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# LIVTENCITY® (active substance: maribavir)

First authorisation in Switzerland: 19 July 2023

Film-coated tablets for the treatment of cytomegalovirus (CMV) infection in adults

## About the medicinal product

The medicinal product LIVTENCITY, containing the active substance maribavir, is a medicinal product for adults who have received an organ or bone marrow transplant and have developed a cytomegalovirus (CMV) infection that has not responded to treatment with certain other antivirals.

CMV is a herpes virus that many people carry without realising it. Normally, the virus remains in the body without causing any harm. However, when the immune system is weakened following an organ or bone marrow transplant, the risk of contracting CMV is increased.

Since this is a rare and life-threatening disease, the medicine has been authorised as an orphan drug. The term "orphan drug" is used to refer to important medicines for rare diseases.

## Mode of action

LIVTENCITY works through the active substance maribavir specifically blocking the CMV enzyme[1] UL97 in the body. This enzyme plays a key role in the replication of the virus. As the active substance maribavir inhibits this enzyme, the spread of the virus in the body can be stopped and the infection controlled.

## Administration

LIVTENCITY is a prescription-only medicine. It is available as a film-coated tablet in the dosage strength of 200 mg.

The recommended dose is 400 mg (2 tablets of 200 mg each) twice daily over a period of 8 weeks. However, the treatment duration may be adjusted based on the patient's individual medical needs.

[1] Enzyme: enzymes are proteins that act as biocatalysts, controlling and accelerating biochemical reactions in the body.

## Efficacy

The efficacy of LIVTENCITY was investigated in Study SHP620-303 in 352 male and female adult patients who had received an organ or bone marrow transplant and had a cytomegalovirus (CMV) infection, which had not responded to treatment with ganciclovir, valganciglovir, foscarnet, or cidofovir (medications that are normally used for the treatment of this type of viral infection). The patients were allocated to an 8-week treatment with 400 mg LIVTENCITY twice daily or a treatment decided by the investigator (ganciclovir, valganciclovir, foscarnet, or cidofovir).

The primary efficacy endpoint[2] was the elimination of the CMV DNA (CMV DNA plasma concentration in the blood below the limit of detection) 8 weeks after the start of treatment.

In the study, the elimination of CMV DNA was observed significantly more frequently in patients who received LIVTENCITY compared to those who received a treatment decided by the investigator.

## Precautions, undesirable effects & risks

LIVTENCITY must not be used in those who are hypersensitive to the active substance or any of the excipients.

The most common undesirable effects (affecting more than 1 in 10 users) are taste disturbances, nausea, diarrhoea, vomiting, and fatigue.

All precautions, risks, and other possible undesirable effects are listed in the Information for patients (package leaflet) and the Information for healthcare professionals.

## Why the medicinal product has been authorised

At the time of the application for authorisation of LIVTENCITY, there was no medication authorised in Switzerland specifically for the treatment of CMV infections and/or diseases in adults who have received an organ or bone marrow transplant and have developed a cytomegalovirus (CMV) infection that has not responded to treatment with certain other antivirals. Accordingly, LIVTENCITY covers an urgent medical need.

The efficacy of LIVTENCITY in eliminating CMV DNA in the blood of patients was proven in Study SHP620-203 and another supporting study.

Although there are some uncertainties regarding the precise treatment effect of the active substance maribavir, these can be accepted given the high medical need, in comparison with the other medications used for treatment of CMV infections/diseases, and the favourable safety profile in the clinical setting.

Taking all the risks and precautions into account, and based on the available data, the benefits of LIVTENCITY outweigh the risks. Swissmedic has therefore authorised the medicinal product LIVTENCITY, containing the active substance maribavir, for use in Switzerland.

[2] Primary efficacy endpoint: The primary endpoint is the main objective of the trial determined before the trial starts. If the primary endpoint is reached or exceeded, the trial proves that a treatment is effective. Secondary endpoints, on the other hand, refer to other effects that do not clearly prove efficacy or that do not allow any clear conclusions to be drawn about the actual target criterion (primary endpoint).

## Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals LIVTENCITY®

Information for patients (package leaflet): Information for patients LIVTENCITY®

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Public Summary SwissPAR.

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