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Questions and answers on Valtrex and associated names (valaciclovir, 250, 500 and 1000 mg tablets)

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

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

What is Valtrex?

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

Valtrex is also used to prevent infection with cytomegalovirus. Cytomegalovirus can cause harmful effects in high-risk populations such as infants and patients who have had a solid organ transplant.

The active substance in Valtrex, valaciclovir, is broken down in the body into two substances, aciclovir and valine (an amino-acid). Aciclovir is an antiviral that works by blocking an enzyme that the viruses need to produce DNA. The blocking of the production of DNA leads to the viruses being unable to multiply.

Valtrex is also available in the EU under other trade names: Talavir, Valaciclovir Allen, Valaciclovir Biogaran, Valaciclovir GSK, Valaciclovir Sandoz, Valaciclovir Winthrop, Valavir, Valherpes, Valtrex S, Virval and Zelitrex.

The company that markets these medicines is GlaxoSmithKline.

Why was Valtrex reviewed?

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

On 22 October 2008, the European Commission referred the matter to the CHMP in order to harmonise the marketing authorisations for Valtrex and associated names 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 recommended that Valtrex 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 adults with mild or moderate immunosuppression (reduced activity of the immune system);
- HSV infections of the skin and mucous membranes including:
  - the treatment of the first episode of genital herpes in immunocompetent patients;
  - the treatment of recurrent episodes of genital herpes in immunocompetent and immunocompromised patients (patients with a weakened immune system);
  - the suppression of the recurrence of genital herpes in immunocompetent and immunocompromised patients;
  - treatment of herpes labialis (cold sores);
  - the treatment and suppression of recurrent ocular (eye) HSV infection;
- the prevention of cytomegalovirus infection and disease following solid organ transplantation in adults and adolescents.

4.2 Posology and method of administration

The Committee harmonised the doses of Valtrex to be used for the different conditions.

- For the treatment of herpes zoster, the recommended dose is 1000 mg three times a day for seven days in immunocompetent adults. Immunocompromised patients should be treated for a further two days after the crusting of their lesions.
- For use in HSV infections of the skin and mucous membranes, the following doses are recommended:
  - 500 mg twice a day for treating immunocompetent patients. For recurrent episodes treatment should be for three to five days. For first episodes, which can be more severe, treatment may be extended to ten days.
  - 2,000 mg twice a day for one day for treating patients with herpes labialis.
  - 1,000 mg twice a day for at least five days for treating immunocompromised patients.

- 500 mg once a day for suppressing the recurrence of HSV infections in immunocompetent adults and 500 mg twice daily in immunocompromised adults. Treatment should be evaluated after six to 12 months.

- For the prevention of cytomegalovirus infection following organ transplantation in adults and adolescents, the recommended dosage is 2000 mg four times a day, to be started as early as possible after the transplant.

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

4.3 Contra-indications

The CHMP recommended that Valtrex should not be used in people who may be hypersensitive (allergic) to valaciclovir, aciclovir or to any of the excipients.

4.6 Pregnancy and lactation

The CHMP recommended that Valtrex should only be used in pregnancy if the potential benefits of treatment outweigh the risks. It should also be used with caution during breast-feeding.

Other changes

The Committee also harmonised other sections of the SmPC, including the sections on special warnings and side effects.

The amended information to doctors and patients is available here.

The European Commission issued a decision on 13 July 2010.

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