

LIVTENCITY FILM-COATED TABLET 200MG

Maribavir

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What Livtency is used for

Livtency 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.

How Livtency works

Livtency is an antiviral prescription medicine used for treating adults who have had an organ or bone marrow transplant and developed a CMV (cytomegalovirus) infection.

Before you use Livtency

-When you must not use it

Do not use Livtency

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

-Before you start to use it

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.

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. It is not known, if Livtency 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

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

Warnings and precautions

- Talk to your doctor or pharmacist before taking Livtency with cyclosporin, tacrolimus, sirolimus and everolimus. Additional blood tests may be needed to check the blood levels of these medicines. High levels of these medicines may cause serious side effects.

-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 Livtency 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 Livtency.

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 Livtency.

How to use Livtency

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

-How much to use

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

-When to use it

Livtency can be taken with or without food.

-How to use it

You can take Livtency 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 use it

It is important that you do not miss or skip doses of Livtency. 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 used too much (overdose)

If you think that you have taken too much Livtency, You should immediately:

- 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.

While you are using it

-Things you must do

Livtency 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 must not do

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

-Things to be careful of

Driving or using machines

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

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.

Serious side effects

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:

- 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.

Less serious side effects

This common side effect goes away once you are off the drug:

- Changes in taste

Speak to your doctor if you have any of these less serious side effects and they worry you:

- 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
- Fever or high temperature

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.

You may report any side effects or 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 Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Livtency

-Storage

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 this medicine out of the sight and reach of children.

-Disposal

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.

Product description

-What it looks like

Livtency 200 mg film-coated tablets are: blue, oval shaped convex debossed with 'SHP' on one side and '620' on the other side.

Pack size:

The tablets are available in bottles with child resistant cap.

Each bottle contains either 28, 56 or 112 film-coated tablets.

Not all pack sizes may be marketed.

-Ingredients

The **active substance** is maribavir. Each tablet contains 200 mg of maribavir.

The **other ingredients** are:

Tablet Core:

magnesium stearate, microcrystalline cellulose, sodium starch glycolate.

Film-coating:

Opadry II Blue 85F105081 (brilliant blue FCF aluminium lake (E133), macrogol/polyethylene glycol, polyvinyl alcohol, purified talc, and titanium dioxide.)

-MAL number

XXX

Manufacturer

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Product Registration Holder

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