

3TC Tablets

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.

1. Why am I taking 3TC tablets?

3TC tablets contain the active ingredient lamivudine. 3TC tablets are used to slow down the progression of human immunodeficiency virus (HIV) infection.

For more information, see Section [1. Why am I taking 3TC tablets?](#) in the full CMI.

2. What should I know before I take 3TC tablets?

Do not use if you have ever had an allergic reaction to lamivudine 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 3TC tablets?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with 3TC tablets and affect how they work.

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 3TC tablets?

- The usual dosage of 3TC tablets is one 150 mg tablet twice a day or 300 mg once a day. For younger children between 3 months to 12 years of age the dose of 3TC tablets will depend on their weight in kilograms (kg).
- Swallow the tablet whole with a glass of water.
- Your doctor may prescribe a different dosage or provide additional instructions.

More instructions can be found in Section [4. How do I take 3TC tablets?](#) in the full CMI.

5. What should I know while taking 3TC tablets?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist, or pharmacist
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	<p>you visit that you are taking 3TC tablets.</p> <ul style="list-style-type: none"> • 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 as prescribed.
Things you should not do	<ul style="list-style-type: none"> • Do not stop using this medicine suddenly or change the dose without talking to your doctor. • Do not give this medicine to anyone else. • Do not use 3TC tablets to treat any other complaints.
Driving or using machines	<ul style="list-style-type: none"> • Be careful driving or operating machinery until you know how 3TC tablets affect you.
Looking after your medicine	<ul style="list-style-type: none"> • Store 3TC tablets in a cool, dry place below 30°C. • Keep the tablets where children cannot reach them.

- Do not store the tablets, or any other medicine in a bathroom, near a sink, in the car or on window sills.
- Keep this medicine in the bottle with the cap tightly closed until you take them.

For more information, see Section [5. What should I know while taking 3TC tablets?](#) in the full CMI.

6. Are there any side effects?

Common side effects that have been reported include nausea, vomiting, diarrhoea, upper abdominal pain, headache, high temperature, lethargy, fatigue, hair loss, joint and muscle pain, skin rash and increased bruising or bleeding. Serious side effects include lumpy skin rash or "hives", swelling of the face, lips, mouth, or throat, wheezing, chest pain or tightness, and fainting, which may indicate an allergic reaction. Severe stomach pain or cramps, nausea or vomiting may indicate pancreatitis.

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.

3TC Tablets

Active ingredient(s): *lamivudine*

Consumer Medicine Information (CMI)

This leaflet provides important information about using 3TC tablets. **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 3TC tablets.**

Where to find information in this leaflet:

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

1. Why am I taking 3TC tablets?

3TC tablets contain the active ingredient lamivudine.

Lamivudine belongs to a group of medicines called antivirals.

3TC tablets are used together with other antivirals to slow down the progression of human immunodeficiency virus (HIV), which can lead to Acquired Immune Deficiency Syndrome (AIDS) and other related illnesses (e.g. AIDS-related Complex or ARC).

3TC tablets do not cure AIDS or kill the HIV virus but prevents further damage to the immune system by stopping production of new viruses.

Your doctor may have prescribed 3TC tablets for another reason.

Ask your doctor if you have any questions about why 3TC tablets have been prescribed for you.

2. What should I know before I take 3TC tablets?

Warnings

Do not take 3TC tablets if:

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

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

- the expiry or "use by" date (EXP) printed on the pack has passed as the tablets may not work as well.
- the packaging is torn or shows signs of tampering.

If you are not sure whether you should be taking 3TC tablets, talk to your doctor.

Check with your doctor if you:

- are allergic to foods, dyes, preservatives, or any other medicines.
- you have, or have ever had, liver problems, for example jaundice, hepatitis, virus affecting the liver, enlarged liver or liver scarring (cirrhosis) or if you have any risk factors for liver problems, e.g. excessive alcohol intake, illegal intravenous drug use with shared equipment, iron or copper storage disorders.
- you have, or have ever had, kidney problems.
- you have, or have ever had, problems with your pancreas.
- you have diabetes.
- you have any other illness, including those that you think are not related to HIV infection.

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

Check with 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 will discuss the risks and benefits of using 3TC tablets if you are pregnant or breastfeeding.

If you stop taking 3TC 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 3TC 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.

3TC tablets are not addictive.

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 3TC tablets and affect how they work.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect 3TC tablets.

4. How do I take 3TC tablets?

How much and when to take 3TC tablets

- The usual dosage of 3TC tablets in adults and adolescents 12 years and older is one 150 mg tablet twice a day or 300 mg once a day. Your doctor may prescribe a different dosage.
- For younger children between 3 months to 12 years of age the dose of 3TC will depend on their weight in kilograms (kg). If you are giving 3TC tablets to a child, follow your doctor's instructions.
- Follow the instructions provided and use 3TC tablets until your doctor tells you to stop.
- 3TC oral solution is also available for younger patients, or those who cannot swallow tablets.

How to take 3TC tablets

- Tablets should be swallowed whole with a glass of water.
- If you cannot swallow the tablet(s), you may crush and combine them with a small amount of food or drink and take all of the dose immediately.

How long to take 3TC tablets

- As this 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 3TC tablets

3TC tablets should be used regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember, then go back to taking it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

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

If you take too many 3TC tablets

If you think that you have taken too many 3TC tablets, 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 3TC tablets?

Things you should do

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

- **Use proper precautions to prevent passing on HIV virus.**

You can still pass on the virus when taking this medicine, by sexual activity or by contamination with infected blood, although the risk is lowered by effective antiretroviral therapy. Discuss with your doctor the precautions needed to avoid infecting other people.

- **Keep in regular contact with your doctor.**

While taking 3TC tablets and/or any other therapy for HIV disease, you may continue to develop other infections and other complications of HIV infection.

Call your doctor straight away if you:

- Become pregnant or are trying to become pregnant.
- Have any problems while taking 3TC tablets, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Remind any doctor, dentist, or pharmacist you visit that you are using 3TC tablets.

Things you should not do

- Do not stop using this medicine suddenly 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 to treat any other complaints unless your doctor says to.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how 3TC tablets affect you.

3TC tablets may cause lethargy or fatigue in some people.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Keep 3TC tablets in the bottle with the cap tightly closed until you take them.
- If you take 3TC tablets out of their pack, they may not keep well.
- Heat and dampness can destroy some medicines.

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

Store it in a cool dry place where it stays below 30°C and 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.

A locked cupboard at least one-and-a half metres above the ground is a good place to store 3TC tablets.

When to discard your medicine

Discard 3TC tablets if your doctor has told you to stop taking them, or the tablets have passed their expiry date.

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.

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

Less serious side effects	What to do
<p>Gastrointestinal:</p> <ul style="list-style-type: none">• Nausea• Vomiting• Diarrhoea• Upper abdominal pain <p>Musculoskeletal and connective tissue:</p> <ul style="list-style-type: none">• Joint and muscle pain• Breakdown of muscle tissue <p>Nervous system:</p> <ul style="list-style-type: none">• Headache• High temperature• Numbness or weakness of the arms and legs• Unusual feelings in any part of the body, such as numbness, burning, tingling or pins and needles <p>Skin and subcutaneous tissue:</p> <ul style="list-style-type: none">• Rash (without any other illness)	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> <p>Should any change in body shape be noticed, seek medical advice.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> ● Increased bruising or bleeding <p>General:</p> <ul style="list-style-type: none"> ● Lethargy ● Fatigue ● Hair loss ● Fat loss or weight gain has been observed with combined antiretroviral therapy. A causal relationship for this has not yet been established. <p>Hepatobiliary:</p> <ul style="list-style-type: none"> ● Increases in enzymes produced by the liver <p>Blood and lymphatic system:</p> <ul style="list-style-type: none"> ● Anaemia or severe anaemia (low red blood cell count). If the production of red blood cells is reduced, you may have symptoms of tiredness or breathlessness. ● Neutropenia (low white blood cell count). A 	

Less serious side effects	What to do
<p>reduction in your white blood cell count can make you more prone to infection.</p> <ul style="list-style-type: none"> ● Reduction in the number of platelets (blood cells important for blood clotting). If you have a low platelet count, you may notice that you bruise more easily. ● Other effects that may show up in blood tests include increased blood levels of sugar, fatty acids (triglycerides) and cholesterol. <p>Digestive and endocrine:</p> <ul style="list-style-type: none"> ● Increases of an enzyme called amylase ● Inflammation of the pancreas (pancreatitis) <p>Metabolic:</p> <ul style="list-style-type: none"> ● Lactic acidosis 	

Serious side effects

Serious side effects	What to do
<p>Immune system:</p> <ul style="list-style-type: none">• 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 and 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. <p>Allergic reaction:</p> <ul style="list-style-type: none">• Skin troubles such as lumpy skin rash or "hives"• Swelling of the face, lips, mouth, or throat which	<p>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. Do not take any more 3TC tablets.</p>

Serious side effects	What to do
<p>may cause difficulty in swallowing or breathing</p> <ul style="list-style-type: none"> ● Wheezing, chest pain or tightness ● Fainting <p>Pancreatitis:</p> <ul style="list-style-type: none"> ● Severe stomach pain or cramps ● Nausea ● Vomiting <p>Lactic acidosis:</p> <ul style="list-style-type: none"> ● If you become very sick, with fast breathing you may have lactic acidosis. The fast breathing is due to high acid levels in the blood. ● Your liver may not be working properly and may become large and fatty. ● This illness occurs more often in women than men. 	

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

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. 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 3TC tablets contain

Active ingredient (main ingredient)	150 mg or 300 mg of lamivudine per tablet
Other ingredients (inactive ingredients)	Microcrystalline cellulose (460) Magnesium stearate (572) Titanium dioxide (171)

	<p>Hypromellose (464)</p> <p>Sodium starch glycollate</p> <p>Macrogol 400 and polysorbate 80 (433)</p> <p>Purified water</p> <p>Black iron oxide (E172) (only in the 300 mg tablets)</p>
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Do not take this medicine if you are allergic to any of these ingredients.

What 3TC tablets look like

3TC 150 mg tablets are white, film-coated, modified diamond shaped tablets engraved "GX CJ7" on one face. (Aust R 54313).

3TC 300 mg tablets are grey, film-coated, modified diamond shaped tablets engraved "GX EJ7" on one face. (Aust R 81359)

3TC tablets are supplied in a white high-density polyethylene bottle, with a plastic cap. Each bottle contains 30 (300 mg) or 60 (150 mg) tablets and is in a carton.

Who distributes 3TC tablets

ViiV Healthcare Pty Ltd
Level 4, 436 Johnston Street,

Abbotsford, Victoria, 3067

Phone: 1800 499 226

www.viivhealthcare.com.au

Counselling is available from your local AIDS council.

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