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Questions and answers on Clenil and associated names (beclometasone dipropionate, 400 and 800 microgram nebuliser suspension)

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

On 15 September 2016, the European Medicines Agency completed a review of Clenil. The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that there is a need to harmonise the prescribing information for Clenil in the European Union (EU).

What is Clenil?

Clenil is a medicine used for the maintenance treatment of asthma in adults and children. It is also used to treat recurrent wheezing (whistling sound made while breathing, caused by narrowed airways or inflammation) in children up to 5 years of age. It is available as a suspension given by inhalation though a nebuliser device, and in asthma it should only be used when the use of other hand-held inhalers is not appropriate.

Clenil contains the active substance beclometasone dipropionate (which belongs to a group of anti-inflammatory medicines commonly known as 'corticosteroids').

Clenil is marketed in the following EU Member States: France, Germany, Greece, Ireland and Italy. It is also available under the trade names of Becloneb, Beclospin and Sanasthmax. The company that markets these medicines is Chiesi and associated companies.

Why was Clenil reviewed?

Clenil 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.

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

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On 19 June 2015, the Italian medicines regulatory agency referred the matter to the CHMP in order to harmonise the marketing authorisations for Clenil 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 agreed that Clenil can be used for the maintenance treatment of asthma in adults and children when the use of pressurised or dry powder inhalers is unsatisfactory or inappropriate.

The Committee agreed that Clenil should no longer be used to treat common bronchostenotic conditions (narrowing of the airways in the lungs) because of the lack of rigorous evidence from adequately designed clinical studies. However, the Committee considered that Clenil can be used to treat recurrent wheezing in children up to 5 years of age because this use is supported by adequate data.

The CHMP also agreed that Clenil should no longer be used to treat allergic rhinitis (inflammation of the nasal passages caused by an allergy, for example hay fever or allergy to dust mites) because the available data do not support this use and other medicines available as nasal sprays may be better tolerated.

4.2 Posology and method of administration

Having harmonised the indication, the CHMP also harmonised recommendations on the doses. The starting dose of Clenil depends on the frequency and severity of symptoms and it can be adjusted until symptoms are under control. The maximum daily dose is 3,200 micrograms in adults and adolescents (up to 1,600 micrograms taken twice a day) and 1,600 micrograms in children below 12 years (up to 800 micrograms taken twice a day). The lowest dose needed to control symptoms should be used.

In children with recurrent wheezing the response to treatment should be carefully monitored; if no benefit is observed within 2-3 months, Clenil should be discontinued. The duration of treatment should not exceed 3 months, unless a diagnosis of asthma is likely.

4.4 Special warnings and precautions for use

In children up to 5 years of age, the decision to start Clenil for the treatment of recurrent wheezing should be determined by the severity and frequency of the wheezing episodes. Regular follow-up is recommended to review the treatment response. If no treatment benefit is observed within 2-3 months or if a diagnosis of asthma is not likely, Clenil should be discontinued to avoid unnecessary long-term exposure to inhaled corticosteroids and associated risks in children.

Other changes

The Committee also harmonised other sections of the SmPC including sections 4.6 (fertility, pregnancy and lactation), 4.8 (side effects), and 5.1 (pharmacodynamics).

The amended information to doctors and patients is available here.

The European Commission issued a decision on this opinion on 11/11/2016.