European Medicines Agency

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EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

VISTIDE

EPAR summary for the public

This document is a summary of the European Public Assessment Report (EPAR). It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the studies performed, to reach their recommendations on how to use the medicine.
If you need more information about your medical condition or your treatment, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis of the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is Vistide?
Vistide is a concentrate that is made up into a solution for infusion (drip into a vein). It contains the active substance cidofovir (75 mg/ml).

What is Vistide used for?
Vistide is used to treat cytomegalovirus (CMV) retinitis, a viral infection of the retina (the light-sensitive surface at the back of the eye). This disease can cause loss of vision. Vistide is used in patients with acquired immunodeficiency syndrome (AIDS) who do not have kidney disease. It should only be used when other medicines are unsuitable.
The medicine can only be obtained with a prescription.

How is Vistide used?
Treatment with Vistide should be prescribed by a doctor who has experience in the management of human immunodeficiency virus (HIV) infection. Before receiving Vistide, the patient's kidneys must be checked, as the medicine must not be given to patients with kidney disease. During the 'induction' phase, Vistide is given as a one-hour infusion of 5 mg per kilogram body weight once a week for the first two weeks. Then, during the 'maintenance' phase, it is given once every two weeks. Treatment is continued for as long as recommended in local guidelines on the management of HIV-infected patients.
To reduce the risk of kidney damage, patients must also take another medicine called probenecid (2 g three hours before the infusion, then 1 g two and eight hours after the infusion) and receive an infusion of one litre of saline solution one hour before the infusion of Vistide. Probenecid is used because it prevents cidofovir building up in the kidneys, and saline is used to prevent dehydration.

How does Vistide work?
The active substance in Vistide, cidofovir, is an antiviral medicine that belongs to the class 'nucleotide analogues'. It blocks the activity of enzymes called 'DNA polymerases' in CMV, which the virus uses to produce DNA. When the virus cannot produce DNA, it cannot reproduce, slowing down the spread of infection.

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How has Vistide been studied?
The effects of Vistide in CMV retinitis in AIDS patients were studied in one treatment study and one maintenance study. The treatment study compared Vistide with no treatment in 48 patients who had not been treated with any medicine for CMV retinitis before. The maintenance study compared two maintenance doses of Vistide (5 and 3 mg/kg body weight) in 100 patients who had stopped responding to, or could not receive other medicines for CMV retinitis (ganciclovir or foscarnet). In both studies, the main measure of effectiveness was the time taken for the disease to get worse.

What benefit has Vistide shown during the studies?
In the treatment study, Vistide was more effective than no treatment. It took an average of 120 days for CMV retinitis to get worse in patients receiving Vistide, compared with 22 days in those who did not receive any treatment. In the maintenance study, the 5-mg/kg dose was more effective than the 3-mg/kg dose (115 days and 49 days, respectively).

What is the risk associated with Vistide?
The most common side effects with Vistide (seen in more than 1 patient in 10) are neutropenia (low white blood cell counts), headache, nausea (feeling sick), vomiting, alopecia (hair loss), rash, proteinuria (protein in the urine), increased blood creatinine levels (a breakdown product of muscles), asthenia (weakness) and fever. For the full list of all side effects reported with Vistide, see the Package Leaflet.
Vistide should not be used in people who may be hypersensitive (allergic) to cidofovir or any of the other ingredients. It should also not be used in patients who have kidney disease or who are taking other medicines that might be harmful to the kidneys, or in patients who cannot take probenecid or other ‘sulfa-containing’ medicines. Vistide should not be injected directly into the eye.

Why has Vistide been approved?
The Committee for Medicinal Products for Human Use (CHMP) decided that Vistide’s benefits are greater than its risks for the treatment of CMV retinitis in patients with AIDS and without kidney disease. The Committee recommended that Vistide be given marketing authorisation.

Other information about Vistide:
The European Commission granted a marketing authorisation valid throughout the European Union for Vistide on 23 April 1997. The marketing authorisation was renewed on 23 April 2002 and on 23 April 2007. The marketing authorisation holder is Gilead Sciences International.

The full EPAR for Vistide is available here.

This summary was last updated in 01-2009.