

Reason for update: Deletion of Brasov manufacturing site and a consequential update to delete Bottle packs (Glass and HDPE bottles) from the container closure system

Market: Ireland

Agency Approval Date:

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Text Issue and Draft No.: Issue 14 Draft 3

Retrovir

100 mg capsules

zidovudine

Information for the patient

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Keep this leaflet. You may need to read it again.

If you have any further questions, ask your doctor or pharmacist.

This medicine has been prescribed for you only. Do not pass it on to others. It may harm them even if their signs of illness seem to be the same as yours.

If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

- 1 What Retrovir is and what it is used for
- 2 What you need to know before you take Retrovir
- 3 How to take Retrovir
- 4 Possible side effects
- 5 How to store Retrovir
- 6 Contents of the pack and other information

- 1 What Retrovir is and what it is used for

Retrovir is used to treat HIV (human immunodeficiency virus) infection.

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 get rid of 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 a type of white blood cells that are important in helping your body to fight infection.

Retrovir is used, in combination with other medicines ('combination therapy'), to treat HIV in adults and children. To control your HIV infection, and to stop your illness getting worse, you must keep taking all your medicines.

If you're 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 it from getting infected with HIV.

HIV infection is spread by sexual contact with someone who's got the infection, or by transfer of infected blood (for example, by sharing injection needles).

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2 What you need to know before you take Retrovir

Don't take Retrovir:

- **if you're allergic** (*hypersensitive*) to zidovudine or any of the other ingredients of Retrovir (listed in Section 6)
- **if you have a very low white blood cell count** (*neutropenia*) **or a very low red blood cell count** (*anaemia*).

Retrovir for newborn babies

Retrovir must not be given to some newborn babies with liver problems, including:

- some cases of *hyperbilirubinaemia* (increased amounts in the blood of a substance called *bilirubin* which may make the skin appear yellow)
- other problems which cause high levels of liver enzymes in the blood.

Take special care with Retrovir

Some people taking Retrovir or combination therapy for HIV are more at risk of serious side effects. You need to be aware of the extra risks:

- **if you have ever had liver disease** (including hepatitis B or C)
 - **if you're seriously overweight** (especially if you're a woman)
- **Talk to your doctor if any of these applies to you.** You may need extra check-ups, including blood tests, while you're taking your medication. **See Section 4 for more information.**

Look out for important symptoms

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're taking Retrovir.

Please read the information in Section 4 of this leaflet. If you have any questions about this information or the advice given:

→ **Talk to your doctor.**

Other medicines and Retrovir

Tell your doctor or pharmacist if you're taking any other medicines, or if you've taken any recently, including herbal medicines or other medicines you bought without a prescription.

Remember to tell your doctor or pharmacist if you begin taking a new medicine while you're taking Retrovir.

Don't take these medicines with Retrovir:

- **stavudine**, used to treat **HIV infection**
- **ribavirin** or injections of ganciclovir to treat **viral infections**
- **rifampicin**, which is an **antibiotic**.

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Some medicines can make it more likely that you'll have side effects, or make side effects worse

These include:

- **sodium valproate**, used to treat **epilepsy**
 - **aciclovir, 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**
 - **fluconazole or flucytosine**, used to treat **fungal infections** such as **candida**
 - **pentamidine or 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're taking any of these.

Some medicines interact with Retrovir

These include:

- **clarithromycin**, which is an **antibiotic**
 - **phenytoin**, used for treating **epilepsy**.
- **Tell your doctor** if you're taking clarithromycin or phenytoin. Your doctor may need to monitor you while you're taking Retrovir.

Pregnancy

If you are pregnant, if you become pregnant, or if you're planning to become pregnant:

→ **Talk to your doctor** about the risks and benefits 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.

Retrovir and similar medicines may cause side effects in unborn babies. If you have taken Retrovir during your pregnancy, your doctor may request regular blood tests and other diagnostic tests to monitor the development of your child. In children whose mothers took NRTIs during pregnancy, the benefit from the protection against HIV outweighed the risk of side effects.

Breast-feeding

Breast-feeding is **not recommended** in women living with HIV, because HIV infection can be passed on to the baby in breast milk.

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

If you are breast-feeding, or thinking about breast-feeding, you should **discuss it with your doctor as soon as possible**.

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Driving and using machines

Retrovir can make you dizzy and have other side effects that make you less alert.

→ **Don't drive or operate machinery** unless you're feeling well.

Retrovir contains sodium

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

You will need regular blood tests

For as long as you're taking Retrovir, your doctor will arrange regular blood tests to check for side effects. There's more information about these side effects in Section 4 of this leaflet.

Stay in regular contact with your doctor

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

→ **Keep in touch with your doctor**, and **don't stop taking Retrovir** without your doctor's advice.

3 How to take Retrovir

Always take this medicine exactly as your doctor has told you to. Check with your doctor or pharmacist if you're not sure.

Swallow the capsules whole, with some water.

Retrovir is also available in liquid form.

How much Retrovir will you need to take?

Adults and adolescents weighing at least 30 kg:

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

Children weighing more than 21 kg and less than 30 kg:

The usual dose of Retrovir is two 100 mg capsules twice daily.

Children weighing at least 14 kg and less than or equal to 21 kg:

The usual dose of Retrovir is one 100 mg capsule taken in the morning and two 100 mg capsules taken in the evening.

Children weighing at least 8 kg and less than 14 kg:

The usual dose of Retrovir is one 100 mg capsule twice daily.

Capsules are not suitable for children weighing less than 8 kg. Your doctor may decide to give your child liquid Retrovir, or to give Retrovir by injection instead.

Pregnancy, childbirth and newborn babies:

You should not normally take Retrovir during the first 14 weeks of your pregnancy. After week 14, the usual dose is 500 mg each day given as one 100 mg capsule five times per day until you start to go into labour. During the labour and birth, your doctor may give you injections of Retrovir, until your

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baby's umbilical cord has been clamped. Your newborn baby may also be given Retrovir to help prevent it from getting infected with HIV.

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.

If you take too much Retrovir

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

If you forget to take Retrovir

If you forget to take a dose, don't worry. You can take your next dose as soon as you remember but not within two hours of your next dose. If you remember within two hours of your next dose, just skip the dose you missed and take your next dose at the usual time. Then continue your treatment as before.

Don't take a double dose to make up for a missed dose.

Don't stop taking Retrovir without advice

Take Retrovir for as long as your doctor recommends. Don't stop unless your doctor advises you to.

4 Possible side effects

During HIV therapy there may be an increase in weight and in levels of blood lipids and glucose. This is partly linked to restored health and life style, and in the case of blood lipids sometimes to the HIV medicines themselves. Your doctor will test for these changes.

Treatment with zidovudine (Retrovir) often causes a loss of fat from legs, arms and face (lipoatrophy). This loss of body fat has been shown to be not fully reversible after discontinuation of zidovudine. 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, Retrovir should be stopped and your HIV treatment changed.

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.

As well as the effects listed below, other conditions can develop during combination therapy for HIV.

→ It is important to read the information in 'Other possible side effects of combination therapy for HIV'.

Very common side effects

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

- headaches
- feeling sick (nausea).

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Common side effects

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

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

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 increased amount in the blood of *bilirubin* (a substance produced in the liver) which may make your skin appear yellow.

Uncommon side effects

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

- 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 taking Retrovir:

- lactic acidosis (excess lactic acid in the blood; see the next section, ‘Other possible side effects of combination therapy for HIV’)
- liver disorders, such as jaundice, enlarged liver or fatty liver
- 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 your nails, your skin, or the skin inside your mouth
- a flu-like feeling — chills, sweating and cough
- tingly feelings in the skin (pins and needles)

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- passing urine more often
- enlarged breasts in men.

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

- a decrease in the number of a type of red blood cell (*pure red cell aplasia*).

Very rare side effects

A very rare side effect that may affect **up to 1 in 10,000** people taking Retrovir, and may show up in blood tests is:

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

If you get any side effects

→ **Talk to your doctor or pharmacist.** This includes any possible side effects not listed in this leaflet.

Other possible side effects of combination therapy for HIV

Some other conditions may develop during HIV treatment.

Old infections may flare up

People with advanced HIV infection (AIDS) have weak immune systems, 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.

In addition to the opportunistic infections, autoimmune disorders (a condition that occurs when the immune system attacks healthy body tissue) may also occur after you start taking medicines for the treatment of your HIV infection. Autoimmune disorders may occur many months after the start of treatment. If you notice any symptoms of infection or other symptoms such as muscle weakness, weakness beginning in the hands and feet and moving up towards the trunk of the body, palpitations, tremor or hyperactivity, please inform your doctor immediately to seek necessary treatment.

If you get any symptoms of infection while you're taking Retrovir:

→ **Tell your doctor immediately.** Don't take other medicines for the infection without your doctor's advice.

Lactic acidosis is a rare but serious side effect

Some people taking 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 people who have liver disease, or in obese (very overweight) people, especially women.

Signs of lactic acidosis include:

- **deep, rapid, difficult breathing**
- **drowsiness**
- **numbness or weakness in the limbs**

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- **loss of appetite, 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.**

You may have problems with your bones

Some people taking combination therapy for HIV develop a condition called *osteonecrosis*. With this condition, parts of the bone tissue die because of reduced blood supply to the bone.

People may be more likely to get this condition:

- if they have been taking combination therapy for a long time
- if they are also taking anti-inflammatory medicines called corticosteroids
- if they drink alcohol
- if their immune systems are very weak
- if they are overweight.

Signs of osteonecrosis include:

- **stiffness in the joints**
- **aches and pains** (especially in the hip, knee or shoulder)
- **difficulty moving.**

If you notice any of these symptoms:

→ **Tell your doctor.**

Other effects may show up in tests

Combination therapy for HIV can also cause:

- **increased levels of lactic acid** in the blood, which on rare occasions can lead to lactic acidosis

This effect may show up in the blood tests you'll have while you're taking Retrovir.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Retrovir

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Do not store above 30 °C (86 °F).

Store it in its original package.

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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.

6 Contents of the pack and other information

What Retrovir contains

The active substance is zidovudine. Each capsule contains 100 mg zidovudine.

The other ingredients are: maize starches, microcrystalline cellulose, sodium starch glycolate, magnesium stearate, titanium dioxide E171, gelatin, black inks opacode 10A1 or 10A2 (shellac, black iron oxide E172, propylene glycol, ammonium hydroxide, 28% (in black ink opacode 10A1 only), strong ammonium solution (in black ink opacode 10A2 only), potassium hydroxide (in black ink opacode 10A2 only)).

What Retrovir looks like and contents of the pack

Retrovir 100 mg capsules are hard, white capsules marked with the code 'GSYJU'. The capsules are supplied in foil blister packs of 100 capsules.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

ViiV Healthcare BV

Van Asch van Wijckstraat 55H

3811 LP Amersfoort

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