

3TC TABLETS / 3TC ORAL SOLUTION

Lamivudine (150 mg, 10 mg/ml)

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What 3TC is used for

3TC is used to treat HIV (human immunodeficiency virus) infection in adults and children.

How 3TC works

3TC is a type of medicine known as an anti-retroviral. It belongs to a group of medicines called *nucleoside analogue reverse transcriptase inhibitors* (NRTIs).

3TC does not cure HIV infection; it reduces the amount of virus in your body, and keeps it at a low level. It also increases the CD4 cell count in your blood. CD4 cells are a type of white blood cell that are important in helping your body to fight infection.

Not everyone responds to treatment with 3TC in the same way. Your doctor will monitor the effectiveness of your treatment.

Before you use 3TC

- When you must not use it

Do not take 3TC

- if you are allergic (hypersensitive) to lamivudine or any of the other ingredients of 3TC.

Check with your doctor if you think this applies to you.

Pregnancy and breast-feeding

If you are pregnant or think you could be, or if you are planning

to become pregnant do not take 3TC without checking with your doctor. Your doctor will consider the benefit to you and the risk to your baby of taking 3TC while you are pregnant. Babies whose mothers took NRTIs (medicines like 3TC) during pregnancy had a reduced risk of being infected with HIV.

Where possible, women who are HIV-positive should not breast-feed. This is because HIV infection can be passed on to the baby in breast milk. If formula feeding is not possible, you should get advice from your doctor. A small amount of the ingredients in 3TC can also pass into your breast-milk.

Talk to your doctor immediately if you are breast-feeding, or thinking about breast-feeding.

- Before you start to use it

Some people taking 3TC or other combination treatments 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 have ever had kidney disease
- if you are diabetic and using insulin.

Talk to your doctor if any of these apply to you. Your doctor may need to adjust your dose, or you may need extra check-ups (including blood tests) while you are taking your medicine.

- Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, if you have taken any recently, or if you start taking new ones. This includes medicines bought without a prescription.

These medicines should not be used with 3TC:

- Emtricitabine, used to treat HIV infection

Some medicines may affect how 3TC works, or make it more likely that you will have side effects. These include:

- sorbitol-containing medicines (usually liquids), used regularly.
- trimethoprim-sulphamethoxazole (also known as co-trimoxazole), (an antibiotic used to treat *Pneumocystis jiroveci* pneumonia (often referred to as PCP) or toxoplasmosis).

Tell your doctor or pharmacist if you are taking any of these.

How to use 3TC

- How much to use

Always take 3TC exactly as your doctor has told you to. Check with your doctor or pharmacist if you are not sure.

150mg scored tablets

Adults and adolescents weighing at least 25 kg

The usual dose of 3TC is:

- One 3TC tablet to be taken twice a day approximately 12 hours apart, or
- Two 3TC tablets taken together once a day.

Children weighing at least 20 kg and less than 25 kg

The usual dose of 3TC is:

- one-half (½) 3TC tablet to be taken in the morning and one whole 3TC tablet to be taken in the evening, or
- one and one-half (1 and ½) 3TC tablets to be taken once daily

Children weighing at least 14 kg and less than 20 kg

The usual dose of 3TC is:

- One-half (½) 3TC tablet, to be taken in the morning and one-

half (½) 3TC tablet to be taken in the evening, or

- One 3TC tablet, to be taken once daily.

Oral solution

Adults and children weighing at least 25 kg

The usual dose of 3TC is either:

- 15 ml to be taken twice daily, or

- 30 ml to be taken once daily.

Children older than three months

Your doctor will decide on the correct dose of 3TC for your child, depending on their weight. The usual dose of 3TC is:

- 5 mg/kg body weight twice daily or
- 10 mg/kg body weight once daily.

Patients with kidney problems

If you have a kidney problem, your doctor may alter your dose. Talk to your doctor if this applies to you.

How to take

Tablets

Swallow the tablets, with some water. 3TC can be taken with or without food.

If you cannot swallow the tablets whole, you may crush and combine them with a small amount of food or drink, and take all the dose immediately.

Oral solution

3TC can be taken with or without food.

Use the oral dosing syringe supplied with the pack to measure your dose accurately.

1. Remove the plastic wrap from the syringe/adaptor.
2. Remove the adaptor from the syringe.
3. Remove the bottle cap and keep it safe.
4. Hold the bottle firmly.
Push the plastic adaptor into the neck of the bottle.
5. Insert the syringe firmly into the adaptor.
6. Turn the bottle upside down.

7. Pull out the syringe plunger until the syringe contains the first part of your full dose.

8. Turn the bottle the correct way up. Remove the syringe from the adaptor.

9. Put the syringe into your mouth, placing the tip of the syringe against the inside of your cheek. Slowly push the plunger in, allowing time to swallow. Do not push too hard and squirt the liquid into the back of your throat or you may choke.

10. Repeat steps 5 to 9 in the same way until you have taken your whole dose. *For example, if your dose is 15 ml, you need to take one and a half syringe- full of medicine.*

11. Take the syringe out of the bottle and wash it thoroughly in clean water. Let it dry completely before you use it again.

12. Close the bottle tightly with the cap, leaving the adaptor in place.

Discard oral solution one month after first opening.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Take 3TC for as long as your doctor recommends. Do not stop unless your doctor advises you to.

- If you forget to use it

If you forget to take a dose, take it as soon as you remember. Do not take a double dose to make up for a missed dose.

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

- If you use too much (overdose)

If you take too much 3TC, tell your doctor or your pharmacist, or contact your

nearest hospital emergency department for further advice. If possible, show them the 3TC pack.

While you are using it

- Things you must do

Check with your doctor or pharmacist before taking your medicine and take it as prescribed by your doctor.

- Things you must not do

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

- Things to be careful of

Some people taking medicines for HIV infection develop other conditions, which can be serious, such as lactic acidosis and old infections flaring up. You need to know about important signs and symptoms to look out for while you're taking 3TC.

Protect other people

HIV infection is spread by sexual contact with someone who has the infection, or by transfer of infected blood (for example, by sharing injection needles). You can still pass on HIV when taking this medicine, although the risk is lowered by effective antiretroviral therapy. Discuss with your doctor the precautions needed to avoid infecting other people.

Oral Solution:

3TC contains sugar

If you are a diabetic, please note that each 150 mg dose (or 15 ml) contains 3 g of sugar.

Side effects

Like all medicines, 3TC can cause side effects, but not everyone gets them.

Possible side effects of

combination therapy for HIV
Combination therapy including 3TC may cause other conditions to 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. If you get symptoms of infection while you are taking 3TC, tell your doctor immediately. Do not take other medicines for the infection without your doctor's advice.

Lactic acidosis is a rare but serious side effect

Some people taking 3TC or other medicines like it (NRTIs) 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 very overweight (*obese*) people, especially women.

Signs of lactic acidosis include:

- deep, rapid, difficult breathing
- drowsiness
- numbness or weakness in the limbs
- feeling sick (nausea), being sick (vomiting)

- stomach pain.

During 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:

Tell your doctor as soon as possible.

Other effects may show up in blood 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
- increased levels of sugar and fats (*triglycerides and cholesterol*) in the blood
- resistance to insulin so if you are diabetic, you may have to change your insulin dose to control your blood sugar.

Common side effects

These may affect up to 1 in 10 people:

- rash
- headache
- lack of energy, generally feeling unwell
- feeling sick (nausea), being sick (vomiting), diarrhoea
- stomach pain
- fever
- joint pain, muscle disorders
- hair loss or thinning of hair

Common side effects that may show up in your blood tests:

- an increase in lactic acid.

You may report any side effects of adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my (Consumers → Reporting Side Effects to Medicine (ConSERF) or Vaccines (AEFI)).

Storage and Disposal of 3TC

- Storage

Keep out of the reach and sight of children.

Do not take 3TC after the expiry date shown on the carton.

Do not store 3TC tablets above 30°C.

Do not store 3TC oral solution above 30°C. Discard 3TC oral solution one month after first opening. 3TC oral solution has a shelf life of 18 months before opening.

- Disposal

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Tablets

3TC tablets 150 mg are white, diamond shaped, scored and engraved with the code "GX CJ7" on both faces.

Cartons containing tablets in a white high density polyethylene (HDPE) bottle, with a child-resistant closure.

Pack size: 60 tablets

Oral solution

3TC oral solution is a clear, colourless to pale yellow solution.

Cartons containing 3TC oral solution 10 mg/ml in a white high density polyethylene (HDPE) bottle, with a child resistant closure. A 10 ml polypropylene oral dosing syringe and a polyethylene adapter are also included in the pack.

Pack size: 240ml HDPE bottle

- Ingredients

- Active ingredient(s)
150 mg or 10 mg/ml lamivudine

- Inactive ingredient(s)

Tablets:

Microcrystalline cellulose,
sodium starch glycollate,
magnesium stearate, Opadryl
YS-1-7706-G-white, purified
water.

Oral solution:

Sucrose (20% w/v), methyl
hydroxybenzoate, propyl
hydroxybenzoate, citric acid
anhydrous, propylene glycol,
sodium citrate, artificial
strawberry flavor, artificial
banana flavor, NaOH/HCl,
water (purified).

- MAL number

3TC Tablets 150mg

- MAL19963153ACRZ

3TC Oral Solution 10mg/ml

- MAL19963152ACRZ

Manufacturer

3TC Tablets 150mg

Delpharm Poznań Spółka
Akcyjna
ul. Grunwaldzka 189
60-322 Poznań
Poland

3TC Oral Solution 10mg/ml

Bora Pharmaceutical
Services Inc.
Mississauga, Canada

Product Registration Holder

GlaxoSmithKline
Pharmaceutical Sdn. Bhd.
HZ.01, Horizon Penthouse, 1 Powerhouse,
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