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Questions and answers on Cymevene and associated names (ganciclovir, 500 mg powder for concentrate for solution for infusion, intravenous)

Outcome of a procedure under Article 30 of Directive 2001/83/EC

On 25 February 2016, the European Medicines Agency completed a review of Cymevene. The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that there is a need to harmonise the prescribing information for Cymevene in the European Union (EU).

What is Cymevene?

Cymevene is an antiviral medicine that is used to treat or prevent infection with cytomegalovirus (CMV) in immunocompromised individuals (people with a weakened immune system).

CMV is a common virus that belongs to the herpes virus family. It can infect almost anyone but usually remains dormant in healthy people, rarely causing symptoms. However, the virus can cause problems in people with a weakened immune system such as people with acquired immune deficiency syndrome (AIDS) or who are undergoing cancer treatment or taking medicines to prevent rejection of an organ transplant. In these patients, CMV can result in severe or life-threatening infections that attack various organs including the lungs, brain and eyes.

Cymevene contains the active substance ganciclovir and is available as a powder to be made into a solution for infusion (drip) into a vein.

Cymevene is marketed in all EU member states with the exception of Latvia, Malta and Slovenia. It is also available in the EU under the names Cymevan, Cymeven i.v. and Citovirax. The company that markets these medicines is F. Hoffmann – La Roche Ltd. and associated companies.

Why was Cymevene reviewed?

Cymevene has been authorised in the EU via national procedures. This has led to divergences across member states in the way the medicine can be used, as seen in the differences in the summaries of product characteristics (SmPCs), labelling and package leaflets in the countries where the medicine is marketed.

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Cymevene was identified as needing harmonisation by the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh).

On 15 September 2014, the European Commission referred the matter to the CHMP in order to harmonise the marketing authorisations for Cymevene in the EU.

What are the conclusions of the CHMP?

The CHMP, in the light of the data submitted and the scientific discussion within the Committee, was of the opinion that the SmPCs, labelling and package leaflets should be harmonised across the EU.

The areas harmonised include:

4.1 Therapeutic indications

The CHMP agreed that Cymevene can be used for the treatment of diseases caused by CMV in immunocompromised patients. Cymevene can also be used to prevent CMV disease in patients with drug-induced immunosuppression (for example after an organ transplant or chemotherapy). The medicine can be used in adults and adolescents from 12 years of age. When prescribing Cymevene, consideration should be given to official guidance on the appropriate use of antiviral agents.

The CHMP also agreed that Cymevene should no longer be indicated for the prevention of CMV disease in patients with AIDS. Since the use of highly active antiretroviral therapy (HAART) has reduced the risk of CMV disease in patients with HIV infection, preventive treatment with Cymevene is no longer considered necessary.

4.2 Posology and method of administration

Having harmonised the indication, the CHMP also harmonised the recommendations on how to use Cymevene. The recommended dose of Cymevene and duration of treatment depend on the weight of the patient and on whether the medicine is used to prevent or treat CMV disease. Patients with reduced kidney function should receive lower doses of Cymevene.

Different treatment schedules should be followed during initial and maintenance treatment, in accordance with treatment guidelines.

Information on the safety and efficacy of Cymevene in children under 12 years of age is limited. The CHMP was unable to make recommendations on such use based on currently available data and further assessment should be carried out.

4.3 Contraindications

Cymevene must not be used in patients allergic to its active substance ganciclovir, to a related antiviral medicine, valganciclovir, or to any other ingredients of the medicine.

It is not known whether ganciclovir passes into breast milk; however this possibility cannot be excluded and therefore breastfeeding must be discontinued in women treated with Cymevene, to avoid potential serious side effects in breastfed infants.

4.6 Fertility, pregnancy and lactation

Ganciclovir has the potential to cause birth defects in humans. For this reason, the CHMP agreed that Cymevene should not be used in pregnant women unless the potential benefit to the mother outweighs the potential risk to the unborn child.

Women who could become pregnant must be advised to use effective contraception during treatment with Cymevene and for at least 30 days after treatment has stopped. Men whose female partner could

become pregnant must be advised to use barrier contraception methods during treatment with Cymevene, and for at least 90 days afterwards.

Other changes

The Committee also harmonised other sections of the SmPC including sections 4.4 (special warnings and precautions for use), 4.5 (interactions) and 4.8 (side effects).

The amended information to doctors and patients is available here.

The European Commission issued an EU-wide legally binding decision on this opinion on 28 April 2016.