Patient Information LIVTENCITY (liv-TEN-city) (maribavir) tablets

What is LIVTENCITY?

LIVTENCITY is a prescription medicine used to treat cytomegalovirus (CMV) infection and disease in adults and children 12 years of age and older weighing at least 77 pounds (35 kg) who have received a transplant, when their infection or disease does not respond to treatment with the medicines ganciclovir, valganciclovir, cidofovir or foscarnet.

It is not known if LIVTENCITY is safe and effective in children under 12 years of age.

Before taking LIVTENCITY, tell your healthcare provider about all your medical conditions, including if you:

- are pregnant or plan to become pregnant. It is not known if LIVTENCITY will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if LIVTENCITY passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby during treatment with LIVTENCITY.

Tell your healthcare provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements. LIVTENCITY may affect the way other medicines work, and other medicines may affect how LIVTENCITY works and cause serious side effects.

Especially tell your healthcare provider if you take a seizure (anticonvulsant) medicine.

- You can ask your healthcare provider or pharmacist for a list of medicines that interact with LIVTENCITY.
- **Do not start a new medicine without telling your healthcare provider.** Your healthcare provider will tell you if it is safe to take LIVTENCITY with other medicines.
- Know the medicines you take. Keep a list of your medicines and show it to your healthcare provider and pharmacist when you get a new medicine.

How should I take LIVTENCITY?

- Take LIVTENCITY exactly as your healthcare provider tells you to take it.
- Take LIVTENCITY 2 times a day.
- Take LIVTENCITY with or without food.
- Swallow LIVTENCITY tablets whole.
- If you are not able to swallow tablets whole, you can break apart (disperse) the tablets in drinking water **or** crush the tablets and mix with drinking water and take by mouth. **See the "Instructions for Use" for detailed instructions** on how to prepare and give a dose of LIVTENCITY tablets by dispersing or crushing tablets and taking by mouth.
- If you have a Nasogastric (NG) or Orogastric (OG) Tube (French size 10 or larger), you can disperse the tablets and take through a NG or OG tube. **See the "Instructions for Use" for detailed instructions** on how to prepare and give a dose of LIVTENCITY tablets through a NG or OG Tube.
- If you take too much LIVTENCITY, call your healthcare provider or go to the nearest hospital emergency room right away.

What are the possible side effects of LIVTENCITY?

The most common side effects of LIVTENCITY include:

changes in taste
nausea
diarrhea
vomiting
tiredness

These are not all the possible side effects of LIVTENCITY.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store LIVTENCITY?

Store LIVTENCITY at room temperature between 68°F to 77°F (20°C to 25°C).

Keep LIVTENCITY and all medicines out of the reach of children.

General information about the safe and effective use of LIVTENCITY.

Medicines are sometimes prescribed for purposes other than those listed in the Patient Information leaflet. Do not use LIVTENCITY for a condition for which it was not prescribed. Do not give LIVTENCITY to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about LIVTENCITY that is written for health professionals.

What are the ingredients in LIVTENCITY?

Active ingredient: maribavir

Inactive ingredients: FD&C Blue #1, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, sodium starch glycolate, titanium dioxide, and talc.

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Instructions for Use LIVTENCITY (liv-TEN-city) (maribavir) tablets, for oral use

This Instructions for Use contains information on how to prepare and give a dose of LIVTENCITY tablets by breaking apart (dispersing) or crushing in drinking water and taking by mouth, or dispersing and giving through a Nasogastric (NG) or Orogastric (OG) Tube. Read this Instructions for Use before you prepare or give the first dose of LIVTENCITY, and each time you get a refill. Ask your healthcare provider or pharmacist if you have any questions.

Important information you need to know before preparing a dose of LIVTENCITY:

- You can break apart (disperse) the tablets in drinking water or crush the tablets and mix with drinking water. The tablet will not be completely dispersed in the mixture.
- Do not mix LIVTENCITY with any liquid other than drinking water.
- LIVTENCITY tablets that have been dispersed in drinking water can be given through a Nasogastric (NG) or Orogastric (OG) tube (French size 10 or larger).
- You can prepare the mixture ahead of time and store at room temperature 68°F to 77°F (20°C to 25°C) for up to 8 hours.

Preparing a dose of LIVTENCITY by dispersing or crushing tablets and taking by mouth:

Gather the following supplies:

- small, clean container to place tablets and water in
- drinking water
- Step 1: Choose a clean, flat work surface. Place all supplies on the work surface.
- Step 2: Wash and dry your hands well.
- **Step 3:** Get the prescribed number of LIVTENCITY tablets needed to prepare the dose.
- **Step 4:** Place the LIVTENCITY tablets into the container.

Note: If you prefer, you can crush the tablets with a spoon before adding water.

Step 5: Add the amount of drinking water needed for your prescribed dose.

Number of Tablets	Amount of Drinking water
2	30 mL
4	60 mL
6	90 mL

- **Step 6:** Swirl the container gently to disperse the tablets in the water and swallow the mixture right away. The mixture will have a bitter taste.
- **Step 7:** Rinse the container with 15 mL of drinking water and swallow the mixture.

Repeat Step 7. Check that no pieces of tablet are left in the container. Repeat **Step 7** until no pieces remain.

Preparing and giving a dose of LIVTENCITY through a Nasogastric (NG) or Orogastric (OG) Tube:

Gather the following supplies:

- 50 mL or 60 mL syringe
- drinking water
- **Step 1:** Remove the cap (if capped) and plunger out of a 50 mL or 60 mL syringe. Add 2 tablets into the syringe body and place the plunger back in the syringe.

Note: Only 2 tablets can be given through the NG or OG tube at a time.

- **Step 2:** Withdraw 30 mL of drinking water into the syringe.
- **Step 3:** Hold the syringe with the tip pointing upward. Pull the plunger back so there is some air space in the syringe. If there is a cap, place the cap back on the syringe. Shake the syringe well for about 30 to 45 seconds or until the tablets are completely dispersed. Be careful not to spill the contents of the syringe.
- **Step 4:** Remove the cap (if capped) from the syringe again and attach the syringe to the NG or OG tube and give the mixture right away.
- **Step 5:** Withdraw 15 mL of drinking water into the same syringe and flush through the NG or OG tube.

Repeat Step 5. Check that no pieces of tablet are left in the syringe. Repeat **Step 5** until no pieces remain.

Note: If your prescribed dose is more than 2 tablets, Repeat **Steps 1 through 5** until you give the full prescribed dose.

Storing LIVTENCITY:

Store LIVTENCITY at room temperature 68°F to 77°F (20°C to 25°C).

Keep LIVTENCITY and all medicines out of the reach of children.

For more information, go to www.explorelivtencity.com or call 1-877-TAKEDA-7 (1-877-825-3327).

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