

UROXATE TABLET 100MG

Flavoxate Hydrochloride (100 mg)

What is in this leaflet

1. What UROXATE is used for
2. How UROXATE works
3. Before you use UROXATE
4. How to use UROXATE
5. While you are using it
6. Side effects
7. Storage and Disposal of UROXATE
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision

What UROXATE is used for

UROXATE is used to relieve symptoms of painful urination, urgent need to urinate, increased frequency of urination especially in the night, lower abdomen pain and inability to control urine flow, which may be due to inflammation of the bladder, prostate gland or urinary tract.

How UROXATE works

UROXATE contains the active ingredient Flavoxate hydrochloride. It works by preventing and relieving muscle spasms and thus inhibiting bladder contractions in the urinary tract in addition to reducing associated pain.

Before you use UROXATE

- When you must not use it

Do not take UROXATE if you:

- are allergic to flavoxate hydrochloride or any other ingredients in the formulation.
- have stomach or intestinal obstruction.
- have bleeding in your stomach or intestine.
- have achalasia (a rare disorder that causes difficulty swallowing).
- have problems in completely empty your bladder (urinary retention).
- have glaucoma (increased pressure in eye).
- are suffering from a condition that causes muscle weakness (myasthenia gravis).

- Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Talk to your doctor if you:

- are suffering from kidney problems.

UROXATE is not recommended for use in children below 12 years of age.

If you are not sure whether you should start taking this medicine, talk to your doctor.

- Taking other medicines

Inform your doctor or pharmacist if you are taking or if you have recently taken any other medicines, including medicines obtained without a prescription.

Some medicines and UROXATE may interfere with each other. It is important to tell your doctor or pharmacist if you are taking:

- Other antimuscarinic drugs (e.g. atropine, scopolamine).
- Other similar medicines used to treat urinary problems e.g. Bethanechol.

- Pregnancy and lactation

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.

Safety use during pregnancy and lactation are unknown. Avoid use in pregnancy unless there is no safer alternative.

It is not known whether this drug passes into breast milk. Consult your doctor before breast-feeding.

How to use UROXATE

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

- How much to use

Adults and children over 12 years old

The recommended dose is one or two tablets three or four times daily. Your doctor may lower your dose after your symptoms have improved.

- When to use it

Swallow the tablet whole with water. This medicine may be taken with or without food. Taking your medicine at about the same time each day will have the best effect. It will also help you remember when to take it.

- How long to use it

Continue taking your medicine for as long as your doctor tells you. This medicine helps to

control your condition but does not cure it. It is important to keep taking this medicine even if you feel well.

- If you forget to use it

Take your dose as soon as you remember, and continue to take it as you would normally. If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Do not take a double dose to make up for the dose that you missed. If you are not sure what to do, ask your doctor or pharmacist.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Take the carton or any remaining tablets you have with you.

Symptoms of overdose may include: increased heart rate, pounding heartbeat, dry mouth, blurred vision, speech disturbance, drowsiness, difficulty in swallowing, restlessness, diarrhoea or constipation, dry hot skin and fever.

While you are using it

- Things you must do

- Always take your medicine exactly according to the instructions given to you by your doctor or pharmacist.
- If you are about to be started on any new medicine, remind your doctor or pharmacist that you are taking UROXATE.
- If you become pregnant, or plan on becoming pregnant while taking UROXATE, tell your doctor immediately.
- Tell your doctor or pharmacist immediately if you notice any side effects, or if the side effects gets serious or anything else that make you feel unwell.

- Things you must not do

- Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not stop taking your medicine or change the dosage without checking with your doctor.
- Do not take UROXATE to treat any other complaints unless your doctor tells you to.

- Things to be careful of

UROXATE contains lactose. If your doctor has told you that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Driving and using machines

UROXATE may cause drowsiness or blurred vision in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Side effects

Like all medicines, UROXATE can cause side effects, although not everybody gets them.

Nausea, vomiting, dry mouth, headache, drowsiness, dizziness, blurred vision and nervousness may occur. If any of these effects persist or worsen, tell your doctor or pharmacist promptly.

Tell your doctor right away if any of these unlikely but serious side effects occur:

- nausea/vomiting/constipation that doesn't go away
- mental/mood changes (e.g. confusion)
- eye pain

Tell your doctor right away if any of these rare but very serious side effects occur:

- chest pain
- fast/pounding heartbeat
- signs of infection (e.g. fever, persistent sore throat)
- difficult/painful urination

A very serious allergic reaction to this drug is rare. However, seek immediate medical attention if you notice any symptoms of a serious allergic reaction, including:

- rash
- itching/swelling (especially of the face, tongue, throat)
- severe dizziness
- trouble breathing

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell. Other side effects not listed above may also occur in some people.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers

→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Serial number

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Storage and Disposal of UROXATE

Storage

Store in a cool, dry place below 30° C. Protect from light.

Do not leave your medicine in the car.

Keep medicine out of the reach of children.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

UROXATE is a white round biconvex film-coated tablet embossed with “SPS” on one side and plain on the other.

- Ingredients

- Active ingredient

Flavoxate hydrochloride 100 mg

- Inactive ingredients

Core tablet: Lactose, sodium starch glycolate, talcum, hypromellose, colloidal silicon dioxide, microcrystalline cellulose, magnesium stearate

Film-coating: Eudragit, titanium dioxide, hypromellose, talcum, polyethylene glycol, simethicone emulsion

- Packing

Blister pack of 10 tablets packed in 100 and 500 tablets per box.

- MAL Number

MAL19989027AZ

Manufacturer

Sriprasit Pharma Co., Ltd.
216 Moo 6 Suanluang, Krathum Baen,
Samut Sakhon 74110, Thailand.

Product Registration Holder

IMEKS Pharma Sdn. Bhd.
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Date of revision

23/10/2024