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EPAR summary for the public

Truberzi

eluxadoline

This is a summary of the European public assessment report (EPAR) for Truberzi. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Truberzi.

For practical information about using Truberzi, patients should read the package leaflet or contact their doctor or pharmacist.

What is Truberzi and what is it used for?

Truberzi is a medicine that acts on the digestive system. It is used for the treatment of adults who have irritable bowel syndrome with diarrhoea. Irritable bowel syndrome is a long-term disorder of the gut with pain or discomfort in the abdomen (belly), bloating and altered bowel habit.

Truberzi contains the active substance eluxadoline.

How is Truberzi used?

Truberzi can only be obtained with a prescription. It is available as tablets containing 75 mg and 100 mg eluxadoline. The recommended dose is 100 mg with food each morning and evening. In patients who get troublesome side effects, the dose can be reduced to 75 mg each morning and evening.

How does Truberzi work?

Eluxadoline, the active substance in Truberzi, is an opioid receptor agonist. This means that it attaches to opioid receptors and acts like the body's natural opioids to calm down waves of contractions along the digestive system. This causes food to remain in the gut for longer, increasing the absorption of

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fluids and so reducing diarrhoea. Because eluxadoline is not absorbed into the blood and distributed around the body, its effects are largely confined to the gut.

What benefits of Truberzi have been shown in studies?

Truberzi was evaluated in two main studies involving over 2,400 patients with irritable bowel syndrome with diarrhoea. In both studies Truberzi was compared with placebo (a dummy treatment) over 26 weeks of treatment during which patients kept a daily record of their irritable bowel syndrome symptoms. Effectiveness was measured as an improvement of over 30% in abdominal pain combined with an absence of very loose stool.

In the first study effectiveness was shown in 29% (125 out of 426) of patients taking Truberzi 100 mg twice a day compared with 19% (81 out of 427) in patients taking placebo. In the second study symptoms improved in 33% (125 out of 382) of patients taking Truberzi 100 mg twice a day compared with 20% (77 out of 382) of patients taking placebo.

What are the risks associated with Truberzi?

The most common side effects with Truberzi (which may affect more than 5 in 100 people) are constipation, nausea (feeling sick) and abdominal pain. Serious side effects include pancreatitis (inflammation of the pancreas) and sphincter of Oddi spasm (a painful condition in which bile and digestive juices are blocked from flowing into the gut). For the full list of all side effects of Truberzi, see the package leaflet.

Truberzi must not be given to patients with liver disorders, those at risk of pancreatitis (such as those who have had problems with their pancreas or who drink alcohol excessively), patients whose gall bladders have been removed or who have disorders affecting secretion of bile into the gut, and those who have had severe or long-term constipation or blocked bowel. Truberzi must not be given to patients treated with a class of medicines known as potent OATP1B1 inhibitors (such as ciclosporin, a medicine that works on the immune system). For the full list of restrictions, see the package leaflet.

Why is Truberzi approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) considered that the benefits of Truberzi are modest but there is an unmet need for treatments of irritable bowel syndrome with diarrhoea. Side effects were mainly limited to the digestive system and mostly mild. The Committee therefore decided that Truberzi's benefits are greater than its risks and recommended that it be approved for use in the EU.

What measures are being taken to ensure the safe and effective use of Truberzi?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Truberzi have been included in the summary of product characteristics and the package leaflet.

Other information about Truberzi

The European Commission granted a marketing authorisation valid throughout the European Union for Truberzi on 19 September 2016.

The full EPAR for Truberzi can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Truberzi, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 09-2016.