

3TC Oral Solution

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 using 3TC Oral Solution?

3TC oral solution contains the active ingredient lamivudine. 3TC oral solution is used together with other antivirals to slow down the progression of human immunodeficiency virus (HIV) infection.

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

2. What should I know before I use 3TC Oral Solution?

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 use 3TC Oral Solution?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with 3TC oral solution 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 use 3TC Oral Solution?

- Adults and adolescents 12 years and older: the normal dose is 15 mL of solution twice a day or 30 ml of solution 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).
- Follow the instructions provided and use 3TC oral solution until your doctor tells you to stop.

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

5. What should I know while using 3TC Oral Solution?

Things you should do	
	<ul style="list-style-type: none">• Remind any doctor, dentist, or pharmacist

	<p>you visit that you are taking 3TC oral Solution.</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 oral solution 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 oral solution affect you.
Looking after your medicine	<ul style="list-style-type: none"> • Store 3TC oral solution in a cool, dry place below 25°C. Discard one month after first opening the bottle.

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| | <ul style="list-style-type: none">• Keep it where children cannot reach it.• Do not store 3TC oral solution, 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. |
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For more information, see Section [5. What should I know while using 3TC Oral Solution?](#) 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 eyelids, 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 Oral Solution

Active ingredient(s): *lamivudine*

Consumer Medicine Information (CMI)

This leaflet provides important information about using 3TC oral solution. **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 oral solution.**

Where to find information in this leaflet:

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

1. Why am I using 3TC Oral Solution?

3TC oral solution contains the active ingredient lamivudine.

3TC oral solution belongs to a group of medicines called antivirals.

3TC oral solution is used together with other antivirals 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).

3TC does 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 oral solution for another reason.

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

2. What should I know before I use 3TC Oral Solution?

Warnings

Do not use 3TC Oral Solution 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 it 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 Oral Solution, 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 oral solution if you are pregnant or breastfeeding.

If you stop taking 3TC Oral Solution

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 oral solution, 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 oral solution is 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 oral solution and affect how it works.

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 oral solution.

4. How do I use 3TC Oral Solution?

How much and when to take 3TC Oral Solution

- Adults and adolescents 12 years and older the normal dose is 15 mL of solution twice a day or 30ml of solution 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 oral solution to a child, follow your doctor's instructions.
- Follow the instructions provided and use 3TC oral solution until your doctor tells you to stop.

How to take 3TC Oral Solution

- 3TC oral solution can be swallowed with a glass of water, if desired.
- Because your medicine helps to control your condition, but does not cure it, you will need to take the solution every day.
- Do not stop taking your medicine without first talking to your doctor.

If you forget to use 3TC Oral Solution

3TC oral solution 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 much 3TC Oral Solution

If you think that you have used too much 3TC Oral Solution, 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 using 3TC Oral Solution?

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 that it was not effective and change your treatment unnecessarily.

Use proper precautions to prevent passing on HIV virus. You can still pass on HIV 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 oral solution and/or any other therapy for HIV disease, you may continue to develop other infections and other complications of HIV infection.

If you are diabetic, blood sugar levels should be monitored, as each adult dose (15 mL) contains 3g of sugar.

Call your doctor straight away if you:

- Become pregnant or are trying to become pregnant.
- Have any problems while taking 3TC oral solution, 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 oral solution.

Things you should not do

- Do not stop taking 3TC 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 oral solution 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 oral solution affects you.

3TC oral solution may cause dizziness in some people.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Keep your 3TC oral solution in the bottle with the cap tightly closed until you take or give it.
- Discard 3TC oral solution one month after first opening the bottle.
- If you take 3TC oral solution out of its pack it may not keep well.
- Heat and dampness can destroy some medicines.

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

Store it in a cool dry place where it stays below 25°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.

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

When to discard your medicine

Discard 3TC oral solution if your doctor has told you to stop taking it, or the oral solution has passed its 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 • unusual feelings in any part of the body, such as numbness, burning, tingling or pins and needles • numbness or weakness of the arms and legs <p>Nervous system:</p> <ul style="list-style-type: none"> • Headache • High temperature <p>Skin and subcutaneous tissue:</p> <ul style="list-style-type: none"> • skin 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 fat gain has been observed with combined antiretroviral therapy. A causal relationship for this has not been established <p>Hepatobiliary:</p> <ul style="list-style-type: none"> • Increases in enzymes produced by the liver 	

Less serious side effects	What to do
<p>Blood and lymphatic system:</p> <ul style="list-style-type: none"> • Anaemia (low red blood cell count). If the production of red blood cells is reduced, you may have symptoms of tiredness or breathlessness. 	<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"> • Neutropenia (low white blood cell count). A reduction in your white blood cell count can make you more prone to infection. • 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 may show up in blood tests including 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 eyelids, face, lips, mouth, or	<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.</p> <p>Do not take any more 3TC oral solution.</p>

Serious side effects	What to do
throat which may cause difficulty in swallowing or breathing	

Serious side effects

Serious side effects	What to do
<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. 	<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.</p> <p>Do not take any more 3TC Oral Solution.</p>

Serious side effects	What to do
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 Oral Solution contains

Active ingredient	Lamivudine 10 mg/mL
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(main ingredient)	
Other ingredients (inactive ingredients)	Sugar (20% sucrose) Methyl hydroxybenzoate (218) Propyl hydroxybenzoate (216) Citric acid Sodium citrate dihydrate Propylene glycol Purified water Artificial strawberry and banana flavouring

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

What 3TC Oral Solution looks like

3TC oral solution is a clear, colourless to pale yellow solution with strawberry and banana flavours.

3TC oral solution is supplied in a white high-density polyethylene bottle, with a plastic cap. The bottle contains 240 mL of solution for oral use only and is in a carton.

(Aust R 64346).

Who distributes 3TC Oral Solution

ViiV Healthcare Pty Ltd

Level 4, 436 Johnston Street,

Abbotsford, Victoria, 3067

Phone: 1800 499 226

www.viivhealthcare.com.au

Counselling is also available from your local AIDS council.

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