Package leaflet: Information for the user

Fesoterodine fumarate 4 mg Prolonged-release Tablets
Fesoterodine fumarate 8 mg Prolonged-release Tablets

FPO

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

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2. What you need to know before you take Fesoterodine fumarate
3. How to take Fesoterodine fumarate
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1. What Fesoterodine fumarate is and what it is used for

This medicinal product 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 fumarate 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 fumarate

Do not take Fesoterodine fumarate if you:
- are allergic to fesoterodine fumarate or any of the other ingredients of this medicine (listed in section 6)
- are not able to completely empty your bladder (urinary retention)
- stomach empties slowly (gastric retention)
- have an eye disease called narrow angle glaucoma (high pressure in the eye), which is not under control
- have excessive weakness of the muscles (myasthenia gravis)
- have ulceration and inflammation of the colon (severe ulcerative colitis)
- have an abnormally large or distended colon (toxic megacolon)
- have severe liver problems
- 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
Talk to your doctor or pharmacist before taking Fesoterodine fumarate if you:
- have difficulties in completely emptying your bladder (for example due to prostate enlargement)
- ever experience decreased bowel movements or suffer from severe constipation
- are being treated for an eye disease called narrow angle glaucoma
- have serious kidney or liver problems, your doctor may need to adjust your dose
- 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
- have a gastrointestinal disease that affects the passage and/or digestion of food
- have heartburn or belching
- 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:
- ECG (heart tracing) abnormality known as QT prolongation or you are taking any medicine known to cause this
- slow heart rate (bradycardia)
- heart disease such as myocardial ischaemia (reduced blood flow to the heart muscle), irregular heartbeat or heart failure
- 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 fumarate
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines bought without a prescription, including herbal medicines.
In particular, tell your doctor if you are taking any of the following medicines. Taking them at the same time as fesoterodine fumarate 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 containing:
- any of the following active substances may increase the break-down of fesoterodine fumarate 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)
- any of the following active substances may increase the blood levels of fesoterodine fumarate: 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)
- active substance methadone (used in the treatment of severe pain and abuse problems)

Pregnancy and breast-feeding
You should not take this medicine if you are pregnant, as the effects of fesoterodine fumarate on pregnancy and the unborn baby are not known.
It is not known whether fesoterodine fumarate is excreted into human milk; therefore, do not breast-feed during treatment with this medicine.
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
This medicine can cause blurred vision, dizziness, and sleepiness. If you experience any of these effects, do not drive or use any tools or machines.

Fesoterodine fumarate contains lactose and sodium
This medicine 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.
This medicine contains less than 1 mmol sodium (23 mg) per prolonged-release tablet, that is to say essentially 'sodium-free'.

3. How to take Fesoterodine fumarate

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 is one 4 mg tablet a day. 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. This medicine 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 fumarate 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 fumarate
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 fumarate
Do not stop taking this medicine without talking to your doctor, as your symptoms of overactive bladder may come back again or become worse once you stop taking this medicine.
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 this medicine and contact your doctor immediately if you develop swelling of the face, mouth or throat.
Side effects listed below have been reported in the following frequencies:

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 Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Fesoterodine fumarate

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 blister and carton. The expiry date refers to the last day of that month.
Fesoterodine fumarate 4 mg prolonged-release tablets: Do not store above 30 °C.
Fesoterodine fumarate 8 mg prolonged-release tablets: This medicine does not require any special temperature storage conditions.
Store in the original package in order to protect from moisture.
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 fumarate contains:
- The active substance is fesoterodine fumarate. Each prolonged-release tablet contains either 4 mg or 8 mg fesoterodine fumarate, equivalent to 3.1 mg or 6.2 mg of fesoterodine.
- The other ingredients are:
  - The tablet core contains: glycerol dibehenate, hypromellose, talc, lactose monohydrate, mirocrystalline cellulose.
  - The tablet coating contains: polyvinyl alcohol, talc, titanium dioxide, glycerol monocaprylocaprate, sodium laurilsulfate, indigo carmine aluminum lake. The 8 mg tablet coating also contains iron oxide red.

What Fesoterodine fumarate **looks like and contents of the pack**
Fesoterodine fumarate 4 mg prolonged-release tablets are light blue, oval, biconvex, film-coated tablets.
Fesoterodine fumarate 8 mg prolonged-release tablets are blue, oval, biconvex, film-coated tablets.
The prolonged-release tablets are packed in OPA/Alu/PVC- Aluminium blisters containing 28 tablets.
Not all pack sizes are marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
STADA, Linthwaite, Huddersfield, HD7 5QH, UK

Manufacturer
Rontis Hellas Medical and Pharmaceutical Products S.A., Larissa Industrial Area, P.O. Box 3012, Larissa, 41 500, Greece

Other formats
To request a copy of this leaflet in braille, large print or audio please call 01484 848164.

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