

Package leaflet: Information for the patient

LIVTENCITY 200 mg film-coated tablets maribavir

▼ 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. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What LIVTENCITY is and what it is used for
2. What you need to know before you take LIVTENCITY
3. How to take LIVTENCITY
4. Possible side effects
5. How to store LIVTENCITY
6. Contents of the pack and other information

1. What LIVTENCITY is and what it is used for

LIVTENCITY is an antiviral medicine that contains the active substance maribavir.

It is a medicine used to treat adults who have had an organ or bone marrow transplant and developed a CMV ('cytomegalovirus') infection that did not go away or came back again after taking another antiviral medicine.

CMV is a virus that a lot of people have without symptoms and normally just stays in the body without causing any harm. However, if your immune system is weakened after you get an organ or bone marrow transplant, you may be at higher risk of becoming ill from CMV.

2. What you need to know before you take LIVTENCITY

Do not take LIVTENCITY

- if you are allergic to the active substance or any of the other ingredients of this medicine (listed in section 6).
- if you take either of these medicines:
 - ganciclovir (used to manage CMV infection)
 - valganciclovir (used to manage CMV infection)

You should not be given LIVTENCITY if any of the above apply to you. If you are not sure, talk to your doctor, pharmacist or nurse before you are given LIVTENCITY.

Warnings and precautions

Talk to your doctor or pharmacist before taking LIVTENCITY if you are already being treated with cyclosporine, tacrolimus, sirolimus or everolimus (medicines to prevent transplant rejection).

Additional blood tests may be needed to check the blood levels of these medicines. High levels of these medicines may cause serious side effects.

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.

Other medicines and LIVTENCITY

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because LIVTENCITY may affect the way other medicines work, and other medicines may affect how LIVTENCITY works. Your doctor or pharmacist will tell you if it is safe to take LIVTENCITY with other medicines.

There are some medicines you must not take with LIVTENCITY. See list under “Do not take LIVTENCITY”.

Also tell your doctor if you are taking any of the following medicines. This is because your doctor may have to change your medicines or change the dose of your medicines:

- rifabutin, rifampicin – for tuberculosis (TB) or related infections
- St. John's wort (*Hypericum perforatum*) – a herbal medicine for depression and sleep problems
- statins, such as atorvastatin, fluvastatin, rosuvastatin, simvastatin, pravastatin, pitavastatin – for high cholesterol
- carbamazepine, phenobarbital, phenytoin – usually for fits or seizures (epilepsy)
- efavirenz, etravirine, nevirapine - used to treat HIV infection
- antacid (aluminium and magnesium hydroxide oral suspension) – for heartburn or indigestion due to excess stomach acid
- famotidine – for heartburn or indigestion due to excess stomach acid
- digoxin – heart medicine
- clarithromycin– antibiotic
- 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

You can ask your doctor, pharmacist or nurse for a list of medicines that may interact with LIVTENCITY.

Pregnancy

If you are pregnant, think you may be pregnant, or are planning to have a baby, ask your doctor for advice before taking this medicine. LIVTENCITY is not recommended in pregnancy. This is because it has not been studied in pregnancy and it is not known if LIVTENCITY will harm your baby while you are pregnant.

Breast-feeding

If you are breast-feeding or are planning to breast-feed, tell your doctor before taking this medicine. Breast-feeding is not recommended while taking LIVTENCITY. This is because it is not known if LIVTENCITY can pass into your breast milk or if this would affect your baby.

Driving and using machines

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

LIVTENCITY contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take LIVTENCITY

Always take this medicine exactly as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

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. You can take this medicine with or without food, as a whole tablet or a crushed tablet.

If you take more LIVTENCITY than you should

If you take too much LIVTENCITY, tell your doctor straight away.

If you forget to take LIVTENCITY

If you miss a dose, and there are less than 3 hours left until your next regular dose is due, then skip the missed dose and go back to your regular schedule. Do not take a double dose to make up for a forgotten dose.

If you stop taking LIVTENCITY

Even if you feel better, do not stop taking LIVTENCITY without talking to your doctor. Taking LIVTENCITY as recommended should give you the best chance of clearing CMV infection and/or disease.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Tell your doctor, pharmacist or nurse if you notice any of the following side effects:

Very common (may affect more than 1 in 10 people):

- changes in the way things taste
- feeling sick (nausea)
- diarrhoea
- being sick (vomiting)
- tiredness (fatigue)

Common (may affect up to 1 in 10 people):

- Increased blood levels of medicines used to prevent transplant rejections
- stomach (abdominal) pain
- loss of appetite
- headache
- weight loss

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or

Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store LIVTENCITY

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date that is stated on the carton and bottle label after EXP. The expiry date refers to the last day of that month.

Do not store above 30 °C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What LIVTENCITY contains

- The active substance is maribavir. Each film-coated tablet contains 200 mg maribavir
- The other ingredients (excipients) are
 - Tablet core:
 - Microcrystalline cellulose (E460(i)), Sodium starch glycolate (see section 2), Magnesium stearate (E470b)
 - Film coating:
 - Polyvinyl alcohol (E1203), Macrogol (i.e. polyethylene glycol) (E1521), Titanium dioxide (E171), Talc (E553b), Brilliant blue FCF aluminum lake (EU) (E133)

What LIVTENCITY looks like and contents of the pack

LIVTENCITY 200 mg film coated tablets are blue, oval shaped convex debossed with “SHP” on one side and “620” on the other side.

The tablets are packaged in high-density polyethylene (HDPE) bottles with child resistant cap contains either 28, 56 or 112 (2 bottles of 56) film-coated tablets.

Not all pack sizes may be marketed.

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