Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986
This medicine is dispensed with a doctor's prescription only

Tarofes 4 mg
Tarofes 8 mg
Sustained-release tablets

Active ingredient
fesoterodine fumarate 4 mg, 8 mg

Inactive ingredients and allergens in this medicine: see section 2 under 'Important information about some of this medicine's ingredients', and section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. WHAT IS THIS MEDICINE INTENDED FOR?

For the treatment of symptoms that may occur in patients with overactive bladder syndrome such as increased urinary frequency and/or urgency and/or urgency incontinence.

Therapeutic group:
Muscarinic receptor antagonist.

2. BEFORE USING THIS MEDICINE

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the other ingredients in this medicine (see section 6).
- You are unable to completely empty your bladder (urinary retention).
- Your stomach empties slowly (gastroparesis).
- You have an eye disease called narrow angle glaucoma (high pressure in the eye), which is not under control.
- You have excessive weakness of the muscles (myasthenia gravis).
- You have severe ulcerative colitis.
- You have an abnormally large or distended colon (toxic megacolon).
- You have severe liver problems.
- You have kidney problems or moderate to severe liver problems and are taking medicines containing any of the following active ingredients: 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).

Special warnings about using this medicine
Before using Tarofes, tell your doctor if:

- You have difficulties in completely emptying your bladder (for example due to prostate enlargement)
- You previously experienced decreased bowel movements or suffer from severe constipation
- You are being treated for an eye disease called narrow angle glaucoma
- You have serious liver or kidney problems. Your doctor may need to adjust your dose
- 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
- You have a gastrointestinal disease that affects the passage and/or digestion of food
- You have heartburn or belching
- You have an infection of the urinary tract. Your doctor may need to prescribe you antibiotics.

- You have one of the following conditions:
  - an ECG abnormality known as QT prolongation, or if you are taking any medicines known to cause this.
  - 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.
  - hypokalaemia - 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 has not yet been established whether it would be effective and safe for them.

Interactions with other medicines
If you are taking or have recently taken other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking:
- medicines containing the active ingredient amantadine (used to treat Parkinson's disease), medicines used to treat psychiatric diseases, like anti-psychotics and anti-depressives, and medicines used to enhance gastrointestinal motility or to relieve stomach cramps or spasm and to prevent travel sickness (for example medicines containing metoclopramide). Taking these medicines together with Tarofes may lead to worsening or increase in the frequency of side effects such as dry mouth, constipation, difficulty in completely emptying your bladder or drowsiness.
- medicines containing any of the following active ingredients that may increase the breakdown 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 ingredients may increase the blood levels of fesoterodine: itraconazole or ketoconazole (used to treat fungal infections), ritonavir, atazanavir, indinavir, saquinavir or nelfinavir (antiviral medicines 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 ingredient methadone (used in the treatment of severe pain and abuse problems).

Using this medicine and food
Swallow the tablet whole with a glass of water, with or without food.

Pregnancy and breastfeeding
You should not take the medicine if you are pregnant, as the effects of fesoterodine on pregnancy and the fetus are not known.
It is not known whether the medicine is excreted into human milk; therefore, do not breastfeed during treatment with Tarofes.
If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, consult your doctor or pharmacist before taking this medicine.

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

Important information about some of this medicine's ingredients
The 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 medicine.

3. HOW TO USE THIS MEDICINE?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.
Only your doctor will determine your dose and how you should take this medicine.

The recommended starting dose is usually 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.

Do not exceed the recommended dose.

Do not crush/split/chew the tablet! This is because the tablets are sustained-release tablets, and the active ingredient should be released through them gradually and over time.

If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forget to take the medicine at the scheduled time, take the medicine as soon as you remember, but do not take more than one tablet a day. Do not take a double dose to make up for the forgotten dose.

Adhere to the treatment as recommended by your doctor.

Even if your health improves, do not stop taking this medicine without consulting your doctor or pharmacist, as your symptoms of overactive bladder may come back or become worse.

Do not take medicines in the dark! Check the label and dose <u>every time</u> you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, using Tarofes may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Stop taking Tarofes and consult your doctor immediately if you have a severe allergic reaction that manifests as swelling of the face, mouth or throat as this may be life-threatening. A serious allergic reaction, including angioedema, occurs rarely.

Very common side effects (may affect more than 1 in 10 people):
Dry mouth, this reaction 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 side effects (may affect up to 1 in 10 people):
Dry eye, constipation, trouble digesting food, straining or pain when emptying the bladder, dizziness, headache, pain in the stomach, diarrhoea, nausea, difficulty sleeping, dry throat.

Uncommon side effects (may affect up to 1 in 100 people):
Urinary tract infection, sleepiness, difficulty tasting, feeling dizzy (vertigo), rash, dry skin, itching, an uncomfortable feeling in the stomach, flatulence, difficulty in completely emptying the bladder (urinary retention), delay in passing urine, extreme tiredness, increased heart rate (tachycardia), palpitations, liver problems, cough, nasal dryness, throat pain, stomach acid reflux, blurred vision.

Rare side effects (may affect up to 1 in 1,000 people):
Urticaria, confusion, numbness around the mouth (hypoaesthesia oral).

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the 'Reporting Side Effects of Drug Treatment' link on the Ministry of Health home page (www.health.gov.il), which opens an online form for reporting side effects, or you can also use this link: https://sideeffects.health.gov.il

5. HOW TO STORE THE MEDICINE?

- Prevent poisoning! To prevent poisoning, keep this and all other medicines in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by your doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions**
  Store below 25°C.

6. ADDITIONAL INFORMATION

In addition to the active ingredient, this medicine also contains:
lactose monohydrate, hypromellose 2208 (4000 mPa·s, 100,000 mPa·s), glycerol dibehenate, microcrystalline cellulose, talc, polyvinyl alcohol (E1203), titanium dioxide (E171), glycerol monocaprylocaprate (type I), sodium laurilsulfate, indigo carmine aluminium lake (E132), purified water.
Tarofes 8 mg also contains iron oxide red (E172).

What the medicine looks like and contents of the pack:
Tarofes 4 mg – oval film-coated tablets, light blue and engraved on one side with the number '4'.
Tarofes 8 mg – oval film-coated tablets, light blue and engraved on one side with the number '8'.

The tablets are marketed in blisters of 28 and 30 tablets.
Not all pack sizes may be marketed.

Registration holder's name and address: Taro International Ltd., 14 Hakitor St., Haifa Bay, 2624761.

Manufacturer's name and address:
Rontis Hellas, Medical and Pharmaceutical Products S.A
Sorou 38, Maroussi, Attiki, 15125, Greece

Revised in August 2024.

Registration number of the medicine in the Ministry of Health's National Drug Registry:
Tarofes 4 mg – 177-24-37079-99
Tarofes 8 mg – 177-25-37080-99

For further information about the medicinal product and for updated patient leaflets in Hebrew, Arabic and English, please scan the code:

Tarofes 4 mg

Tarofes 8 mg

https://israeldrugs.health.gov.il/#!/medDetails/177%2024%2037079%2099
https://israeldrugs.health.gov.il/#!/medDetails/177%2025%2037080%2099

For a printed copy of the patient information leaflet in English, please contact the registration holder by email Info@taro.com or by phone 1-800-464-664.