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Questions and answers on the shortage of Vistide

The European Medicines Agency has been notified of a voluntary recall of a batch of the antiviral medicine Vistide, used to treat a viral infection of the eye in patients with acquired immunodeficiency syndrome (AIDS). As there are no other batches of Vistide in the supply chain at the present time, this will result in shortages of this medicine in the EU Member States where the product is marketed. To deal with the situation, the Agency recommended that a letter should be sent to healthcare professionals in the countries affected by the shortage explaining the supply situation in their country.

What is Vistide?

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 AIDS who do not have kidney disease. It should only be used when other medicines are unsuitable.

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.

Vistide received a marketing authorisation valid throughout the European Union on 23 April 1997. It is available in the following Member States: Austria, France, Germany, Ireland, Italy, Netherlands, Poland, Portugal, Spain, Sweden and United Kingdom.

What is the cause of the shortage?

During routine packaging, floating particles were observed in a batch of Vistide (batch B120217). The batch, which had been distributed to Germany, Italy and Spain, is currently being recalled. The recall is a precautionary measure, and no reports of adverse events attributable to the particles have been received.

While the issue is being investigated, the company that markets Vistide, Gilead Sciences International Ltd, has halted production of Vistide. There are no concerns over the quality and safety of Vistide currently available on the market, but supplies are very limited. As no other batches are available to

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replace the affected batch, shortages are expected in all the EU Member States where the product is marketed.

It is currently unknown how long the shortage will last.

What are the recommendations of the CHMP?

The CHMP has agreed that the company should provide a letter to healthcare professionals in the countries where Vistide is marketed, informing them of the shortage in their country. Other medicines are available in the EU for the treatment of CMV retinitis.

What are the recommendations for patients?

- Patients are informed of an upcoming shortage of Vistide. Patients who are currently treated with Vistide may need to switch to alternative treatments.
- During the shortage, the treating doctor will select the best alternative treatment for each patient.
- Patients who have any questions should speak to their doctor or pharmacist.

What are the recommendations for prescribers?

- Healthcare professionals will receive information on the shortage of Vistide in their country.
- Any adverse reactions that the patient may experience should be reported to the national competent authorities and should be treated as per standard medical practice.