

LIVTENCITY®

Consumer Medicine Information (CMI) summary

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

▼ This medicine is new. Please report side effects. See the [full CMI](#) for further details.

1. Why am I taking LIVTENCITY?

LIVTENCITY contains the active ingredient maribavir. LIVTENCITY is a prescription medicine to treat adults with post-transplant cytomegalovirus (CMV) infection and disease who are resistant, refractory or intolerant to one or more prior therapies.

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

2. What should I know before I take LIVTENCITY?

Do not take if you have ever had an allergic reaction to LIVTENCITY 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 LIVTENCITY?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with LIVTENCITY 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 LIVTENCITY?

- The recommended dosage of LIVTENCITY is 400 mg (two 200 mg tablets) orally twice daily. LIVTENCITY can be taken with or without food. The tablet can be taken as a whole tablet, a crushed tablet, or a crushed tablet through nasogastric or orogastric tube.
- More instructions can be found in Section [4. How do I take LIVTENCITY?](#) in the full CMI.

5. What should I know while taking LIVTENCITY?

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 LIVTENCITY.</p> <ul style="list-style-type: none"> • Take the tablets regularly, as instructed by the healthcare professional.
Things you should not do	<ul style="list-style-type: none"> • Do not stop taking this medicine suddenly. • Even if you feel better, do not stop taking LIVTENCITY without talking to your doctor.
Driving or using machines	<ul style="list-style-type: none"> • LIVTENCITY has no influence on your ability to drive or use machines.
Looking after your medicine	<ul style="list-style-type: none"> • Keep LIVTENCITY in a cool dry place where the temperature is below 30°C. Do not freeze.

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

6. Are there any side effects?

The most common side effects include changes in taste, nausea, diarrhea, vomiting, anaemia, tiredness, and fever.

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.

- ▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

LIVTENCITY®

Active ingredient: *maribavir*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I taking LIVTENCITY?

LIVTENCITY contains the active ingredient maribavir. LIVTENCITY is an antiviral prescription medicine used for treating adults who have had an organ or bone marrow transplant and developed a CMV (cytomegalovirus) infection.

LIVTENCITY is used to treat CMV infection and disease in adults.

CMV is a common virus in many people, that does not show any symptoms. Normally, CMV stays in their body, and it does not hurt them. However, if your immune system is weak after you get an organ or bone marrow transplant, you may be at high risk of becoming ill from CMV.

2. What should I know before I take LIVTENCITY?

Warnings

Do not take LIVTENCITY if:

- you are allergic to maribavir, or any of the ingredients listed at the end of this leaflet.
- you take either of these medicines:
 - ganciclovir
 - valganciclovir.

Check with your doctor if you:

- take any medicines for any other condition

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. It is not known, if LIVTENCITY will harm your unborn baby.

Talk to your doctor if you are breastfeeding or intend to breastfeed. It is not known, if LIVTENCITY passes into your breast milk.

Children and adolescents

LIVTENCITY is not for use in children and adolescents under 18 years old. This is because LIVTENCITY has not been tested in this age group.

Warnings and precautions

- Talk to your doctor or pharmacist before taking LIVTENCITY with cyclosporin, tacrolimus, sirolimus and everolimus. Additional blood tests may be needed.

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 LIVTENCITY and affect how it works. Some examples include:

- cyclosporin, tacrolimus, sirolimus and everolimus – used to prevent transplant rejection
- rifabutin, rifampicin – for mycobacterial infections
- St. John's wort (*Hypericum perforatum*) – herbal product
- statins such as, atorvastatin, Fluvastatin, rosuvastatin, simvastatin – for high cholesterol
- carbamazepine, phenobarbital, phenytoin – for fits or seizures
- antacid (aluminium and magnesium hydroxide oral suspension) – acid reducing medicine
- famotidine, omeprazole, or pantoprazole – acid reducing medicine
- digoxin – heart medicine
- erythromycin – antibiotic
- sulfasalazine – anti-inflammatory
- ketoconazole and voriconazole – for fungal infections
- diltiazem – heart medicine
- dextromethorphan – cough medicine
- warfarin – anticoagulant

- oral contraceptive steroids – for birth control
- midazolam – used as a sedative.

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

Your doctor may have to change the dose of your other medicines.

Your doctor or pharmacist have more information on medicines to be careful with or avoid while taking LIVTENCITY.

4. How do I take LIVTENCITY?

How much to take

Follow the instructions provided and take LIVTENCITY until your doctor tells you to stop.

- The recommended dose is 400 mg twice a day. That means you take two tablets of LIVTENCITY 200 mg in the morning, and another two tablets of 200 mg in the evening.

When to take LIVTENCITY

- LIVTENCITY can be taken with or without food.

How to take LIVTENCITY

- You can take LIVTENCITY as whole, dispersed, or crushed tablets by mouth, or as dispersed tablets

through nasogastric or feeding tubes (French size 10 or larger).

- The mixture will have a bitter taste
- The tablets will not be completely dissolved in the mixture
- The mixture may be prepared ahead of time and stored at room temperature for up to 8 hours.

Oral administration of dispersed tablets:

1. Place 2 tablets (400 mg) into a suitable container (tablets can be crushed into finer particles in the container) and add 30 mL of drinking water (other liquids have not been tested) to make a mixture
2. Stir or swirl the container gently to keep the particles in suspension and administer the mixture before the particles settle
3. Rinse the container with 15 mL of drinking water and administer the rinsing water
4. Repeat Step 3 until no particles are left in the container by visual confirmation.

If your healthcare provider tells you to take 800 mg, then place 4 tablets into 60 mL of drinking water to make the mixture. If your healthcare provider tells you to take 1200 mg, then place 6 tablets into 90 mL of drinking water to make a mixture. Follow the Steps 2 - 4 as above.

Nasogastric (NG) or orogastric (OG) tube administration of dispersed tablets:

1. Remove the plunger out of a 50- or 60-mL syringe. Add 2 tablets (400 mg) into the syringe body and place the plunger back in the syringe.

2. Withdraw 30 mL of drinking water into the syringe and hold the syringe with the tip pointing upward. Pull the plunger further to a higher volume position to have some air space in the syringe. Shake the syringe well (careful not to spill the contents) for about 30 to 45 seconds or until the tablets are mixed well.
3. Once the tablets are mixed well in the syringe, attach the syringe to the NG or OG tube and give the mixture all at once before it settles.
4. Withdraw 15 mL of water using the same syringe and flush through the same NG or OG tube.
5. Repeat Step 4 and make sure no particles are left in the syringe by visually checking. If particles remain, repeat Step 4.

If your healthcare provider tells you to take 800 mg, repeat Steps 1 - 5 two times. If your healthcare provider tells you to take 1200 mg, repeat Steps 1 - 5 three times. The same syringe, NG or OG tube can be used.

If you forget to take LIVTENCITY

It is important that you do not miss or skip doses of LIVTENCITY. If you miss your dose, take it as soon as you remember.

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 LIVTENCITY

If you think that you have taken too much LIVTENCITY,

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 LIVTENCITY?

Things you should do

LIVTENCITY tablets should be taken regularly at the same time each day.

Know the medicines you take. Keep a list of medicines and show it to your doctor and/pharmacist when you get a new medicine.

Things you should not do

- Do not stop taking this medicine suddenly
- Do not start or stop taking another medicine without telling your doctor first.

Driving or using machines

LIVTENCITY has no influence on your ability to drive or use machines.

Looking after your medicine

- Store below 30°C. Do not freeze.

Store it in a cool dry place 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 windowsills.

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.

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
<ul style="list-style-type: none">• Changes in taste	This common side effect goes away once you are off the drug.
<ul style="list-style-type: none">• Low levels of red blood cells (shown in blood tests). This may make you feel tired or look pale (anaemia)• Nausea or feeling sick• Vomiting• Tiredness• Diarrhoea• Headache• Loss of appetite• Weight loss• Stomach (upper abdominal) pain• Cramps or muscle weakness• Low levels of potassium or magnesium (shown in blood tests), which may cause some of the symptoms above	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
<ul style="list-style-type: none"> • Fever or high temperature 	

The dose of some medicines you take to prevent transplant rejection, may need to be adjusted, while you take LIVTENCITY. Your doctor/pharmacist will advise you.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • Low levels of white blood cells (shown in blood tests); the symptoms may include high fever, severe chills, sore throat, or mouth ulcers • Swelling of hands, ankles, or feet • High blood pressure • Kidney problems: this may make you urinate more or less than usual, swollen feet, feeling tired or weak, muscle cramps, back pain, drowsiness. 	<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>

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 LIVTENCITY contains

Active ingredient (main ingredient)	maribavir
Other ingredients (inactive ingredients)	Tablet core:

magnesium stearate,
microcrystalline cellulose,
sodium starch glycollate.

Film-coating:

brilliant blue FCF
aluminium lake (E133),
macrogol/ polyethylene
glycol, polyvinyl alcohol,
purified talc, and titanium
dioxide.

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

What LIVTENCITY looks like

LIVTENCITY 200 mg (AUST R 380132) film-coated tablets are: blue, oval shaped convex debossed with 'SHP' on one side and '620' on the other side.

The tablets are available in bottles with child resistant cap. Each bottle contains either 28 or 56 film-coated tablets.

Not all pack sizes may be distributed.

Who distributes LIVTENCITY

Takeda Pharmaceuticals Australia Pty Ltd
Level 39; 225 George Street

Sydney, NSW 2000

Australia

Telephone: 1800 012 612

This leaflet was prepared in October 2022.

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