

Serious allergic reactions have happened in some people after taking 1 or 2 doses of Truberzi. Stop taking Truberzi right away and get emergency medical care if you have signs or symptoms of an allergic reaction, including:

- swelling of your face, lips, mouth, tongue, and/or throat
- shortness of breath or other breathing problems
- chest pain or tightness
- itching
- rash
- hives

Severe constipation that can lead to hospitalization has happened after taking Truberzi. Stop taking Truberzi and call your doctor right away if you develop severe constipation while taking Truberzi. Avoid taking Truberzi with any other medicines that may cause constipation (see Section 2: Other medicines and Truberzi).

Other side effects can include

Common: may affect up to 1 in 10 people

- dizziness;
- sleepiness;
- constipation;
- feeling sick (nausea);
- stomach ache;
- being sick (vomiting);
- gas (flatulence);
- feeling bloated;
- heartburn or acid reflux;
- rash;
- abnormal blood test results (increased levels of certain liver enzymes).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Truberzi

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on blister and the carton after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Truberzi contains

- The active substance is eluxadoline. Each tablet contains 100 mg of eluxadoline.
- The other ingredients are:
Core tablet: silicified microcrystalline cellulose (E460); colloidal anhydrous silica (E551); crospovidone, type B (E1202); mannitol (E421) and magnesium stearate (E572).
Film-coating: polyvinyl alcohol (E1203); titanium dioxide (E171); macrogol 3350 (E1521); talc (E553b); iron oxide yellow (E172) and iron oxide red (E172).

What Truberzi looks like and contents of the pack

The film-coated tablets are modified capsule-shaped, pink-orange to peach and debossed with 'FX100' on one side.

The tablets are packed in PCTFE/PVC/Al-blisters. Truberzi is available in packs containing 28 or 56 film-coated tablets and in a multipack of 168 film-coated tablets comprising 3 cartons, each containing 56 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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Medical product no longer authorised

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site:
<http://www.ema.europa.eu>.

Medicinal product no longer authorised