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Questions and answers on Dexamethasone Alapis (dexamethasone, oral solution, 0.4 mg/ml)

Outcome of a procedure under Article 29 of Directive 2001/83/EC as amended

The European Medicines Agency has completed an arbitration procedure following a disagreement among Member States of the European Union (EU) regarding the authorisation of the medicine Dexamethasone Alapis. The Agency's Committee for Medicinal Products for Human Use (CHMP) has concluded that the benefits of Dexamethasone Alapis outweigh its risks, and the marketing authorisation can be granted in Malta and in the following Member States of the EU: Belgium, Bulgaria, Cyprus, Germany, Greece, Portugal, Romania and the United Kingdom.

What is Dexamethasone Alapis?

Dexamethasone Alapis is a medicine that contains the active substance dexamethasone. It is available as an oral solution (0.4 mg/ml). The active substance in Dexamethasone Alapis, dexamethasone, belongs to a group of anti-inflammatory medicines known as corticosteroids. It works by entering cells and blocking the production of vascular endothelial growth factor (VEGF) and prostaglandins, substances that are involved in inflammation and swelling.

Dexamethasone Alapis is intended for use principally as an anti-inflammatory or immunosuppressant (a medicine that reduces the activity of the immune system) in a range of specific disorders affecting different parts of the body, including the blood, liver, kidney, stomach and gut, muscles, eye, lungs and skin, as well as in certain cancers and in the management of anaphylaxis (severe allergic reaction).

Why was Dexamethasone Alapis reviewed?

Alapis S.A. submitted Dexamethasone Alapis to Malta for a decentralised procedure. This is a procedure where one Member State (the 'reference Member State', in this instance Malta) assesses a medicine with a view to granting a marketing authorisation that will be valid in this country as well as in other Member States (the 'concerned Member States', in this instance Belgium, Bulgaria, Cyprus, Germany, Greece, Portugal, Romania and the United Kingdom).

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
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However, the Member States were not able to reach an agreement and the Maltese medicines regulatory agency referred the matter to the CHMP for arbitration on 30 May 2011.

The German medicines regulatory authority was of the opinion that the data submitted to support the application did not provide sufficient evidence to demonstrate the safety and effectiveness of Dexamethasone Alapis. The grounds for the referral were that the application, which was supported by published literature rather than studies carried out with Dexamethasone Alapis, because dexamethasone has a history of well-established use in the EU for at least 10 years, was mainly supported by literature demonstrating the safety and efficacy of dexamethasone in tablet form rather than oral solution form and the bridging data provided were not considered adequate to conclude on the benefit-risk profile of the oral solution form.

What are the conclusions of the CHMP?

Based on evaluation of the currently available data and the scientific discussion within the Committee, the CHMP concluded that the data submitted was sufficient to show that Dexamethasone Alapis could be used safely and effectively based on the well established use of dexamethasone. The CHMP concluded that the benefits of Dexamethasone Alapis outweigh its risks, and therefore the marketing authorisation for Dexamethasone Alapis should be granted in all concerned Member States.

The European Commission issued a decision on 24 October 2011.