

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE
PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986**

The medicine is dispensed with a doctor's prescription only

TRUDO 4 mg

TRUDO 8 mg

Prolonged release tablets

Composition:

Each **Trudo 4 mg** tablet contains:

Fesoterodin fumarate 4 mg

Each **Trudo 8 mg** tablet contains:

Fesoterodin fumarate 8 mg

For the list of inactive and allergenic ingredients in the preparation, see section 6 "Further information" and in section 2 "Important information about some of the ingredients of the medicine".

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the 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.

This medicine is not usually intended for children under 18 years of age.

1. WHAT IS THE MEDICINE INTENDED FOR?

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

Therapeutic group:

Muscarinic receptor antagonist.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- you are sensitive (allergic) to the active ingredient, or to any of the additional ingredients contained in the medicine (see section 6 “Further information”).
- you are unable to completely empty your bladder (urinary retention).
- your stomach empties slowly (gastric retention).
- you have an eye disease called narrow angle glaucoma (high intraocular pressure), which is not under control.
- you have severe 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 you 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 medicines for treating HIV), clarithromycin, telithromycin (used to treat bacterial infections) and nefazodone (used to treat depression).

Special warnings regarding use of the medicine

Before treatment with Trudo, tell the 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. The doctor may need to adjust your dose.
- you have a disease called autonomic neuropathy, in which you notice symptoms such as changes in 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. The doctor may need to prescribe you antibiotics.
- you have one of the following conditions:
 - an ECG abnormality called QT prolongation, or if you are taking medicines that can cause this.
 - slow heart rate (bradycardia).
 - you are suffering from a heart disease such as myocardial ischemia (reduced blood flow to the heart muscle), irregular heartbeat or heart failure.
 - hypokalemia – a condition in which there are abnormally low levels of potassium in the blood.

Children and adolescents

Do not give the medicine to children and adolescents under 18 years of age since it still has not been determined if the medicine is effective and safe for them.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Especially 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 for relief in cases of stomach cramps and spasms and to prevent travel sickness (for example, medicines containing metoclopramide).

Taking these medicines together with **Trudo** may lead to worsening or an increase in the frequency of side effects such as dry mouth, constipation, difficulty in completely emptying your bladder or sense of drowsiness.

- medicines containing any of the following ingredients that may increase the breakdown of fesoterodine and thereby decrease the effect of the medicine: St. John's wort (herbal medicine), rifampicin (used to treat bacterial infections), carbamazepine, phenytoin and phenobarbital (used, among other things, to treat epilepsy).
- medicines containing any of the following active ingredients may cause an increase in blood levels of fesoterodine: itraconazole or ketoconazole (used to treat fungal infections), ritonavir, atazanavir, indinavir, saquinavir or nelfinavir (antiviral medicines used to treat 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 treat depression or for smoking cessation), quinidine (used to treat arrhythmias) and cinacalcet (used to treat hyperparathyroidism).
- medicines containing the active ingredient methadone (used to treat severe pain and addiction problems).

Use of the medicine and food

Swallow the tablet whole with a glass of water, with or without food.

Pregnancy and breastfeeding

Do not use 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 breast milk; therefore, do not breastfeed during the course of treatment with **Trudo**.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, consult the doctor or pharmacist before taking the medicine.

Driving and operating machinery

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

Important information about some of the ingredients of the medicine

Trudo contains lactose. If you have been told by the doctor that you have an intolerance to certain types of sugar, consult the doctor before you take this medicine.

3. HOW SHOULD THE MEDICINE BE USED?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

The dosage and treatment regimen will be determined by the doctor only.

The recommended starting dosage is usually one 4 mg tablet once a day. Based on your response to the medicine, the doctor may prescribe you a higher dosage – one 8 mg tablet once a day.

Do not exceed the recommended dose.

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

If you took an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take this 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 compensate for the forgotten dose.

Adhere to the treatment regimen as recommended by the doctor.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor or pharmacist, since the symptoms of overactive bladder may come back or become worse.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of **Trudo** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Stop taking Trudo and refer to a doctor immediately if you suffer from 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 – effects that occur in more than one user in ten:

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 refer to a dentist when in doubt.

Common side effects – effects that occur in 1-10 in 100 users:

Dry eye, constipation, problems digesting food, straining or pain when emptying the bladder, dizziness, headache, stomach pain, diarrhea, nausea, difficulty sleeping, dry throat.

Uncommon side effects – effects that occur in 1-10 in 1,000 users:

Urinary tract infection, sleepiness, impaired sense of taste, 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 – effects that occur in 1-10 in 10,000 users:

Urticaria, confusion, numbness around the mouth.

If a side effect occurs, if one of the side effects worsens, or if you suffer from side effects not mentioned in the leaflet, consult with the doctor.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” found on the Ministry of Health homepage (www.health.gov.il), that directs you to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il>

Additionally, you can report to “Unipharm Ltd.”.

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place, out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** Store below 25°C and in a place protected from light.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

Trudo 4 mg:

Hypromellose (Methocel K100M), Xylitol, Microcrystalline cellulose, Lactose anhydrous, Hypromellose (Methocel K4M), Glyceryl dibehenate, Coating blend white (Hypromellose, Titanium dioxide, Polyethylene glycol 400), Talc.

Trudo 8 mg:

Hypromellose (Methocel K100M), Xylitol, Microcrystalline cellulose, Lactose anhydrous, Hypromellose (Methocel K4M), Glyceryl dibehenate, Coating blend blue (Hypromellose, Titanium dioxide, Polyethylene glycol 400, FD&C blue #1), Talc.

Trudo 4 mg and **Trudo 8 mg** contain 28.5 mg lactose anhydrous per tablet.

What the medicine looks like and the contents of the package:

Trudo 4 mg are round, biconvex, white tablets, with a score line.

Trudo 8 mg are round, biconvex, light blue tablets, with a score line.

Trudo 4 mg and **Trudo 8 mg** are packaged in trays (blister) which are inserted into a carton package.

There are **Trudo 4 mg** and **Trudo 8 mg** package sizes of 28, 30, 56 or 60 tablets.

Not all package sizes may be marketed.

Registration holder and address: Unipharm Ltd., P.O. Box 16545, Tel Aviv, 6116401.

Manufacturer and address: Unipharm Ltd., "Mevo Carmel" Industrial Park.

Revised in May 2026.

Registration numbers of the medicine in the National Drug Registry of the Ministry of Health:

Trudo 4 mg: 181 98 37766 99

Trudo 8 mg: 181 99 37767 99



01A26

117768010