

COMBIVIR

lamivudine 150 mg and zidovudine 300 mg tablets

Australia and New Zealand Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you start taking COMBIVIR tablets.

This leaflet answers some common questions about COMBIVIR. It does not contain all 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 COMBIVIR tablets against the benefits they expect it will 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 COMBIVIR tablets are used for

COMBIVIR contains both lamivudine and zidovudine which belong to a group of medicines called antiretrovirals.

Please note that these medicines are also available separately: lamivudine alone is 3TC, (tablets and oral solution) and zidovudine alone is RETROVIR (capsules and syrup).

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

COMBIVIR 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.

COMBIVIR 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 COMBIVIR 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.

The long-term risks and benefits of taking COMBIVIR are not known.

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

COMBIVIR is not addictive.

Before you take COMBIVIR tablets

When you must not take them

- **Do not take COMBIVIR tablets if you have ever had an allergic reaction to either lamivudine (trade name 3TC) or zidovudine (trade name RETROVIR), 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, hay fever, lumpy rash ("hives") or fainting.

- **Do not take COMBIVIR tablets if you are pregnant, trying to become pregnant or breastfeeding, unless your doctor says you should.**

Your doctor should discuss with you the risks and benefits of using COMBIVIR tablets if you are pregnant or breastfeeding.

- **Do not take COMBIVIR if you have**
 - **kidney disease**
 - **liver disease**

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

If you have certain health conditions, your doctor may advise that you take a lower dose of lamivudine and/or zidovudine, the active ingredients in COMBIVIR tablets. Lamivudine is available separately as 3TC tablets and oral solution, and zidovudine is available as RETROVIR capsules and syrup. Ask your doctor if you are not sure whether you should take COMBIVIR.

- **Do not take COMBIVIR tablets after the expiry date (EXP) printed on the pack.**

If you take them after the expiry date has passed, they may not work as well.

- **Do not take COMBIVIR tablets if the packaging is torn or shows signs of tampering.**

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

Before you start to take them

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.**
- **you have, or have ever had, hepatitis B infection.**

- **you have, or have ever had, liver problems.**

When you stop taking COMBIVIR Tablets

If you have a long-standing viral infection of your liver (hepatitis B) it may flare up. This can cause serious illness particularly if your liver is already not working very well. If you have both HIV and hepatitis B, when you stop taking your COMBIVIR tablets, your doctor is likely to arrange tests from time to time to check how well your liver is working and to measure virus levels.

Taking other medicines

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

If you take ribavirin and COMBIVIR together it may cause or worsen anaemia. 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 COMBIVIR.

There is little information about the way other medicines might affect the way that COMBIVIR works, or how COMBIVIR 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 COMBIVIR with other medicines.

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

- Ribavirin, paracetamol
- Phenytoin, oxazepam, lorazepam.
- Aspirin, codeine, morphine, methadone, rifampicin, indomethacin, ketoprofen, naproxen, cimetidine, clofibrate, probenecid.
- Pentamidine, pyrimethamine, dapsone, atovaquone, amphotericin, flucytosine, ganciclovir, trimethoprim, sulfamethoxazole, interferon, clarithromycin.
- Vincristine, vinblastine and doxorubicin
- Aciclovir, inosine pranobex, adriamycin, ciprofloxacin
- Stavudine, zalcitabine or emtricitabine
- Sorbitol-containing medicines (usually liquids) used regularly

COMBIVIR should not be taken with stavudine or zalcitabine

Use in children

COMBIVIR is not recommended for use in children under 12 years of age. Because it is a fixed dose combination tablet it cannot be adjusted according to the size and weight of the patient.

How to take COMBIVIR tablets

Your doctor will tell you how many COMBIVIR tablets to take and how often to take them. You will also find this information on the label of your medicine.

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

The usual dosage of COMBIVIR tablets is one tablet, twice a day.

How to take them

Your COMBIVIR tablets should be swallowed with a drink of water. Do not halve the tablet.

When to take them

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

How long to take them

Because your medicine helps to control your condition, but does not cure it, you will need to take the tablets every day.

Do not stop taking your medicine without first talking to your doctor.

If you forget to take them

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. (In Australia telephone 131126. In New Zealand telephone 0800 764766 or 0800 POISON), or go to accident and emergency at your nearest hospital, if you think you or anyone else may have taken too many COMBIVIR tablets. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Keep these telephone numbers handy.

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

While you are taking COMBIVIR tablets

Things you must do

Tell your doctor or pharmacist that you are taking COMBIVIR tablets 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 COMBIVIR works. You must tell your doctor or pharmacist that you are taking COMBIVIR 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 COMBIVIR tablets, or change the dose without first checking with your doctor.

Do not take COMBIVIR tablets to treat any other complaints unless your doctor tells you to.

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

Do not give this medicine to children under 12 years of age. Because it is a fixed dose combination tablet it cannot be adjusted according to the size and weight of the patient.

Things to be careful of

Be careful driving or operating machinery until you know how COMBIVIR tablets affect you.

COMBIVIR tablets taken alone generally do not cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, COMBIVIR tablets 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 COMBIVIR tablets, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like other medicines, COMBIVIR tablets 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 COMBIVIR in later stages of HIV disease.

While you are taking COMBIVIR, 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 COMBIVIR, 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 COMBIVIR or taking COMBIVIR 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:

- sweating, body odour, chills, swelling of lips and/or tongue, flu-like symptoms, fever, increased sensitivity to pain, back pain, enlarged glands, chest pain, weakness, weight loss, generally feeling unwell, breast enlargement in male patients.
- widening of blood vessels, possibly leading to low blood pressure or feeling faint.
- constipation, difficulty in swallowing, gas from stomach or bowel, diarrhoea, bleeding gums or nose, blood in

stools, mouth ulcers, heartburn, vomiting, loss or reduction in appetite, nausea.

- abdominal discomfort and pain.
- 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, fatigue/tiredness.
- cough, sore throat, hay fever, sinus problems, hoarseness, changes to perception of taste.
- 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.
- increased bruising or bleeding.
- blood chemistry changes, with excess acidity of the blood.
- unusual feelings in any part of the body, such as numbness, burning, tingling or pins and needles.

- hair loss

Treatment with COMBIVIR 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 COMBIVIR should be stopped and your HIV treatment changed. If you stop taking COMBIVIR, 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 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 COMBIVIR tablets, 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
- hay fever
- lumpy 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 a condition called pancreatitis.

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. 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 COMBIVIR tablets.

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 COMBIVIR alone, or also have taken other antiretroviral medication(s). Less is known about possible side-effects of taking COMBIVIR 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 COMBIVIR tablets

Storage

Keep this medicine where young children cannot reach them.

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

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

Do not store the tablets, or any other medicine, in a bathroom or near a sink.

Do not leave them in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep your COMBIVIR tablets in their pack until it is time to take them.

If you take COMBIVIR tablets out of their pack they may not keep well.

Disposal

If your doctor tells you to stop taking COMBIVIR tablets, or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets left over.

Product description

What COMBIVIR tablets looks like.

COMBIVIR tablets are white to off-white, capsule-shaped and stamped with "GXFC3". Tablets are available in blister packs inside a carton. Each carton contains 60 tablets.

Ingredients

COMBIVIR contains the active ingredients lamivudine (150 mg) and zidovudine (300 mg).

COMBIVIR tablets also contain the following inactive ingredients:

microcrystalline cellulose, sodium starch glycollate, silicon dioxide, magnesium stearate, hypromellose, titanium dioxide, macrogol and polysorbate 80.

COMBIVIR does not contain gluten.

Supplier

ViiV Healthcare Pty Ltd

Level 4, 436 Johnston Street

Abbotsford, Victoria, 3067

Australia

Further Information

This is not all the information that is available on COMBIVIR tablets. 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, for example in public libraries.

Do not throw this leaflet away.

You may need to read it again.

This leaflet was prepared on

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The information provided applies only to: COMBIVIR tablets.

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COMBIVIR tablets, lamivudine 150 mg and zidovudine 300 mg:

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