

RETROVIR *Zidovudine*

(100mg capsules)



+BODY POSITIVE →

• NEW ZEALAND •

WHAT IS IN THIS LEAFLET

Please read this leaflet carefully before you start taking RETROVIR capsules or oral solution, or are given RETROVIR by IV infusion.

This leaflet answers some common questions about RETROVIR. It does not contain all of the available information.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking RETROVIR against the benefits this medicine is expected to have for you. If you have any concerns about taking this medicine, ask your doctor or pharmacist.

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

WHAT IS RETROVIR USED FOR

RETROVIR contains the active ingredient zidovudine, which belongs to a group of medicines called antiretrovirals.

Please note that the active ingredient in RETROVIR, zidovudine, is also available as a combination medicine, Combivir™, along with lamivudine, another antiretroviral.

RETROVIR capsules and oral solution are used, in combination with other antiretrovirals, for the long term treatment of HIV infected adults and children. RETROVIR slows down the progression of human immunodeficiency virus (HIV) infection, which can lead to Acquired Immune Deficiency Syndrome (AIDS) and other related illnesses, such as AIDS-related Complex (ARC).

RETROVIR IV infusion is used for short term treatment of these conditions in people who cannot take RETROVIR capsules or oral solution. RETROVIR IV infusion is also used during childbirth in HIV-infected mothers to reduce the risk of HIV transmission to the baby.

RETROVIR does not cure AIDS or HIV infection, but slows down production of human immunodeficiency virus. In this way it stops ongoing damage to the body's immune system, which fights infection.

RETROVIR does not reduce your risk of passing HIV infection to others. You will still be able to pass on the HIV virus by sexual activity or by passing on blood or body secretions which carry the HIV virus. You should continue to take all the appropriate precautions.

While taking RETROVIR and/or any other therapy for HIV disease, you may continue to develop further infections and other complications of HIV disease. You should keep in regular contact with your doctor.

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

RETROVIR is not addictive.

Use in children

RETROVIR may be used in children. The RETROVIR oral solution is particularly suitable for younger children. RETROVIR IV infusion may also be used in newborn babies to reduce their risk of contracting the HIV virus during delivery.

BEFORE YOU TAKE RETROVIR

When you must not take it

- Do not take RETROVIR capsules or oral solution, or have an IV infusion of RETROVIR, if you have ever had an allergic (hypersensitivity) reaction to zidovudine (RETROVIR). Symptoms of an allergic reaction may be mild or severe. They usually include some or all of the following: wheezing, swelling of the lips/mouth, difficulty in breathing, hay fever, lumpy rash ("hives") or fainting.
- Do not take RETROVIR capsules or oral solution, or have an IV infusion of RETROVIR, if you have ever had an allergic reaction to any of the other ingredients in the formulations listed at the end of this leaflet.
- If you have certain blood disorders, your doctor may advise that you take a lower dose of RETROVIR or that you take a break from RETROVIR. Ask your doctor if you are not sure whether you should take RETROVIR.
- Do not take or use RETROVIR after the expiry date (EXP) on the packaging. If you take this medicine after the expiry date has passed it may not work as well.
- Do not take or use RETROVIR if the packaging is torn or shows signs of tampering, if the capsules look discoloured or damaged, if the oral solution looks lumpy or discoloured, if the solution for IV infusion looks cloudy or discoloured, or has been premixed for your infusion more than 48 hours earlier.

If you're not sure whether you should be taking RETROVIR capsules or oral solution, or be given an IV infusion of RETROVIR, talk to your doctor.

Before you start to take RETROVIR

You must tell your doctor if:

- You are allergic to any foods, dyes, preservatives or any other medicines.
- You are taking or have recently taken any other medicines.
- You have, or ever have had, liver problems.
- You have kidney disease.
- You are pregnant or planning to become pregnant. It is not known if RETROVIR is harmful to an unborn baby in the early stages of pregnancy. It is not recommended that this medicine be used by women until they are more than 14 weeks pregnant. If you are prescribed RETROVIR earlier than 14 weeks, your doctor will have weighed up the expected benefits to you against any possible risks to your unborn baby. Note that while use of RETROVIR during pregnancy can reduce the chance that your baby will get HIV, some may get it even with this treatment.
- You are breastfeeding or are planning to breastfeed. RETROVIR passes into breast milk, so it is recommended that mothers taking this medicine do not breastfeed. Breastfeeding may also increase the risk of passing on the HIV virus to the baby.

Taking other medicines

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

Tell your doctor if you are taking any of the following:

- Phenytoin (Dilantin™), a medicine used to treat epilepsy
- Rifampicin (Rifadin™, Rifinah™), a strong antibiotic used for several serious infections.
- Other antiretrovirals, such as lamivudine (3TC™) or stavudine (Zerit™) Probenecid (Benemid™), a medicine used to treat gout

- Non-steroidal anti-inflammatory medicines to reduce pain, stiffness and inflammation, including:
 - aspirin (Aspec™, Aspro™, Aspro Clear™, Cardiprin™, Cartia™, Disprin™, Ecotrin™, Alka-Seltzer™, Solprin™, Codral Forte™, Pirophen™)
 - indomethacin (Arthrexin™, Indocid™, Indocid R™, Rheumacin™, Rheumacin SR™)
 - ketoprofen (, Orudis™, Oruvail™)
 - naproxen (Naprosyn™, Naprosyn SR™, Apo-Naproxen™, Naxen™, Noflam™, Noflam™, Naprogesic™, Synflex™)
- Some types of medicines used to produce calmness or help you sleep, such as oxazepam (Benzotran™, Ox-Pam™, Serepax™) or lorazepam (Ativan™, Lorepam™, Lorzem™)
- Cimetidine (Apo-Cimetidine™, Cytine™, , Tagamet™), a medicine used to treat stomach ulcers.
- Narcotic painkillers, such as morphine (RA Morph Mix™, Kapanol™, LA Morph™, MST Continus™, RMS™, Sevredol™)
- codeine (Alpha-Codeine Phosphate™, Codral Forte™, , Pirophen™, Apo-Paracodeine™, Panadeine™, Mersyndol™, Codral Cold and Flu™, Nurofen Plus™)
- methadone (Biodone™, Methaforte™, Pallidone™)
- Clofibrate (Atromid™) a medicine for lowering blood cholesterol levels
- Pyrimethamine a medicine for malaria
- Certain other medicines likely to be used in the treatment of HIV infection, AIDS and ARC, including:
 - Pentamidine (Pentacarinat™)
 - Co-trimoxazole (Bactrim™, Septrin™, Trimel™, Trisul™)
 - Amphotericin (Fungilin™, Fungizone™)
 - Flucytosine (Alcobon™)
 - Ganciclovir (Cymevene™)
 - Aciclovir (Zovirax™)
 - Interferon (Intron-A, Roferon-A, Wellferon™, Betaferon™, Imukin™)

- Dapsone (Dapsone™), used for leprosy

- Some medicines used to treat cancer, including: Vincristine (Vincristine™) Vinblastine (Velbe™) Doxorubicin (Adriamycin™).

Your doctor or pharmacist will be able to tell you what to do when taking RETROVIR capsules or oral solution, or when you are given a RETROVIR IV infusion, while you are taking other medicines.

HOW TO TAKE RETROVIR

Your doctor will tell you how many RETROVIR capsules or how much RETROVIR oral solution to take and how often. You will also find this information on the labelling of your medicine.

Do not take or give extra RETROVIR medicine. Do not take RETROVIR or any medicine more often than you have been told.

If you have been prescribed RETROVIR IV infusion, it will be given to you in hospital by a slow drip into a vein by a doctor or nurse.

How much to take

For adults and children over 12 years of age:

RETROVIR capsules and oral solution: The usual total daily dose is 500mg to 600mg, taken in smaller doses two to three times during the day, e.g. 200mg three times a day.

RETROVIR IV infusion: The usual dose is 1mg to 2mg per kilogram of body weight, given every four hours.

For children aged three months to 12 years:

RETROVIR capsules and oral solution: The recommended dose is 360 to 480mg per square metre of body surface area (the area of skin the child has). The daily dose of

RETROVIR will be calculated by your child's doctor.

RETROVIR IV infusion: Your doctor will calculate how much to give your child.

In pregnant women from 14 weeks of pregnancy:

RETROVIR capsules or oral solution: The recommended total daily dose is 500mg, 100mg five times daily.

During labour and delivery:

RETROVIR IV infusion: The usual dose is 2mg per kilogram of body weight over the first hour, then continuous infusion at a rate of 1mg per kilogram per hour, until the time that the umbilical cord is cut. Alternatively, capsules have been given by mouth with a higher dose from 36 weeks gestation then higher again during labour.

The newborn baby is then given RETROVIR oral solution at a recommended dose of 2mg per kilogram of body weight every six hours, starting within 12 hours of birth, until the baby is six weeks old. If a newborn baby cannot or will not swallow medicine, RETROVIR IV infusion is given, at a recommended dose of 1.5mg per kilogram of body weight, infused over 30 minutes every six hours until the baby is six weeks old. Your doctor will work this out.

Kidney or liver disease or blood changes

The recommended dose for RETROVIR is reduced in people with kidney or liver disease and depends on how well these organs are working. It may also be reduced if the blood cells are low.

How to take it

RETROVIR capsules should be swallowed with a drink of water.

RETROVIR oral solution should be swallowed. A 10ml oral dosing syringe is

provided with the oral solution, so you can measure your dose correctly.

RETROVIR capsules and oral solution can be taken with or without food.

RETROVIR IV infusion is given by a slow drip into a vein in hospital by a doctor or nurse.

How long to take it

RETROVIR helps to control your condition but does not cure it. If you have been prescribed capsules or oral solution you will need to take it every day. Do not stop taking your medicine without first talking to your doctor.

If you are being given RETROVIR IV infusion, your doctor will decide how many infusions you need.

If you forget to take it

If it is almost time for your next dose of RETROVIR capsules or oral solution, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, then go back to taking it as you would normally.

Do not take a double dose to make up for the one that you missed.

IF YOU TAKE TOO MUCH (OVERDOSE)

Immediately telephone your doctor or Poisons Information Centre (03-474-7000) or go to the accident and emergency department at your nearest hospital, if you think that you or anyone else may have taken too much RETROVIR. Do this even if there are no signs of poisoning or discomfort. You may need urgent medical attention.

Keep telephone numbers for these places handy.

An overdose of RETROVIR may cause symptoms similar to those listed under the "Side Effects" heading, especially vomiting, headache and tiredness. It could also have serious effects on your red and white blood cell counts.

If you are not sure what to do, contact your doctor or pharmacist.

WHILE YOU ARE TAKING RETROVIR

Things you must do

Tell your doctor or pharmacist that you are taking RETROVIR if you are about to be started on any new medicines.

Other medicines might affect the way that RETROVIR works. You must tell your doctor or pharmacist that you are taking RETROVIR before you start taking any medicines you buy from a pharmacy, health food shop or supermarket.

Tell your doctor if you become pregnant or are trying to become pregnant, or you are breastfeeding.

If you are taking RETROVIR capsules or oral solution, tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed. Otherwise your doctor may think that it is not working for you and change your medicine unnecessarily.

Things you must not do

If you are taking RETROVIR capsules or oral solution, do not stop taking your medicine or change the dose, without first checking with your doctor.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not use RETROVIR capsules or oral solution to treat any other complaints unless your doctor says to.

Things to be careful of

Be careful driving or operating machinery until you know how treatment with RETROVIR affects you. As with many other medicines, RETROVIR may cause headache and tiredness in some people.

POSSIBLE SIDE EFFECTS

Check with your doctor as soon as possible if you have any problems while taking RETROVIR capsules or oral solution, or when you are given RETROVIR IV infusion even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like many other medicines, RETROVIR capsules, oral solution and IV infusion can cause some side effects. If they occur, they are most likely to be minor and temporary. However, some may be serious and need medical attention.

It is not known whether many of these side effects are due to taking RETROVIR alone or taking RETROVIR with other medicines. Some of these symptoms may also occur as part of HIV infection, AIDS or AIDS-related Complex (ARC).

The side effects listed below have been reported:

Common and Mild

- Nausea, vomiting, stomach pain, diarrhoea
- Tiredness, generally feeling unwell
- Headache, dizziness
- Aching muscles
- Changes in blood tests for liver enzymes or bilirubin

These side effects are common but not usually serious. Contact your doctor if they

concern you. They will normally improve over the first few weeks.

Uncommon

- Tingling or numbness of the hands or feet
- Anxiety, depression
- Trouble sleeping, feeling sleepy, loss of mental clarity
- Cough
- Feeling short of breath
- Loss of appetite, change in taste
- Excessive air in the stomach or bowel (wind), feeling uncomfortable in the stomach (indigestion)
- Colour changes in nails, skin or inside the mouth
- Skin rash, itchy skin, sweating
- Passing urine more often
- Breast enlargement in men
- Muscle problems, loss of strength
- Chest pain
- Fever, chills, symptoms similar to the 'flu

These side effects are uncommon or rare but not usually serious. Contact your doctor or pharmacist if they concern you.

While you are taking RETROVIR, it is very important that your doctor keeps a close check on your health and takes blood samples to monitor levels of red and white blood cells. If you develop anaemia (low red blood cell count) or neutropenia (low white blood cell count), your doctor may reduce your RETROVIR dose or stop treatment with RETROVIR, and recommend standard treatment for these side effects. Your doctor may also perform tests to ensure that your liver is working properly.

- Low red blood cell count (anaemia) can cause tiredness, headaches, being short of breath when exercising, dizziness and looking pale
- Low white blood cell count (neutropenia) can cause frequent infections such as fever, severe chills, sore throat or mouth ulcers.

If you think that RETROVIR is causing you to have an allergic (hypersensitivity) reaction, TELL YOUR DOCTOR

IMMEDIATELY. Symptoms of an allergic reaction may be mild or severe. They usually include some or all of the following:

- Wheezing
- Swelling of the lips/mouth
- Difficulty in breathing
- Hayfever
- Bumpy skin rash ("hives")
- Fainting.

If you have any of the following symptoms soon after starting to take your medicine, do not take any more COMBIVIR tablets and tell your doctor immediately or go to the accident and emergency department at your nearest hospital.

- Severe stomach pain or cramps.
- Nausea.
- Vomiting.

These side effects may be due to inflammation of the pancreas which is rare.

If you are on medication for HIV and become very sick, with fast breathing, stop taking COMBIVIR tablets and consult your doctor immediately. You may have a condition known as "lactic acidosis". The fast breathing is due to high acid levels in the blood. This can be life threatening but is rare.

See your doctor if you feel generally unwell with loss of appetite, nausea, vomiting, itching, yellowness of the skin or eyes or dark coloured urine. It is likely you will have to stop taking COMBIVIR tablets.

Other potentially serious side effects include:

- Low blood platelet count – bleeding or bruising more easily than usual
- Other blood effects
- Seizures (fits)
- a disease of the heart muscle. The muscle is weakened and therefore the heart does not beat as well as it could. The heart is then not able to pump enough blood through the body. It may cause fatigue, chest pain, and palpitations (fast or irregular heart beat)

Most of these effects are uncommon or rare but may be serious. Contact a doctor promptly if you think you have any of these side effects.

Ask your doctor or pharmacist if you have any questions about the side effects of RETROVIR.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor or pharmacist if you don't understand something on this list.

Do not be alarmed by this list of side effects. You may not experience any of them. Most tend to occur at higher doses of RETROVIR, and the more common ones tend to become less troublesome after a few weeks of treatment. If anything worries you, please talk to your doctor.

AFTER TAKING RETROVIR

Storage

Keep this medicine where young children cannot reach it. A locked cupboard at least one and a half metres off the ground is a good place to store medicines.

Keep RETROVIR capsules in a cool, dry place away from light where the temperature stays below 30°C.

Keep your RETROVIR capsules in their pack until it is time to take them. If you take RETROVIR capsules out of their pack they may not work as well.

Keep RETROVIR oral solution in a cool, dry place where the temperature stays below 30°C.

If you are taking RETROVIR oral solution, always screw the lid on the bottle after taking your medicine, otherwise it may not work as well.

RETROVIR IV infusion is stored in a hospital ward or pharmacy in a cool dry place where the temperature stays below 30°C.

Disposal

If your doctor tells you to stop taking RETROVIR capsules or oral solution, or your medicine has passed its expiry date, ask your pharmacist what to do with any leftover medicine.

If you have been given RETROVIR IV infusion, hospital staff will dispose of any solution left over after your infusion is finished.

PRODUCT DESCRIPTION

What RETROVIR looks like

RETROVIR capsules are white with a dark blue band around the middle, printed with WELLCOME 100 and coded Y9C. They come in bottles, each containing 100 capsules.

RETROVIR oral solution is a clear, pale yellow, strawberry flavoured, sugar-free liquid. It comes in a 200ml amber (brown) glass bottle. The pack contains a 10ml oral dosing syringe which should be fitted to the bottle before you use it, and closed with the cap provided.

RETROVIR IV infusion is a clear, almost colourless liquid. It comes in a 20ml amber (brown) glass vial and is diluted before use.

Ingredients

RETROVIR capsules

- Zidovudine,
- Starches,
- Titanium dioxide,
- Microcrystalline cellulose,
- Sodium starch glycollate,
- Magnesium stearate,
- Gelatin,

- Indigo carmine,
- Aluminium lake,
- Black iron oxide.

RETROVIR oral solution

- Zidovudine,
- Hydrogenated glucose syrup,
- Glycerol,
- Citric acid, Sodium benzoate,
- Saccharin sodium,
- Strawberry flavour,
- White sugar flavour,
- Purified water.

RETROVIR IV infusion

- Zidovudine,
- Hydrochloric acid,
- Sodium hydroxide,
- water.

RETROVIR for IV infusion is diluted with a weak glucose solution before use.

Manufacturer

Your RETROVIR medicine is distributed by:

GlaxoSmithKline NZ Ltd
 Quay Tower
 Cnr Albert & Customs Streets
 Private Bag 106600
 Downtown, Auckland
 NEW ZEALAND
 Ph (09) 367-2900
 Fax (09) 367-2910

FURTHER INFORMATION

This is not all the information that is available on RETROVIR capsules and oral solution. If you have any more questions or are not sure about anything, ask your doctor or pharmacist.

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition.

You may also be able to find general information about your disease and its treatment from books in public libraries, or on the Internet.

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