PACKAGE LEAFLET

Package leaflet: Information for the user

Fesoterodine Accord 8 mg prolonged-release tablets
fesoterodine fumarate

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 or nurse.
- 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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Fesoterodine is and what it is used for

Fesoterodine contains an active substance called fesoterodine fumarate, and is a so called antimuscarinic treatment which reduces the activity of an overactive bladder and it is used in adults to treat the symptoms.

Fesoterodine treats the symptoms of an overactive bladder such as
- not being able to control when you empty your bladder (called urgency incontinence)
- suddenly needing to empty your bladder (called urgency)
- having to empty your bladder more often than usual (called increased urinary frequency).

2. What you need to know before you take Fesoterodine

Do not take Fesoterodine:
- if you are allergic to fesoterodine or to peanut or soya or to any of the other ingredients of Fesoterodine (listed in section 6) (see section 2, "Fesoterodine contains lactose and soya lecithin")
- if you are not able to completely empty your bladder (urinary retention)
- if your stomach empties slowly (gastric retention)
- if you have an eye disease called narrow angle glaucoma (high pressure in the eye), which is not under control
- if you have excessive weakness of the muscles (myasthenia gravis)
- if you have ulceration and inflammation of the colon (severe ulcerative colitis)
- if you have an abnormally large or distended colon (toxic megacolon)
- if you have severe liver problems.
- if you have kidney problems or moderate to severe liver problems and are taking medicines containing any of the following active substances: itraconazole or ketoconazole (used to treat fungal infections), ritonavir, atazanavir, indinavir, saquinavir or nelfinavir (antiviral medicine for treating HIV), clarithromycin or telithromycin (used to treat bacterial infections) and nefazodone (used to treat depression).

Warnings and precautions
Fesoterodine may not always be suitable for you. Talk to your doctor before taking Fesoterodine, if any of the following apply to you:
- if you have difficulties in completely emptying your bladder (for example due to prostate enlargement)
- if you ever experience decreased bowel movements or suffer from severe constipation
- if you are being treated for an eye disease called narrow angle glaucoma
- if you have serious kidney or liver problems, your doctor may need to adjust your dose
- if you have a disease called autonomic neuropathy which you notice from symptoms such as changes in your blood pressure or disorders in the bowel or sexual function
- if you have a gastrointestinal disease that affects the passage and/or digestion of food
- if you have heartburn or belching.
- if you have an infection of the urinary tract, your doctor may need to prescribe some antibiotics

Heart problems: Talk to your doctor if you suffer from any of the following conditions
- you have an ECG (heart tracing) abnormality known as QT prolongation or you are taking any medicine known to cause this
- you have a slow heart rate (bradycardia)
- you suffer from heart disease such as myocardial ischaemia (reduced blood flow to the heart muscle), irregular heartbeat or heart failure
- you have hypokalaemia, which is a manifestation of abnormally low levels of potassium in your blood.

Children and adolescents
Do not give this medicine to children and adolescents below 18 years of age because it is yet to be established whether it would work for them and whether it would be safe.

Other medicines and Fesoterodine
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Your doctor will tell you whether you can take Fesoterodine with other medicines.

Please inform your doctor if you are taking medicines according to the following list. Taking them at the same time as fesoterodine may make side effects such as dry mouth, constipation, difficulty in completely emptying your bladder or drowsiness more serious or occur more often:
- medicines containing the active substance amantadine (used to treat Parkinson's disease).
- certain medicines used to enhance gastrointestinal motility or to relieve stomach cramps or spasm and to prevent travel sickness like medicines containing metoclopramide.
- certain medicines used to treat psychiatric diseases, like anti-depressives and neuroleptics.

Please also inform your doctor if you are taking any of the following medicines:
- medicines containing any of the following active substances may increase the break-down of fesoterodine and thus decrease its effect: St. John's Wort (herbal medicinal product), rifampicin (used to treat bacterial infections), carbamazepine, phenytoin and phenobarbital (used, among others, to treat epilepsy).
- medicines containing any of the following active substances may increase the blood levels of fesoterodine: itraconazole or ketoconazole (used to treat fungal infections), ritonavir, atazanavir, indinavir, saquinavir or nelfinavir (antiviral medicine for treating HIV), clarithromycin or telithromycin (used to treat bacterial infections), nefazodone (used to treat depression), fluoxetine or paroxetine (used to treat depression or anxiety), bupropion (used for smoking cessation or to treat depression), quinidine (used to treat arrhythmias) and cinacalcet (used to treat hyperparathyroidism).
- medicines containing the active substance methadone (used in the treatment of severe pain and abuse problems)

Pregnancy and breast-feeding
You should not take Fesoterodine if you are pregnant, as the effects of fesoterodine on pregnancy and the unborn baby are not known.

It is not known whether fesoterodine is excreted into human milk; therefore, do not breast-feed during treatment with Fesoterodine.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines
Fesoterodine can cause blurred vision, dizziness, and sleepiness. If you experience any of these effects, do not drive or use any tools or machines.

Fesoterodine contains lactose and soya lecithin
Fesoterodine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Fesoterodine contains soya lecithin. If you are allergic to peanut or soya, do not use this medicinal product.

3. How to take Fesoterodine

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

The recommended starting dose of Fesoterodine is one 4 mg tablet a day. Other products are available for the recommended starting dose of 4 mg. Based on how you respond to the medicine, your doctor may prescribe you a higher dose; one 8 mg tablet a day.

You should swallow your tablet whole with a glass of water. Do not chew the tablet. Fesoterodine can be taken with or without food.

To help you remember to take your medicine, you may find it easier to take it at the same time every day.

If you take more Fesoterodine than you should
If you have taken more tablets than you have been told to take, or if someone else accidentally takes your tablets, contact your doctor or hospital for advice immediately. Show them your pack of tablets.

If you forget to take Fesoterodine
If you forget to take a tablet, take your tablet as soon as you remember, but do not take more than one tablet in one day. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Fesoterodine
Do not stop taking Fesoterodine without talking to your doctor, as your symptoms of overactive bladder may come back again or become worse once you stop taking Fesoterodine.

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 could be serious
Serious allergic reactions including angioedema occurred rarely. You should stop taking Fesoterodine and contact your doctor immediately if you develop swelling of the face, mouth or throat.

Other side effects

Very common (may affect more than 1 in 10 people)
You may get a dry mouth. This effect is usually mild or moderate. This may lead to a greater risk of dental caries. Therefore, you should brush your teeth regularly twice daily and see a dentist when in doubt.

Common (may affect up to 1 in 10 people)
- dry eye
- constipation
- trouble digesting food (dyspepsia)
- straining or pain when emptying the bladder (dysuria)
- dizziness
- headache
- pain in the stomach
- diarrhoea
- feeling sick (nausea)
- difficulty sleeping (insomnia)
- dry throat

Uncommon (may affect up to 1 in 100 people)
- urinary tract infection
- sleepiness (somnolence)
- difficulty tasting (dysgeusia)
- vertigo
- rash
- dry skin
- itching
- an uncomfortable feeling in the stomach
- wind (flatulence)
- difficulty in completely emptying the bladder (urinary retention)
- delay in passing urine (urinary hesitation)
- extreme tiredness (fatigue)
- increased heart beat (tachycardia)
- palpitations
- liver problems
- cough
- nasal dryness
- throat pain
- stomach acid reflux
- blurred vision

Rare (may affect up to 1 in 1,000 people)
- urticaria
- confusion

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
HPRA Pharmacovigilance
Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Fesoterodine

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

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

This medicinal product does not require any special storage condition.

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 Fesoterodine contains

- The active substance is fesoterodine fumarate.

Each prolonged-release tablet contains 8 mg fesoterodine fumarate corresponding to 6.2 mg of fesoterodine

- The other ingredients are:

The tablet core: cellulose microcrystalline (E460), hypromellose (E464), lactose anhydrous, silicon dioxide (E551), magnesium stearate (E572).
The coating: titanium dioxide (E171), polyvinyl alcohol-part. hydrolyzed (E1203), talc (E553b), soya lecithin (E322), xanthan gum (E415), indigo carmine aluminium lake (E132).

What Fesoterodine looks like and contents of the pack

Fesoterodine Accord 8 mg prolonged-release tablets are Blue colored, oval shaped, film coated tablets, debossed with "F ||" on one side and plain on other side. The size of the tablet is approximately 13.2 x 6.65 mm.

Fesoterodine is available in blister pack of 14, 28, 30, 56, 84 or 100 prolonged-release tablets. In addition, Fesoterodine is also available in child resistant closure HDPE bottles containing 90 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Accord Healthcare Ireland Limited
Euro House
Euro Business Park
Little Island

Cork T45 K857
Ireland

Manufacturer
Laboratori Fundació Dau
C/ C, 12-14 Pol.
Ind. Zona Franca,
Barcelona, 08040, Spain

Accord Healthcare Polska Sp. z.o.o.
Ul. Lutomierska 50, 95-200,
Pabianice, Poland

Accord Healthcare B.V.
Winthontlaan 200, 3526 KV
Utrecht, Netherland

Pharmadox Healthcare Limited
KW20A Kordin
Industrial Park,
Paola PLA 3000, Malta

This medicine is authorized in the Member States of the European Economic Area (EEA) under the following names:

Name of Member State	**Name of the medicinal product**
Netherlands	Fesoteridine Accord 8mg tablettenmet verlengde afgifte
Germany	Fesoterodine Accord 8mg Retardtabletten
Finland	Fesoterodine Accord 8 mg depottabletti
Sweden	Fesoterodin Accord
Denmark	Fesoterodin Accord
Norway	Fesoterodin Accord
Czech Republic	Fesoterodine Accord
Hungary	Fesoterodine Accord 8mg retard tabletta
Cyprus	Fesoterodine Accord 8mg prolonged-release tablets
Ireland	Fesoterodine Accord 8 mg prolonged-release tablets
United Kingdom	Fesoterodine 8 mg prolonged-release tablets

This leaflet was last revised in May 2023.