treatment, they may find that old, hidden infections 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 taking RETROVIR, 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 often causes a loss of fat from legs, arms, face and buttocks (lipoatrophy). Your doctor should monitor for signs of lipoatrophy. Tell your doctor if you notice any loss of fat from your legs, arms, face and buttocks. When these occur, your doctor will assess if RETROVIR should be stopped and your HIV treatment changed. If you stop taking RETROVIR, 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 rare but serious side effect

Some people taking RETROVIR, or other medicines like it (NRTIs), 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.

If you get side effects

Tell your doctor or pharmacist if any of the side effects gets severe or troublesome, or if you notice any side effects not listed in this leaflet. You may report any side effects of adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my (Consumer → Reporting Side Effects to Medicine (ConSERF) or Vaccines (AEFI))

Storage and Disposal of RETROVIR

- Storage

Keep RETROVIR out of the sight and reach of children.

Do not take RETROVIR after the expiry date shown on the carton. Discard any remaining oral solution one month after first opening. Do not store RETROVIR above 30 °C. Protect RETROVIR from light.

- Disposal

Do not throw away any medicines via waste water or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product Description

- What it looks like

It is clear, pale yellow, strawberry-flavoured. RETROVIR is supplied in amber glass bottle of 200ml with a child resistant high density polyethylene outer cap and inner polypropylene cap with a polyethylene wad, with either a 1 ml or 10 ml oral-dosing syringe in the pack which should be fitted to the bottle before use.

- Ingredients

- Active ingredient(s)
Zidovudine
- Inactive ingredient(s)
Hydrogenated glucose syrup, glycerol, citric acid, sodium benzoate, saccharin sodium, strawberry flavour, white sugar flavour, purified water.

- MAL number

MAL19930308ACRZ

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Product Registration Holder

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