**FRONT SIDE** / PLEASE, INCLUDE YOUR DESIGN ON THIS KEYLINE

**Package leaflet: Information for the patient**

**Fesoterodine fumarate 4 mg prolonged-release tablets**

**Fesoterodine fumarate 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.
- 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 Fesoterodine fumarate is and what it is used for
2. What you need to know before you take Fesoterodine fumarate
3. How to take Fesoterodine fumarate
4. Possible side effects
5. How to store Fesoterodine fumarate
6. Contents of the pack and other information


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READING DIRECTION

## 1. What Fesoterodine fumarate is and what it is used for

Fesoterodine fumarate 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)

READING DIRECTION

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## 2. What you need to know before you take Fesoterodine fumarate

**Do not take Fesoterodine fumarate :**

- if you are allergic to fesoterodine or to any of the other ingredients of Fesoterodine fumarate (listed in section 6) (see section 2, "Fesoterodine fumarate contains lactose and fructose")
- 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 fumarate, 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 fumarate**

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 fumarate 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).

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READING DIRECTION

**Pregnancy and breast-feeding**

You should not take Fesoterodine fumarate 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 fumarate.

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 fumarate 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 Fructose

Fesoterodine fumarate 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 fumarate contains 72 mg Fructose in each tablet.

## 3. How to take Fesoterodine fumarate

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

The recommended starting dose of Fesoterodine fumarate 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. Fesoterodine fumarate 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.

READING DIRECTION

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**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 Fesoterodine fumarate without talking to your doctor, as your symptoms of overactive bladder may come back again or become worse once you stop taking Fesoterodine fumarate.

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 fumarate and contact your doctor immediately if you develop swelling of the face, mouth or throat as this may be life-threatening.

**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
- confusión
- numbness around mouth (hypoaesthesia oral)

**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
Website: 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 carton and the blister after "EXP". The expiry date refers to the last day of that month.

Do not store above 25ºC.

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.

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## 6. Contents of the pack and other information

**What Fesoterodine fumarate contains**

- The active substance is fesoterodine fumarate.

*Fesoterodine fumarate 4 mg*

Each prolonged-release tablet contains 4 mg fesoterodine fumarate, equivalent to 3.1 mg of fesoterodine.

*Fesoterodine fumarate 8 mg*

Each prolonged-release tablet contains 8 mg fesoterodine fumarate, equivalent to 6.2 mg of fesoterodine.

- The other ingredients are:

The tablet core: Fructose, Lactose monohydrate, Microcrystalline cellulose, Hypromellose K100M Premium (type 2208), Hypromellose K4M (type 2208), Glycerol dibehenate, talc.

The coating: polyvinyl alcohol, titanium dioxide (E171), macrogol (4000), talc, indigo carmine aluminum lake.

**What Fesoterodine fumarate looks like and contents of the pack**

Fesoterodine fumarate 4 mg prolonged-release tablets are blue elliptical, biconvex and debossed with "F4" on one side and plain on the other side.

Fesoterodine fumarate 8 mg prolonged-release tablets are dark blue elliptical, biconvex and debossed with "F8" on one side and plain on the other side.

Fesoterodine fumarate is available in blister packs of 14, 28, 30, 56, 84, 98 and 100 prolonged-release tablets.

Please note that not all the above pack sizes may be marketed.

**Marketing Authorisation Holder**

**Laboratories Liconsa S.A**

Dulcinea s/n,

28805 Alcala de Henares

Madrid, Spain

**Manufacturer**

Laboratorios Liconsa, S.A.

Avda. Miralcampo, Nº 7,

Pol. Ind. Miralcampo

19200 Azuqueca de Henares

Guadalajara

SPAIN

**Laboratorios Normon, S.A.**

Ronda de Valdecarrizo, 6, Tres Cantos – 28760 Madrid,

SPAIN

**This medicinal product is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:**

**This leaflet was last revised in March, 2024**

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