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# Questions and answers on Mometasone Furoate Sandoz (mometasone furoate nasal spray, 50 microgram/dose)

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

On 19 July 2012, the European Medicines Agency completed an arbitration procedure following a disagreement among Member States of the European Union (EU) regarding the authorisation of the medicine Mometasone Furoate Sandoz. The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that the benefits of Mometasone Furoate Sandoz outweigh its risks, and that the marketing authorisation can be granted in the Netherlands and in the following Member States of the EU: Belgium, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Italy, Luxembourg, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and the United Kingdom, as well as Norway.

## What is Mometasone Furoate Sandoz?

Mometasone Furoate Sandoz is a medicine that contains the active substance mometasone furoate. It is available as a nasal spray. Mometasone Furoate Sandoz is used in adults and children from six years of age to treat the symptoms of seasonal allergic or perennial rhinitis (inflammation of the nasal passages caused by an allergy such as hay fever, or which occurs throughout the year). It is also used to prevent moderate to severe symptoms of seasonal allergic rhinitis before the pollen seasons starts. In addition, it is used in adults to treat the symptoms of nasal polyps (growths in the lining of the nose).

The active substance, mometasone furoate, belongs to the group 'glucocorticoids'. It works by attaching to receptors in various types of immune cells, leading to a reduction in the release of substances that are involved in the inflammation process, and thereby reducing the symptoms of allergy.

Mometasone Furoate Sandoz is a 'hybrid medicine'. This means that it is similar to a 'reference medicine' already authorised in the EU that contains the same active substance, but which is given using a different type of nasal spray device. The 'reference medicine' for Mometasone Furoate Sandoz is called Nasonex.

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## Why was Mometasone Furoate Sandoz reviewed?

Sandoz B.V. submitted an application for Mometasone Furoate Sandoz to the Dutch medicines regulatory agency for a decentralised procedure. This is a procedure where one Member State (the 'reference Member State', in this instance the Netherlands) 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, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Italy, Luxembourg, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and the United Kingdom, as well as Norway).

However, the Member States were not able to reach an agreement, and the Spanish medicines regulatory agency referred the matter to the CHMP for arbitration on 23 February 2012.

The grounds for the referral were concerns over the type of *in vitro* (experimental) studies carried out to demonstrate that Mometasone Furoate Sandoz is comparable to Nasonex (that it produces the same levels of the active substance in the nose as Nasonex). The Spanish agency therefore considered that the results from the *in vitro* studies could not be used to predict how well the medicine would work in patients. In addition, there were concerns over the methodology used to analyse these *in vitro* results.

## What are the conclusions of the CHMP?

Based on the evaluation of the currently available data and the scientific discussion within the Committee, the CHMP recognised some of the concerns of the Spanish agency, but concluded that overall it was sufficiently demonstrated that possible differences between Mometasone Furoate Sandoz and the reference medicine would not affect the benefit-risk balance of the product, taking into account all the *in vitro* data. Also, data from a clinical study provided additional evidence that Mometasone Furoate Sandoz nasal spray works as well as Nasonex nasal spray in patients. The CHMP therefore concluded that the benefits of Mometasone Furoate Sandoz outweigh its risks and recommended that the marketing authorisation be granted in the concerned Member States.

The European Commission issued a decision on 08 October 2012.