

# COMBIVIR

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## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

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### 1. Why am I taking COMBIVIR?

COMBIVIR contains the active ingredients lamivudine and zidovudine. COMBIVIR is used, alone or in combination 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 (ARC)).

For more information, see Section [1. Why am I taking COMBIVIR?](#) in the full CMI.

### 2. What should I know before I take COMBIVIR?

Do not use if you have ever had an allergic reaction to COMBIVIR or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I take COMBIVIR?](#) in the full CMI.

### **3. What if I am taking other medicines?**

Some medicines may interfere with COMBIVIR and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### **4. How do I take COMBIVIR?**

- The usual dosage of COMBIVIR is one tablet twice a day.
- Swallow the tablet whole with a glass of water.

More instructions can be found in Section [4. How do I take COMBIVIR?](#) in the full CMI.

### **5. What should I know while taking COMBIVIR?**

| <b>Things you should do</b> |  |
|-----------------------------|--|
|                             | <ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are taking COMBIVIR.</li></ul> |

|                                    |   |
|------------------------------------|---|
|                                    | <ul style="list-style-type: none"> <li>• For as long as you are taking COMBIVIR, your doctor will arrange for you to have regular blood tests to check for side effects.</li> </ul>   |
| <b>Things you should not do</b>    | <ul style="list-style-type: none"> <li>• Do not stop using this medicine suddenly or change the dose without talking to your doctor.</li> <li>• Do not take this medicine to treat any other complaints.</li> <li>• Do not give this medicine to children under the age of 12.</li> </ul> |
| <b>Driving or using machines</b>   | <ul style="list-style-type: none"> <li>• Be careful before you drive or use any machines or tools until you know how COMBIVIR affects you.</li> <li>• COMBIVIR may cause headache and tiredness in some people.</li> </ul>  |
| <b>Looking after your medicine</b> | <ul style="list-style-type: none"> <li>• Store COMBIVIR below 30°C in the pack.</li> <li>• Keep this medicine in the pack until it is time to take it.</li> </ul>   |

For more information, see Section [5. What should I know while taking COMBIVIR?](#) in the full CMI.

## **6. Are there any side effects?**

Side effects that have been reported include sweating, body odour, chills, swelling of the lips/tongue, flu-like symptoms, fever, increased sensitivity to pain, back pain, enlarged glands, chest pain, weakness, weight loss, loss of appetite, vomiting or nausea, generally feeling unwell, breast enlargement in men, widening of blood vessels leading to low blood pressure and feeling faint, fainting, constipation, gas from the stomach or bowel, blood in the stool, diarrhoea, difficulty in swallowing, mouth ulcers, bleeding gums, heartburn, abdominal discomfort or pain, muscle aches or pains, muscle shaking or spasm or twitching, muscle disease, enlarged fatty liver, abnormal results of liver function blood tests, confusion, depression, nervousness, loss of mental clarity, dizziness, headaches, sleeplessness, fatigue or 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, sensitivity to light, hearing loss, passing too much urine or increased frequency of urination, increased bruising or bleeding, hair loss. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# COMBIVIR

**Active ingredients:** *lamivudine and zidovudine*

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using COMBIVIR. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using COMBIVIR.**

**Where to find information in this leaflet:**

- [1. Why am I taking COMBIVIR?](#)
- [2. What should I know before I take COMBIVIR?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take COMBIVIR?](#)
- [5. What should I know while taking COMBIVIR?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I taking COMBIVIR?

**COMBIVIR contains the active ingredients lamivudine and zidovudine.**

COMBIVIR belongs to a group of medicines known as antiretrovirals.

**COMBIVIR is used, alone or in combination 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 (ARC)).**

COMBIVIR does not cure AIDS or HIV infection however it slows down production of HIV in the body. In this way it stops ongoing damage to the body's immune system which fights infection.

You can still pass on HIV when taking this medicine through sexual activity or through passing on blood or bodily secretions which carry the HIV virus, although the risk is lowered by taking antiretroviral therapy.

You should use proper precautions to prevent this from occurring. Discuss with your doctor the precautions needed to avoid infecting other people.

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

The active ingredients in COMBIVIR are available separately. Lamivudine is available under the brand name 3TC (tablets and oral solution) and zidovudine is available under the brand name Retrovir (capsules and oral solution).

## 2. What should I know before I take COMBIVIR?

### Warnings

#### Do not use COMBIVIR if:

- you are allergic to lamivudine, zidovudine or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

- you have kidney or liver disease
- you have a reduced red blood cell count (anaemia) or white blood cell count (neutropenia)
- are pregnant, trying to become pregnant or breastfeeding

#### Check with your doctor if you:

- have any other medical conditions
- have or have had hepatitis B

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 COMBIVIR your doctor is likely to arrange tests from time to time to check how well your liver is working and to measure virus levels.

- take any medicines for any other condition

- are allergic to any other foods, dyes, preservatives or any other medicines

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## **Pregnancy and breastfeeding**

Talk to your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Your doctor can discuss with you the benefits and risks of taking COMBIVIR whilst pregnant or breastfeeding.

## **Symptoms of infection and inflammation**

People with advanced HIV infection (AIDS) have weak immune systems and are more likely to develop serious infections (opportunistic infections). When they start treatment, the immune system becomes stronger and so the body starts to fight infections.

Symptoms of infection and inflammation may develop, caused by either:

- old, hidden infections flaring up at the body fights them
- the immune system attacking healthy body tissue (autoimmune disorders)



The symptoms of autoimmune disorders may develop many months after you start taking medications to treat your HIV infection.

Symptoms may include:

- muscle weakness and/or muscle pain
- joint pain or swelling
- weakness beginning in the hands or feet and moving towards the trunk of the body
- palpitations or tremor
- hyperactivity (excessive restlessness and movement)

If you get symptoms of infection or if you notice any of the symptoms above, tell your doctor immediately. Do not take other medicines for the infection without your doctor's advice.

## **Children and adolescents**

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

### **3. What if I am taking other medicines?**

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

**Some medicines may interfere with COMBIVIR and affect how it works.**

If you take ribavirin (e.g. Ibvayr) and COMBIVIR together it may cause or worsen anaemia (low red blood cells). Tell your doctor if you notice symptoms of anaemia such as tiredness and shortness of breath.

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

- paracetamol, a medicine used to treat pain
- other medicines used to treat pain such as aspirin, codeine, morphine, methadone, indometacin, ketoprofen, naproxen
- ribavirin
- medicines used in epilepsy including phenytoin
- medicines used to treat anxiety and insomnia including oxazepam, lorazepam
- rifampicin, a medicine used to treat tuberculosis
- cimetidine, a medicine used to treat heartburn, stomach ulcers
- clofibrate, a medicine used to treat high cholesterol, high triglycerides
- probenecid, a medicine used in the treatment of gout
- antimicrobial medicines such as pentamidine, atovaquone
- medicines used to treat parasite infections including pyrimethamine, dapsone
- amphotericin, flucytosine, medicines used to treat fungal infections
- other antiviral medicines such as aciclovir, ganciclovir, interferon, inosine pranobex, stavudine, zalcitabine, emtricitabine

- clarithromycin, sulfamethoxazole, trimethoprim and ciprofloxacin, antibacterial medicines
- medicines used in the treatment of cancer including vincristine, vinblastine and doxorubicin
- sorbitol-containing medicines (usually liquids) which are used regularly

**COMBIVIR should not be taken with stavudine or zalcitabine.**

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect COMBIVIR.**

## **4. How do I take COMBIVIR?**

### **How much to take**

- The usual dosage of COMBIVIR is one tablet twice a day
- Follow the instructions provided and use COMBIVIR until your doctor tells you to stop.

### **When to take COMBIVIR**

- Your doctor or pharmacist will tell you when to take COMBIVIR each day.

### **How to take COMBIVIR**

- Swallow the tablet whole with a drink of water.
- Do not halve the tablet.

## **If you forget to take COMBIVIR**

COMBIVIR should be taken regularly at the same time each day.

**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 and then go back to taking your medicine as you would normally.**

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

## **If you take too much COMBIVIR**

If you think that you have used too much COMBIVIR, you may need urgent medical attention.

**You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## **5. What should I know while taking COMBIVIR?**

### **Things you should do**

Ensure you have blood tests when you are meant to. It is important that your doctor monitors your health and checks the levels of red and white blood cells. If you develop anaemia or neutropenia your doctor may reduce your dose or stop COMBIVIR.

### **Tell your doctor straight away if you:**

- become pregnant or intend to become pregnant
- have not taking COMBIVIR as intended

Remind any doctor, dentist or pharmacist you visit that you are taking COMBIVIR.

This is especially important for any medicines that might have an effect on your liver, kidneys, red or white blood cells or other cells in the body.

### **Things you should not do**

- Do not stop using this medicine or change the dose.
- Do not give this medicine to anyone else, even if their symptoms seem similar to yours.
- Do not use this medicine to treat any other complaints unless your doctor tells you to.
- Do not give this medicine to children under the age of 12.

## **Stay in regular contact with your doctor**

COMBIVIR helps to control your condition, but it is not a cure for HIV infection. You need to keep taking it everyday to stop your illness from getting worse. Because COMBIVIR does not cure HIV infections, you may still develop other infections and illnesses linked to HIV.

## **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how COMBIVIR affects you.**

COMBIVIR may cause headache and tiredness in some people.

## **Looking after your medicine**

Follow the instructions on the pack on how to take care of your medicine properly.

Store it in a cool dry place (below 30°C) away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

**Keep it where young children cannot reach it.**

## **Getting rid of any unwanted medicine**

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## **6. Are there any side effects?**

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

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 (e.g. 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, discuss with your doctor immediately.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### **Less serious side effects**

| <b>Less serious side effects</b>   | <b>What to do</b>  |
|--|--|
| <b>Psychiatric disorders:</b> <ul style="list-style-type: none"><li>• confusion, depression, nervousness, loss of mental clarity</li></ul> | <b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b> |

| <b>Less serious side effects</b>   | <b>What to do</b> |
|--|-------------------|
| <p><b>Nervous system disorders:</b></p> <ul style="list-style-type: none"> <li>● dizziness, seizures, severe headaches</li> <li>● unusual feelings in any part of the body, such as numbness, burning, tingling or pins and needles</li> <li>● vision problems, sensitivity to light</li> </ul> <p><b>Gastrointestinal disorders:</b></p> <ul style="list-style-type: none"> <li>● constipation, gas from the stomach or bowel, blood in the stool, diarrhoea, abdominal pain</li> <li>● vomiting or nausea</li> <li>● difficulty in swallowing, mouth ulcers, bleeding gums</li> <li>● heartburn</li> </ul> <p><b>Skin disorders:</b></p> <ul style="list-style-type: none"> <li>● acne, itchiness, skin rash, changes in nail, skin or mouth colour</li> </ul> |                   |



| <b>Less serious side effects</b>  | <b>What to do</b> |
|---|-------------------|
| <p><b>Metabolic disorders:</b></p> <ul style="list-style-type: none"> <li>● weight loss, loss of appetite</li> </ul> <p><b>Respiratory disorders:</b></p> <ul style="list-style-type: none"> <li>● cough, sore throat, hay fever, sinus problems, hoarseness, changes to perception of taste</li> </ul> <p><b>Blood system disorders:</b></p> <ul style="list-style-type: none"> <li>● widening of blood vessels leading to low blood pressure and feeling faint, fainting</li> <li>● increased bruising or bleeding</li> </ul> <p><b>Musculoskeletal disorders:</b></p> <ul style="list-style-type: none"> <li>● muscle aches or pains, muscle shaking or spasm or twitching, muscle disease</li> </ul> <p><b>Urinary disorders:</b></p> <ul style="list-style-type: none"> <li>● passing too much urine or increased frequency of urination</li> </ul> <p><b>General disorders:</b></p> |                   |

| <b>Less serious side effects</b>  | <b>What to do</b> |
|---|-------------------|
| <ul style="list-style-type: none"> <li>● generally feeling unwell</li> <li>● flu-like symptoms, fever, sweating, chills</li> <li>● weakness, sleeplessness, fatigue or tiredness</li> <li>● increased sensitivity to pain, back pain, enlarged glands, chest pain</li> </ul> <p><b>Side effects that may show up in blood tests:</b></p> <ul style="list-style-type: none"> <li>● abnormal results of liver function blood tests</li> </ul> <p><b>Other:</b></p> <ul style="list-style-type: none"> <li>● body odour</li> <li>● hair loss</li> <li>● hearing loss</li> <li>● swelling of the lips/ tongue</li> <li>● breast enlargement in men</li> </ul> |                   |

## Serious side effects

| Serious side effects  | What to do  |
|---|---|
| <p data-bbox="204 432 770 479"><b>Blood system disorders:</b></p> <ul data-bbox="204 510 770 745" style="list-style-type: none"><li data-bbox="204 510 770 622">● reduced red blood cell count (anaemia)</li><li data-bbox="204 633 770 745">● reduced white blood cell count (neutropenia)</li></ul> <p data-bbox="204 768 770 1216">The frequency and severity of anaemia and neutropenia are greater in patients with advanced HIV disease or in patients who start taking COMBIVIR in the later stages of HIV disease.</p> <p data-bbox="204 1249 627 1296"><b>Allergic reactions:</b></p> <ul data-bbox="204 1328 770 1664" style="list-style-type: none"><li data-bbox="204 1328 770 1664">● swelling of the lips, tongue, wheezing or difficulty breathing, rash, hives on the skin. These are all signs of an allergic reaction</li></ul> <p data-bbox="204 1697 499 1744"><b>Pancreatitis:</b></p> <ul data-bbox="204 1776 770 1933" style="list-style-type: none"><li data-bbox="204 1776 770 1933">● signs of an inflamed pancreas (pancreatitis) such as severe stomach</li></ul> | <p data-bbox="817 432 1377 813"><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p> |

| <b>Serious side effects</b>   | <b>What to do</b> |
|---|-------------------|
| <p data-bbox="248 250 767 353">pain or cramps, nausea, vomiting</p> <p data-bbox="201 376 719 763">If you experience any of these symptoms soon after starting treatment with COMBIVIR stop taking this medicine and contact your doctor immediately.</p> <p data-bbox="201 801 735 853"><b>Change in body shape:</b></p> <p data-bbox="201 887 775 1682">Treatment with COMBIVIR may cause a loss of fat from the legs, arms and face (lipoatrophy). If this occurs tell your doctor and they will assess if you should stop taking COMBIVIR and your HIV treatment be changed. If you stop taking T COMBIVIR it may take several months to see any lost fat return and you might not regain it all.</p> <p data-bbox="201 1720 568 1771"><b>Lactic acidosis:</b></p> <p data-bbox="201 1805 719 2018">If you are taking medication for HIV and become unwell with fast breathing, stop taking</p> |                   |

| <b>Serious side effects</b>   | <b>What to do</b> |
|---|-------------------|
| <p>COMBIVIR and talk to your doctor immediately. This might be 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 and can be life threatening. This illness occurs more often in women than men.</p> |                   |

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

**See your doctor if you feel generally unwell with a loss of appetite, nausea, vomiting, itching, yellowness of the skin or eyes or have dark coloured urine.**

Other side effects not listed here may occur in some people.

### **Reporting side effects**

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side

effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## **7. Product details**

This medicine is only available with a doctor's prescription.

### **What COMBIVIR contains**

|   |   |
|---|---|
| <b>Active ingredients<br/>(main ingredient)</b>     | lamivudine<br>zidovudine  |
| <b>Other ingredients<br/>(inactive ingredients)</b> | hypromellose<br>macrogol<br>magnesium stearate<br>microcrystalline cellulose<br>polysorbate 80<br>silicon dioxide<br>sodium starch glycollate<br>titanium dioxide |

**Do not take this medicine if you are allergic to any of these ingredients.**

## **What COMBIVIR looks like**

COMBIVIR tablets available in blister packs are white to off-white film-coated capsule-shaped scored tablets, engraved with "GXFC3" on both tablet faces (AUST R 61489). The blister pack contains 60 tablets.

Not all pack sizes and types may be marketed.

## **Who distributes COMBIVIR**

ViiV Healthcare Pty Ltd

Level 4, 436 Johnson Street

Abbotsford VIC 3067

Australia

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