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Questions and answers on Famvir and associated names (famciclovir, 125, 250, 500 and 750 mg tablets)

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

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

What is Famvir?

Famvir is an antiviral medicine that contains the active substance famciclovir. It is used to treat infection with herpes viruses including varicella zoster which causes shingles, and herpes simplex (HSV) which can cause cold sores or genital herpes.

The active substance in Famvir, famciclovir, is converted in the body into a substance called penciclovir. Penciclovir is an antiviral. It works by blocking the production of DNA by herpes viruses. The blocking of the production of DNA leads to the viruses being unable to multiply.

Famvir is also available in the EU under other trade names: Famciclovir-Sandoz, Famciclovir-SB, Famciclovir-SB Zoster, Famvir Zoster and Oravir.

The company that markets these medicines is Novartis.

Why was Famvir reviewed?

Famvir is 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.

Famvir was identified as needing harmonisation by the Co-ordination Group on the Mutual and Decentralised Procedures – Human (CMD(h)).

On 27 November 2008, the European Commission referred the matter to the CHMP in order to harmonise the marketing authorisations for Famvir and associated names in the EU.

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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 Famvir should be used for:

- the treatment of herpes zoster (shingles) and ophthalmic zoster (shingles around the eye) in immunocompetent adults (patients with an immune system that works normally);
- the treatment of herpes zoster in immunocompromised adults (reduced activity of the immune system);
- treatment of first and recurrent episodes of genital herpes in immunocompetent adults;
- treatment of recurrent episodes of genital herpes in immunocompromised adults;
- the suppression of recurrence of genital herpes in immunocompetent and immunocompromised adults.

4.2 Posology and method of administration

For herpes zoster, the recommended dose is 500 mg three times a day, for seven days in immunocompetent adults and for ten days in immunocompromised adults.

For genital herpes in immunocompetent adults, the recommended dose for the first episode is 250 mg three times a day for five days. Recurrent episodes should be treated with 125 mg twice a day for five days.

For recurrent genital herpes in immunocompromised adults, the recommended dose is 500 mg twice a day for seven days.

For the suppression of the recurrence of genital herpes, the recommended dose is 250 mg twice a day in immunocompetent adults and 500 mg twice a day in immunocompromised adults. This treatment should be assessed after 12 months.

The Committee recommended that the doses of Famvir should be adjusted in patients with impaired kidney function.

4.3 Contra-indications

Famvir should not be used in people who may be hypersensitive (allergic) to famciclovir, penciclovir or to any of the other ingredients.

Other changes

Other sections harmonised include the sections on special warnings, pregnancy and lactation and side effects.

The amended information to doctors and patients is available here.

The European Commission issued a decision on 27 July 2010.

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