

3TC[®]

Lamivudine tablets 150 mg, oral solution 10 mg/mL

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you start taking 3TC tablets or oral solution.

This leaflet answers some common questions about 3TC. It does not contain all of the available information.

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

What 3TC is used for

3TC contains the active ingredient lamivudine, which belongs to a group of medicines called antiretrovirals.

Please note that the active ingredient in 3TC, lamivudine, is also available as a combination medicine, Combivir[®], containing another antiretroviral medicine called zidovudine.

3TC is used, in combination with other antiretrovirals, for the treatment of HIV infected adults and children.

3TC does not cure AIDS or HIV infection, but slows down production of human immunodeficiency virus. In this way it stops ongoing damage to the body's immune system, which fights infection.

3TC 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 body secretions which carry the HIV virus. You should continue to take all the appropriate precautions.

While taking 3TC and/or any other therapy for HIV disease, you may

continue to develop further infections and other complications of HIV disease. You should keep in regular contact with your doctor.

The long term risks and benefits of taking 3TC are not known.

Your doctor may have prescribed 3TC for another reason. Ask your doctor if you have any questions about why 3TC has been prescribed for you.

3TC is not addictive.

Before you take 3TC

When you must not take it

- Do not take 3TC tablets or oral solution if you have ever had an allergic (hypersensitivity) reaction to lamivudine alone (3TC) or in combination with another antiretroviral medicine called zidovudine (Combivir), or to zidovudine alone (Retrovir[®]).
- Do not take 3TC tablets or oral solution if you have ever had an allergic reaction to any of the other ingredients in 3TC listed at the end of this leaflet.
- Do not take 3TC tablets or oral solution if you are pregnant, trying to become pregnant or breastfeeding, unless your doctor says you should.

Your doctor may discuss with you the risks and benefits of taking 3TC if you are pregnant or breastfeeding.

If you have certain health conditions, your doctor may advise that you take a lower dose of 3TC. Ask your doctor if you are not sure whether you should take 3TC.

- Do not take 3TC tablets or oral solution after the expiry date (EXP) on the packaging. If you take them after the expiry date has passed they may not work as well.
- Do not take 3TC tablets or oral solution if the packaging is torn or shows signs of tampering, if the tablets look discoloured or damaged, or if the oral solution looks lumpy or discoloured.

If you're not sure whether you should be taking 3TC tablets or oral solution, talk to your doctor.

Before you start to take 3TC

You must tell your doctor if:

- You are allergic to any foods, dyes, preservatives or any other medicines.
- You are taking or have recently taken any other medicines.
- You have, or ever have had, hepatitis B virus (HBV) infection.
- You have, or ever have had, liver problems.
- You have kidney disease.
- You have pancreatitis (inflammation of the pancreas)
- You have diabetes; an adult dose of 3TC oral solution contains 3g of sucrose.

When you stop taking 3TC

If you have a long-standing viral infection of your liver called hepatitis B, it may flare up when you stop taking 3TC. This can cause serious illness, particularly if your

liver is already not working very well. If you have both HIV and hepatitis B virus, when you stop taking your 3TC tablets or oral solution, your doctor is likely to arrange tests from time to time to check how well your liver is working and to measure your 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.

Tell your doctor if you are taking an antibacterial (antibiotic) medicine called trimethoprim (Triprim™) used for urinary tract infection. Trimethoprim is also used in combination with another antibacterial medicine called sulphamethoxazole (co-trimoxazole, also known as Bactrim™, Septrin™, Trimel™, Trisul™) used to treat *Pneumocystis jiroveci* lung infection (often referred to as PCP).

Tell your doctor if you are taking zalcitabine or emtricitabine.

Tell your doctor if you are regularly taking sorbitol-containing medicines (usually liquids).

Your doctor or pharmacist will be able to tell you what to do when taking 3TC tablets or oral solution with other medicines.

Use in children

3TC can be used in children. The 3TC oral solution is particularly suitable for younger children.

How to take 3TC

Your doctor will tell you how many 3TC tablets or how much 3TC oral solution to take and how often.

You will also find this information on the labelling of your medicine.

Do not take or give extra 3TC tablets or oral solution. Do not take 3TC or any medicine more often than you have been told.

How much to take

3TC Tablets:

For adults, adolescents and children weighing at least 25 kg:

The usual dose is 300 mg of lamivudine daily. This can be taken as one, 150 mg tablet twice daily or two 150 mg tablets, once daily.

For children weighing at least 20 kg and less than 25 kg:

The usual dose is 225 mg of lamivudine daily. This may be taken as either one-half of a 150 mg scored tablet (75 mg) in the morning and one whole 150 mg tablet in the evening, or one and a half 150 mg scored tablets (225 mg) once daily.

Children weighing at least 14 and less than 20 kg:

The usual dose is 150 mg lamivudine daily. This may be administered as either one half of a 150 mg scored tablet (75 mg) twice daily or one whole 150 mg tablet once daily.

3TC oral solution:

For adults, adolescents and children weighing at least 25 kg:

The usual dose is 300 mg (30 mL) lamivudine daily. This may be administered as either 150 mg (15 mL) twice daily or 300 mg (30 mL) once daily.

For children aged at least three months and weighing less than 25 kg:

The usual dose is 4 mg per kilogram of body weight twice daily or 8 mg per kilogram once daily, up to a maximum of 300 mg daily. The daily dose of 3TC will be calculated by your child's doctor.

The recommended dose for 3TC is reduced in people with kidney disease and depends on how well their kidneys are working.

How to take it

3TC tablets should be swallowed with a drink of water.

3TC oral solution should be swallowed from a spoon able to measure 15 ml of fluid.

3TC tablets and oral solution can be taken with or without food.

How long to take it

Because your medicine helps to control your condition but does not cure it, you will need to take 3TC every day. Do not stop taking your medicine without first talking to your doctor.

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 one that you missed.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (0800 POISON, 0800 764 766) or go to the accident and emergency department at your nearest hospital, if you think that you or anyone else may have taken too much 3TC. Do this even if there are no signs of poisoning or discomfort. 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 3TC

Things you must do

Tell your doctor or pharmacist that you are taking 3TC tablets or oral solution if you are about to be started on any new medicines, including medicines you buy from a pharmacy, health food shop or supermarket.

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

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed. Otherwise your doctor may think that it is not working for you and change your medicine unnecessarily.

Things you must not do

Do not stop taking 3TC tablets or oral solution, 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 3TC tablets or oral solution 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 treatment with 3TC affects you. As with many other medicines, 3TC tablets and oral solution 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 3TC tablets or oral solution, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like many other medicines, 3TC tablets and oral solution 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. It is not known whether many of these side effects are due to taking 3TC alone or taking 3TC while taking other medicines. Some of these symptoms may also occur as part of HIV infection, AIDS or AIDS-related Complex (ARC).

While you are taking 3TC, 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 (a low red cell count), neutropenia (a low white cell

count) or lactic acidosis (a build up of lactic acid in the blood) your doctor may reduce your 3TC dose or stop treatment with 3TC, and recommend standard treatment for these side effects.

Other effects that may show up in a blood test include increased levels of sugar and fats (*triglycerides* and *cholesterol*).

Your doctor may also perform tests to ensure that your liver is working properly.

Other side effects include:

- Nausea (feeling as if you are about to vomit), vomiting
- Bleeding or bruising more easily than normal
- Tiredness, dizziness
- Mouth ulcers, sore throat
- Pain in the upper abdomen
- Diarrhoea
- Joint pains
- Muscle aches and pains, muscle spasm, shaking or twitching, muscle weakness
- Headache
- Unusual sensations, such as numbness, burning, tingling, or “pins and needles”
- Skin rash
- Hair loss
- Fatigue and a general feeling of “unwellness”
- Fever, severe chills

If you think that 3TC is causing you to have an allergic (hypersensitivity) reaction, TELL YOUR DOCTOR IMMEDIATELY.

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 breathing
- Hayfever, lumpy rash (“hives”) and/or fainting.

Ask your doctor or pharmacist if you have any questions about the side effects of 3TC tablets or oral solution.

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 something on this list.

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

After taking 3TC

Storage

Keep this medicine where young children cannot reach it. A locked cupboard at least one and a half metres off the ground is a good place to store medicines.

Keep 3TC tablets in a cool, dry place where the temperature stays below 30°C.

Keep your 3TC tablets in their pack until it is time to take them.

If you take 3TC tablets out of their pack they may not work as well.

Keep 3TC oral solution in a cool, dry place where the temperature stays below 25°C.

If you are taking 3TC oral solution, always screw the lid on the bottle after taking your medicine, otherwise it may not work as well.

Discard 3TC oral solution one month after first opening the bottle.

Disposal

If your doctor tells you to stop taking 3TC tablets or oral solution, or your medicine has passed its expiry date, ask your pharmacist what to do with any leftover medicine.

Product description

What 3TC looks like

3TC tablets are white, diamond-shaped, and engraved with **GX CJ7** on one side and **3TC** on the other side. They come in white bottles, each containing 60 tablets.

3TC oral solution is a colourless to pale yellow, strawberry and vanilla flavoured liquid. It comes in a 240 mL white bottle. A 10 mL oral dosing syringe and an adaptor are also included in the pack.

Ingredients

3TC tablets

Lamivudine 150 mg,
Microcrystalline cellulose,
Sodium starch glycollate,
Magnesium stearate,
Hydroxypropylmethyl cellulose,
Titanium dioxide, Macrogol
Polysorbate 80

3TC oral solution

Lamivudine 150 mg/10 ml,
Sucrose (20% w/v),
Methylhydroxybenzoate,
Propylhydroxybenzoate,
Citric acid anhydrous,
Propylene glycol, Sodium citrate,
Artificial strawberry flavour,
Artificial banana flavour,
Purified water

Sponsor Details

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Downtown
Auckland 1143
New Zealand

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Further information

This is not all the information that is available on 3TC tablets and oral solution. 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 in public libraries, or on the Internet.

Date of Preparation

This leaflet was prepared on:
31 January 2017

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Version 6.0