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Package leaflet: Information for the user
TERALEVE 4 mg, 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 TERALEVE is and what it is used for**
2. **What you need to know before you take TERALEVE**
3. **How to take TERALEVE**
4. **Possible side effects**
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6. **Contents of the pack and other information**

1. What TERALEVE is and what it is used for

TERALEVE 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.

TERALEVE 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 TERALEVE

Do not take TERALEVE
- if you are **allergic** to fesoterodine or to peanut or soya or to any of the other ingredients of TERALEVE (listed in section 6) (see section 2, "Fesoterodine contains lactose and glycerol")
- 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
TERALEVE may not always be suitable for you. **Talk to your doctor** before taking TERALEVE, 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 TERALEVE
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 TERALEVE with other medicines.

Please inform your doctor if you are taking medicines according to the following list. Taking them at the same time as TERALEVE 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 TERALEVE 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 TERALEVE.

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

TERALEVE contains lactose, glycerol and sodium
TERALEVE 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.

TERALEVE contains glycerol which may cause headache, stomach upset and diarrhea.

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

3. How to take TERALEVE

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 TERALEVE 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. TERALEVE 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 TERALEVE 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 TERALEVE
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 TERALEVE
Do not stop taking TERALEVE 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 TERALEVE 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 the 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 TERALEVE

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.

TERALEVE 4 mg:
Do not store above 30°C.
Store in the original package in order to protect from moisture.

TERALEVE 8 mg:
This product 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 TERALEVE Tablet contains
The active substance is fesoterodine fumarate.

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

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

The other ingredients are:
Tablet core: glycerol dibehenate, hypromellose, talc, lactose monohydrate, celullose, microcrystalline.
Coating: poly(vinyl alcohol), talc, titanium dioxide, glycerol monocaprylocaprate, sodium laurilsulfate, indigo carmine aluminum lake.

TERALEVE 8 mg: iron oxid red

What TERALEVE Tablet looks like and the contents of the pack
TERALEVE 4 mg prolonged-release tablets are light blue, oval, biconvex, film-coated tablets with dimensions approximately 13 mm by 6 mm, and engraved on one side with the number '4'.

TERALEVE 8 mg prolonged-release tablets are blue, oval, biconvex, film-coated tablets with dimensions approximately 13 mm by 6 mm, and engraved on one side with the number '8'.

TERALEVE is available in OPA/Alu/PVC-Alu packs of 7, 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
Dr. Reddy's Laboratories (UK) Ltd, 410 Cambridge Science Park, Milton Road, Cambridge, CB4 0PE, United Kingdom

Manufacturer
Rontis Hellas, Medical and Pharmaceutical Products S.A, Sorou 38, Maroussi, Attiki, 15125, Greece

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PC XXXX
pharmacode number

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Weight specification: 50 g/m^2