30 September 2010
EMA/CHMP/466386/2010 rev.
EMEA/H/A-30/001266

Questions and answers on Daivobet and associated names (calcipotriol/betamethasone gel and ointment, 50 micrograms/0.5 mg per g)

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

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

What is Daivobet?

Daivobet is used to treat adults with psoriasis (a disease causing red, scaly patches on the skin). It is available as a gel and ointment and is used topically (applied on the skin).

Daivobet contains two active substances: calcipotriol and betamethasone. Calcipotriol, a substance derived from vitamin D, acts through receptors in the skin to prevent the multiplication of cells that cause the scaly patches in psoriasis. Betamethasone is an anti-inflammatory medicine that helps to reduce the inflammation and itching that occur with psoriasis.

Daivobet is also available in the EU under the trade name Dovobet. The company that markets these medicines is Leo Pharmaceutical Products.

Why was Daivobet reviewed?

Daivobet ointment was authorised in some Member States through a mutual recognition procedure and in others through national procedures. Daivobet gel was authorised via a decentralised procedure. Because of this, there are some differences in the summaries of product characteristics (SmPCs), labelling and package leaflets in the countries where the medicines are marketed.

On 10 March 2010, Leo Pharmaceutical Products referred Daivobet to the CHMP in order to harmonise the marketing authorisations for the product 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.

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The areas harmonised include:

4.1 Therapeutic indications

The CHMP agreed that Daivobet ointment is to be used for the treatment of adults with plaque psoriasis where it is possible to use a topical medicine. Daivobet gel is for the treatment of psoriasis on the scalp or mild to moderate plaque psoriasis on other parts of the body.

4.2 Posology and method of administration

Daivobet should be applied once a day on the affected areas of the skin. No more than 15 g of the gel or ointment should be used in one day. The recommended treatment period for the ointment is four weeks. For the gel, the recommended treatment period is four weeks for scalp psoriasis and eight weeks for non-scalp psoriasis. Further treatment can be given under medical supervision.

4.3 Contra-indications

Daivobet should not be used in patients who may be hypersensitive (allergic) to the active substances or to any other ingredient. Daivobet must not be used in patients who have some types of psoriasis that is red and flaking off or filled with pus. It must also not be used in patients with abnormal levels of calcium in their blood.

The Committee also harmonised a list of contra-indications related to skin conditions, including viral lesions of the skin, fungal or bacterial skin infections, parasitic infections and skin problems caused by tuberculosis or syphilis. For the full list, see the harmonised SmPC.

Other changes

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

The amended information to doctors and patients is available here.

The European Commission issued a decision on 30 September 2010.

Rapporteur:	Patrick Salmon (Ireland)
Co-rapporteur(s):	Jens Ersbøll (Denmark)
Referral start date:	20 April 2010
Company responses provided on:	16 June 2010
Opinion date:	22 July 2010