

RETROVIR

capsules and syrup

zidovudine

Consumer Medicine Information

What is in this leaflet?

Please read this leaflet carefully before you start RETROVIR.

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

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

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.

Keep this leaflet with the medicine.

You may need to read it again.

What RETROVIR is used for

RETROVIR contains zidovudine which belongs to a group of medicines called antiretrovirals.

RETROVIR is used, alone or with other antiretrovirals, to slow down the progression of human immuno-deficiency virus (HIV) infection, which can lead to Acquired Immune Deficiency Syndrome (AIDS) and other related illnesses (e.g. AIDS-related Complex or ARC).

RETROVIR does not cure AIDS or HIV infection, but slows 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 bodily secretions, which carry the HIV virus. You should continue to take all appropriate precautions.

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

RETROVIR has been extensively studied but for limited periods of time. The long-term risks and benefits of taking RETROVIR are not known; especially in patients without symptoms of HIV infection, or with early HIV disease.

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.

Before you take RETROVIR

When you must not take it

- **Do not take RETROVIR if you weigh less than 30 kg.**
- **Do not take RETROVIR if you have ever had an allergic reaction to zidovudine or any of the ingredients listed at the end of this leaflet.**

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, lumpy rash ("hives") or fainting.

- **Do not take RETROVIR if you are pregnant, trying to become pregnant or breastfeeding, unless your doctor says you should.**
Your doctor will discuss the risks and benefits of using RETROVIR if you are pregnant or breastfeeding.
- **Do not take RETROVIR if you have a reduced red blood cell count (anaemia) or a reduced white blood cell count (neutropenia).**
Ask your doctor if you are not sure whether you should take RETROVIR.
- **Do not take RETROVIR after the expiry date (EXP) printed on the pack.**
If you take it after the expiry date has passed, it may not work as well.
- **Do not take RETROVIR if the packaging is torn or shows signs of tampering.**

If you're not sure whether you should be taking RETROVIR, talk to your doctor.

Before you start to take it

You must tell your doctor if:

- you are allergic to foods, dyes, preservatives or any other medicines.
- you are taking or have taken any other medicines.

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.

If you take ribavirin and RETROVIR together it may cause or worsen anaemia. Please contact your doctor if you notice symptoms of anaemia (such as tiredness and shortness of breath). Your doctor will advise you whether you should stop taking RETROVIR.

There is little information about the way other medicines might affect the way that RETROVIR works, or how RETROVIR affects other medicines. Particular care is needed when taking the painkiller, paracetamol. Your doctor or pharmacist will be able to tell you what to do when taking RETROVIR with other medicines.

Tell your doctor if you are taking any of the medicines below:

- Phenytoin, oxazepam, lorazepam.
- Aspirin, codeine, morphine, methadone, indomethacin, ketoprofen, naproxen, cimetidine, clofibrate, probenecid.
- Pentamidine, pyrimethamine, dapsone, atovaquone, amphotericin, flucytosine, ganciclovir, interferon, clarithromycin.
- Vincristine, vinblastine and doxorubicin

Use in children

The risks and benefits for children taking RETROVIR has not been established.

How to take RETROVIR

The Pharmacist's label on the pack will tell you how to take RETROVIR. If there is

something you do not understand, ask your doctor or pharmacist.

How much to take

The usual dosage of RETROVIR is 500 mg to 600 mg each day. Take this as a divided dose, which may be from two up to five separate doses.

A daily dose of 1000 mg, in two divided doses, is also prescribed.

How to take it

Your RETROVIR should be swallowed with a drink of water.

When to take it

Your doctor or pharmacist will be able to tell you when you should take your RETROVIR.

How long to take it

Your doctor or pharmacist will be able to tell you how long you should take your RETROVIR.

If you forget to take it

If it is almost time for your next dose, 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 dose that you missed.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 131126) for advice, if you think you or anyone else may have taken too much RETROVIR, even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Keep telephone numbers for these places handy.

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.

There is little information about the way 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 medicines you buy from a pharmacy, health food shop or supermarket. This is especially important regarding medicines which might have an effect on the kidneys, liver, red or white blood cells or other body cells.

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

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Things you must not do

Do not stop taking RETROVIR, 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 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 RETROVIR affects you.

RETROVIR taken alone generally does not cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, RETROVIR may cause headache and tiredness in some people.

Side-Effects

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

Like other medicines, RETROVIR 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.

The most serious side-effects include:

- reduced red blood cell count (anaemia).
- reduced white blood cell count (neutropenia).

The frequency and severity of anaemia and neutropenia are greater in patients with advanced HIV disease, or in patients who start taking RETROVIR in later stages of HIV disease.

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 or neutropenia, your doctor may reduce or stop the dose of RETROVIR, or recommend standard treatment for these conditions. Ask your doctor any questions you may have.

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

The side-effects listed below have been reported:

- body odour, chills, swelling of lips and/or tongue, flu-like symptoms, increased sensitivity to pain, back pain, enlarged glands, chest pain, weakness, weight loss, generally feeling unwell.
- widening of blood vessels, possibly leading to low blood pressure or feeling faint.
- constipation, difficulty in swallowing, gas from stomach or bowel, bleeding gums or nose, blood in stools, mouth ulcers, heartburn, vomiting, loss or reduction in appetite, nausea.
- muscle aches or pains, muscle shaking or spasm or twitching, muscle disease.
- enlarged fatty liver, abnormal results of blood tests of liver function, inflammation of the pancreas.
- confusion, depression, nervousness, fainting, loss of mental clarity, dizziness, seizures, severe headache, sleeplessness.

- cough, sore throat, hayfever, sinus problems, hoarseness.
- acne, itchiness, skin rash, changes in nail, skin or mouth colour.
- vision problems, hearing loss, sensitivity to light.
- passing too much urine, pain, difficulty or increased frequency of passing urine.
- reduction in all blood cells.
- blood chemistry changes, with excess acidity of the blood.

Treatment with RETROVIR 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 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 including increased blood levels of sugar, fatty acids (triglycerides) and cholesterol.

Within the first few weeks of treatment with anti-HIV medicines, some people, particularly those that have been HIV positive for some time, may develop inflammatory reactions (eg pain, redness, swelling, high temperature) which may resemble an infection and may be severe. It is thought that these reactions are caused by a recovery in the body's ability to fight infections, previously suppressed by HIV.

If you become concerned about any new symptoms, or any changes in your health after starting HIV treatment, please discuss with your doctor immediately.

Ask your doctor or pharmacist to answer any questions you may have. If you experience any of these side-effects, and they concern you, see your doctor or pharmacist.

If you think you are having an allergic reaction to RETROVIR, TELL YOUR DOCTOR IMMEDIATELY or go to the Accident and Emergency department at your nearest hospital. Symptoms usually include some or all of the following:

- wheezing
- swelling of the lips/mouth
- difficulty in breathing
- hayfever
- lumpy rash ("hives")
- fainting

If you are on medication for HIV and become very sick, with fast breathing, stop RETROVIR 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. Your liver may not be working properly and gets big and fatty. This can be life threatening. This illness occurs more often in women than men.

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, or if the blood tests of your liver function are abnormal. It is likely you will have to stop taking RETROVIR.

This is not a complete list of all possible side-effects. Others may occur in some people and there may be some side-effects not yet known.

Side-effects may depend on whether you take RETROVIR alone, or also have taken other antiretroviral medication(s). Less is known about possible side-effects of taking RETROVIR with other antiretrovirals.

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 anything in this list.

Do not be alarmed by this list of possible side-effects. You may not experience any of them.

After taking RETROVIR

Storage

Keep this medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Keep RETROVIR in a cool, dry place where it stays below 30°C.

Do not store it, or any other medicine, in a bathroom or near a sink. Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep your RETROVIR in its pack until it is time to take it.

If you take RETROVIR out of its pack it may not keep well.

Disposal

If your doctor tells you to stop taking RETROVIR, or that RETROVIR has passed its expiry date, ask your pharmacist what to do with any RETROVIR left over.

Product description

What RETROVIR looks like.

RETROVIR capsules come in two strengths:

- RETROVIR 100 mg capsules are opaque white cap and body coded GSYJU. Bottles or blister packs contain 100 capsules.
- RETROVIR 250 mg capsules are opaque blue cap and opaque white body coded GSJV2. A blister pack contains 40 or 60 capsules*.

*Not all pack sizes are marketed.

RETROVIR syrup is as a pale yellow, strawberry flavoured liquid and is supplied in a 200mL bottle with a syringe, syringe adapter and a plastic cap.

Ingredients

RETROVIR contains the active ingredient zidovudine.

RETROVIR capsules inactive ingredients: maize starch, microcrystalline cellulose, sodium starch glycolate, magnesium stearate, gelatin, titanium dioxide, indigo carmine (250 mg capsules only) and polysorbate 80. Printing ink ingredients: shellac, shellac glaze-45% (20% esterified) in ethanol, iron oxide black, propylene glycol, ammonium hydroxide, ammonia and potassium hydroxide.

RETROVIR syrup contains glycerol, citric acid, sodium benzoate, sodium saccharin, maltitol solution, Strawberry Flavour 500286E, White Sugar Flavour 3112044 and purified water.

RETROVIR does not contain gluten.

Supplier

ViiV Healthcare Pty Ltd
Level 4,
436 Johnston St,
Abbotsford
Victoria, 3067
Australia.

Further Information

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, for example in public libraries, also from the AIDS council in your State.

Do not throw this leaflet away.

You may need to read it again.

This leaflet was prepared on 27 June 2017

The information provided applies only to:
RETROVIR.

Trade marks are owned by or licensed to the ViiV Healthcare group of companies.

RETROVIR Capsules, Zidovudine 100 mg:
AUST R 178834 (bottle), AUST R 178383
(blister)

RETROVIR Capsules, Zidovudine 250 mg:
AUST R 178384

RETROVIR Syrup, Zidovudine 50 mg/5mL:
AUST R 41043.

© 2017 ViiV Healthcare group of companies
or its licensor.

Version 6.0