

COMBIVIR™ Tablets

Lamivudine 150mg and zidovudine 300mg tablets



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What is in this leaflet?

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

This leaflet answers some common questions about COMBIVIR tablets. 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 COMBIVIR tablets 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 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
 - very reduced red blood cell count (anaemia),
 - very reduced white blood cell count (neutropenia).

If you have certain health conditions like those listed above, your doctor may advise that you take the ingredients of COMBIVIR separately so that the dose of each ingredient can be adjusted for you. The ingredients in COMBIVIR are lamivudine, available separately as 3TC and zidovudine, available as RETROVIR. 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 COMBIVIR

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 hepatitis virus levels.

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. In particular tell your doctor if you are taking any of the following medicines:

- Phenytoin (Dilantin™), a medicine used to treat epilepsy
- Rifampicin (Rifadin™, Rifinah™), a strong antibiotic used for several serious infections.
- Other antiretrovirals, such as 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 (Naprogesic™, Naprosyn™, Naprosyn SR™, Naxen™, Noflam™, Noflam™, Synflex™)
- Some types of medicines used to produce calmness or help you sleep, such as oxazepam (Benzotran™, Ox-Pam™, Serepax™) or lorazepam (Ativan™, Lorapam™, Lorzem™)

- Cimetidine (Apo-Cimetidine™, Cytine™, Tagamet™), a medicine used to treat stomach ulcers.
- Narcotic painkillers, such as morphine (RA Morph Mix™, Kapanol™, LA Morph™, M-Eslon™, 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™)
- 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™).

Some medicines may affect the way other medicines work. Your doctor or pharmacist will be able to tell you what to do when taking COMBIVIR with other medicines.

Use in children

COMBIVIR is not recommended for use in children under 12 years of age. Because it is a tablet containing two medicines in set doses it cannot be adjusted for children.

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.

Do not take or give extra tablets. Do not take the tablets more often than you have been told.

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.

When to take them

Your doctor or pharmacist will be able to tell you when you should take your COMBIVIR tablets. It doesn't matter if they are taken with food or without food.

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 (0800 POISON or 0800 764 766) 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 telephone numbers for these places 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 or blood 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.
- Remember to have your blood tests as the doctor advises.

Things you must not do

- Do not stop taking COMBIVIR tablets, 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 COMBIVIR tablets to treat any other complaints unless your doctor says so.
- Do not give this medicine to children under 12 years of age. Because it is a tablet containing two medicines in set doses it cannot be adjusted for children.

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. Some of these symptoms may occur as part of HIV infection, AIDS or AIDS-related Complex or may be from taking other medicines at the same time as COMBIVIR.

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 inflammation of the pancreas, a rare side effect.

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.

The most serious side-effects include:

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

If you think you have either of the above side effects, contact your doctor promptly. The doctor may also see if these are occurring from results of your blood tests. If you have blood changes your doctor may reduce or stop the dose of COMBIVIR. Low white and red blood cell counts are more common and more severe in patients with advanced HIV disease, or in patients who start taking COMBIVIR in later stages of HIV disease. Ask your doctor any questions you may have.

Other potentially serious side effects include:

- Low blood platelet count - bleeding or bruising more easily than usual
- Other blood effects
- Seizures (fits)
- Temporary paralysis or weakness of muscles
- 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.

Common and Mild Side Effects

- Nausea, vomiting, stomach pain, diarrhoea
- Skin rash, hair loss
- Tiredness, generally feeling unwell, fever
- Headache, dizziness
- Aching muscles, joint pain
- 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.

Uncommon Side Effects

- Tingling or numbness of the hands or feet
- Anxiety, depression
- Trouble sleeping, feeling sleepy, loss of mental clarity,
- Cough
- Loss of appetite, change in taste
- Excessive air in the stomach or bowel (wind), indigestion
- Colour changes in nails, skin or inside the mouth
- Skin rash, itchy skin, sweating
- Passing urine more often
- Breast enlargement in men
- Muscle disorders
- 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. Ask your doctor or pharmacist any questions you may have. 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 it. 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 look 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 glycolate, silicon dioxide, magnesium stearate, hypromellose, titanium dioxide, macrogol 400 and polysorbate 80.

COMBIVIR does not contain gluten.

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 January 2004 (Issue 2).

The information provided applies only to: Combivir tablets™

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Manufacturer

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Further Information

COMBIVIR tablets are only available if prescribed by a doctor.

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.