27 June 2014
EMA/376438/2014
EMEA/H/A-30/001354

Questions and answers on Sandostatin and associated names (octreotide, 0.05 mg/1 ml, 0.1 mg/1 ml, 0.5 mg/1 ml and 1 mg/5 ml, solution for injection or infusion)

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

On 26 June 2014, the European Medicines Agency completed a review of Sandostatin. The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that there is a need to harmonise the prescribing information for Sandostatin in the European Union (EU).

What is Sandostatin?

Sandostatin is a medicine that contains the active substance octreotide. Octreotide is a synthetic substance that mimics the activity of the natural hormone somatostatin. Like somatostatin, octreotide blocks the release of hormones found in the body, particularly growth hormone (which consequently reduces the release of insulin-like growth factor 1, IGF-1) but also others such as thyroid-stimulating hormone (TSH) and various gut hormones.

Sandostatin has been authorised in the EU since the 1980s for treating various conditions, including acromegaly (a disease in which the pituitary gland produces too much growth hormone, leading to excess growth of body tissues and organs), gastro-entero-pancreatic endocrine tumours (tumours that arise from cells in the gut which release hormones that control various functions of the digestive system), prevention of complications following pancreatic surgery, and bleeding gastro-oesophageal varices (enlarged veins in the oesophagus or stomach that bleed).

Sandostatin is available as a solution to be injected under the skin or to be diluted before giving it by infusion (drip) into a vein. The medicine is marketed in all the EU Member States.

The company that markets these medicines is Novartis.

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Why was Sandostatin reviewed?

Sandostatin is 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.

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

On 22 May 2013, the European Commission referred the matter to the CHMP in order to harmonise the marketing authorisations for Sandostatin 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

After reviewing the available data supporting the medicine's use, the CHMP agreed that Sandostatin should continue to be used for the following conditions:

- Symptomatic control and reduction of growth hormone and IGF-1 plasma levels in patients with acromegaly who are inadequately controlled by surgery or radiotherapy. Sandostatin is also indicated for patients with acromegaly who are unfit or unwilling to undergo surgery, or in the interim period until radiotherapy becomes fully effective.
- Relief of symptoms associated with functional gastro-entero-pancreatic endocrine tumours. Sandostatin is not an anti-tumour therapy and is not curative in these patients.
- Prevention of complications following pancreatic surgery.
- Emergency management to stop bleeding and to protect from re-bleeding owing to gastro-oesophageal varices in patients with cirrhosis (scarring of the liver). Sandostatin is to be used in association with specific treatments such as endoscopic sclerotherapy.
- Treatment of TSH-secreting pituitary adenomas (benign tumours of the pituitary gland):
  - when secretion has not normalised after surgery and/or radiotherapy;
  - in patients in whom surgery is inappropriate;
  - in patients who have received radiotherapy, until the radiotherapy is effective.

However, Sandostatin should no longer be used to control diarrhoea associated with AIDS as initiation of HIV treatment is the current standard of care.

4.2 Posology and method of administration

Having harmonised the indications, the CHMP also harmonised recommendations on the doses and duration of treatment with Sandostatin.

4.3 Contraindications

The CHMP agreed that hypersensitivity (allergy) to octreotide or any other ingredients in Sandostatin should be the only contraindication.

Other changes

The CHMP also harmonised other sections of the SmPC including sections 4.4 (special warning and precautions for use), 4.6 (pregnancy and lactation) and 4.8 (side effects).

The amended information to doctors and patients is available here.

A European Commission decision on this opinion will be issued in due course.