21 July 2016
EMA/CHMP/467320/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Truberzi

eluxadoline

On 21 July 2016, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Truberzi, intended for the treatment of adults with irritable bowel syndrome with diarrhoea (IBS-D). The applicant for this medicinal product is Aptalis Pharma SAS.

Truberzi will be available as 75 and 100 mg film-coated tablets. The active substance of Truberzi is eluxadoline, a locally acting, mixed mu opioid receptor (μOR) agonist and delta opioid receptor (δOR) antagonist. Eluxadoline is also an agonist at the kappa opioid receptor (κOR) normalising gastrointestinal transit and defecation. It has been shown to reverse hyperalgesic responses in an animal model of acute colitis-induced visceral pain.

The benefits with Truberzi in patients with IBS-D are its ability to increase days with no diarrhoea and to improve pain. The rate of patients with no diarrhoea and reduced pain for at least 50% of the days over a 26 week period was about 11.5 percentage points higher with Truberzi 100 mg than with placebo, whereas the difference was about 7 percentage points with Truberzi 75 mg.

The most common side effects are constipation (7% and 8% of patients receiving 75 mg and 100 mg respectively), nausea (8% and 7% of patients receiving 75 mg and 100 mg respectively) and abdominal pain/abdominal distension (7% and 7% of patients receiving 75 mg and 100 mg respectively). Serious adverse reactions include pancreatitis (0.2% and 0.3% of patients receiving 75 mg and 100 mg respectively) and sphincter of Oddi spasm (0.2% of patients receiving 75 mg and 0.8% of patients receiving 100 mg).

The full indication is: "Truberzi is indicated in adults for the treatment of irritable bowel syndrome with diarrhoea (IBS-D)." It is proposed that Truberzi be subject to medical prescription.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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