Package leaflet: Information for the patient

Truberzi 100 mg film-coated tablets
Eluxadoline

This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet
1. What Truberzi is and what it is used for
2. What you need to know before you take Truberzi
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1. What Truberzi is and what it is used for

Truberzi is a medicine that contains the active substance eluxadoline. It is used to treat irritable bowel syndrome ('IBS') with diarrhoea (IBS-D) in adults.

IBS is a common gut disorder. The main symptoms of IBS-D include:
- stomach ache;
- stomach discomfort;
- diarrhoea;
- urgent bowel movements.

Truberzi acts on the surface of your gut to restore the normal function of your bowels and block the sensation of pain and discomfort in IBS-D patients.

2. What you need to know before you take Truberzi

Do not take Truberzi:
- if you are allergic to eluxadoline or any of the other ingredients of this medicine (listed in section 6);
- if you have, or have had, pancreatitis (inflammation of the pancreas);
- if you don’t have a gallbladder by birth or your gallbladder has been surgically removed;
- if you have, or have had, problems with alcohol abuse, alcohol addiction, or if you drink alcohol;
- if you have, or have had, any blockage in your gallbladder, bile ducts, or pancreas (such as gallstones, tumour, duodenal diverticulum);
- if you have, or have had, disease or dysfunction of the sphincter of Oddi (a small round muscle in your upper belly that controls the flow of bile and pancreatic fluids into your upper intestine);
- if you have liver disease with decreased liver function;
- if you have had constipation for a while or if constipation is the main symptom of your IBS (called ‘IBS with constipation’ [IBS-C]);
- if you have, or may have, a blockage in your intestine/bowels;
- If you take medicines that may increase the level of the concentration of eluxadoline in the blood (so-called OATP1B1 inhibitor, e.g. ciclosporin).

Talk to your doctor or pharmacist if you are unsure if any of the above apply to you.

Warnings and precautions
Stop taking Truberzi and seek medical attention immediately if you develop any of the following while taking this medicine:
- new or worsening pain in the belly, with or without nausea and vomiting;
  - pain may begin soon after you start Truberzi. You may feel pain on the right side of your belly or the upper area of the belly, right below the ribs. The pain may feel like it is moving through to your back or shoulder;
  - these symptoms are uncommon and may indicate pancreas or bile duct system problems (i.e. inflammation of the pancreas or spasm of the sphincter of Oddi);
    - your risk of developing pancreas or bile duct system problems may be higher if you drink alcohol in excess,
    - the spasm of the sphincter of Oddi usually goes away when you stop Truberzi.
- constipation lasting longer than 4 days.

Please report to your doctor:
- how much alcohol you drink (e.g. daily number of drinks);
- if you experience any effects, such as dizziness and sleepiness.

Take special care if you are 65 years of age or older, as there is a higher risk that you may have certain side effects (see section 4).

Children and adolescents
Truberzi should not be given to children and adolescents less than 18 years old as there is no information about its use in this age group.

Other medicines and Truberzi
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Avoid frequent use of loperamide (a medicine used to treat diarrhoea) if you are taking Truberzi as this may increase the risk of constipation. Avoid taking Truberzi with any other medicines that may cause constipation such as opioids (e.g. fentanyl [used to treat pain]) or anticholinergics (e.g. atropine [used to treat cardiac disorders among other indications]).

Some medicines may increase the level of Truberzi in the blood. These medicines can include:
- ciclosporin (immunosuppressant used to reduce inflammation);
- gemfibrozil (used to lower lipid levels);
- atazanavir, lopinavir, ritonavir, saquinavir, tipranavir (antiretrovirals used to treat HIV);
- rifampicin (antibiotic used to treat infections).
Do not take Truberzi with any of the above medicines.

Truberzi may increase the level of some medicines in the blood. These medicines can include:
- rosuvastatin (statin used to treat high cholesterol and to prevent cardiovascular disease);
- valsartan and olmesartan (used to treat high blood pressure);

Truberzi may decrease the level of some medicines in the blood. These medicines can include:
- erythromycin (used to treat infections);
- midazolam (a medicine to sedate you when you e.g. undergo endoscopic procedures);
- nifedipine (used to treat high blood pressure);
- alfentanil, fentanyl (opioid analgesic used to treat pain);
- dihydroergotamine, ergotamine (used to treat migraine);
- pimozide (used to treat mental disorders);
- quinidine (used to treat heart diseases);
- sirolimus, tacrolimus (immunosuppressant used for the control of body’s immune response).

If any of the above applies to you, tell your doctor or pharmacist before taking Truberzi. Check with your doctor or pharmacist if you are not sure.

Pregnancy and breast-feeding
Truberzi should not be taken whilst pregnant or breast-feeding. If you are pregnant or breast-feeding or you think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Driving and using machines
It is unlikely that Truberzi will affect your ability to drive or use tools or machines. However, you may experience side effects such as sleepiness or dizziness while taking Truberzi which might affect your ability to drive or use machines. Do not drive or use machines while taking this medicine until you know how it affects you.

3. How to take Truberzi

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

The recommended dose is one 100 mg tablet twice a day.
The tablets should be taken orally with food in the morning and in the evening.

If you take more Truberzi than you should
If you have taken more Truberzi than you should, tell your doctor or seek urgent medical assistance.

If you forget to take Truberzi
Do not take a double dose to make up for a forgotten dose. Take the next dose at the next scheduled time and continue as normal.

If you stop taking Truberzi
Do not stop taking Truberzi without first talking to your doctor as your symptoms may worsen.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some side effects can be serious
Stop taking Truberzi, and seek medical attention immediately if you have new or worsening stomach pain, with or without nausea and vomiting, while taking Truberzi. These symptoms occur uncommonly (may affect up to 1 in 100 people) and may indicate pancreas or bile duct system problems (e.g. inflammation of the pancreas or spasm of the sphincter of Oddi).

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:

**United Kingdom**
Yellow Card Scheme
Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

**Ireland**
HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: [www.hpra.ie](http://www.hpra.ie)
e-mail: medsafety@hpra.ie

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**
Allergan Pharmaceuticals International Limited
Clonshaugh Industrial Estate
Coolock
Dublin 17
Ireland

**Manufacturer**
Warner Chilcott Deutschland GmbH
Dr.-Otto-Roehm-Strasse 2-4,
64331 Weiterstadt,
Germany

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

**Ireland/ United Kingdom**
Allergan Ltd
Tel: + 44 (0) 1628 494026

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**Other sources of information**