Urispas®

200 mg Film-coated tablets
Flavoxate hydrochloride

Read all of this leaflet carefully before you start taking this medicine
- 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 symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT URISPAS® IS AND WHAT IT IS USED FOR

Urispas® 200 mg film-coated tablets belong to a group of medicines which relieve and prevent muscle spasms. Urispas® contains an anti-spasmodic which works by inhibiting bladder contractions in the urinary tract in addition to reducing associated pain.

Urispas® is used to treat muscle spasms of the urinary tract which may be a result of inflammation of the bladder, prostate gland or urethra. Urispas® can also be used to relieve symptoms which may occur as a result of surgery, cystoscopy or catheterisation such as painful urination, excessive urination at night and the inability to control urine flow.

2. BEFORE YOU TAKE URISPAS®

Do not take Urispas®
- if you are allergic (hypersensitive) to flavoxate hydrochloride or any of the other ingredients of this medicine (listed in section 6)
- if you have a history of, suffer from or think you may have a blockage of the stomach, bowel or urinary tract
- if you have or have recently had intestinal lesions or bleeding
- if you have a muscular inability to swallow (achalasia)
- if you suffer from rare hereditary problems of galactose intolerance, the Lapp lactose deficiency or glucose-galactose malabsorption

Urispas® is not recommended for children under 12 years of age.

Take special care with Urispas®
Before you start taking Urispas®, tell your doctor:
- if you suffer from or think you may have glaucoma (a disease associated with increased eye pressure) especially closed angle cases
- if you have any urinary infections

Taking other medicines, herbal or dietary supplements
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding
The safety of this medicine for use during pregnancy has not been established. It is not recommended for use if you are pregnant, think you are pregnant or are planning on becoming pregnant.
Urispas® is not recommended for use during breast-feeding as it is not known if this medicine passes into breast milk.
Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
Do not drive or operate machinery if you experience drowsiness, blurred vision or vertigo whilst taking Urispas®.

Important information about some of the ingredients of Urispas®.
This product contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Urispas®.

3. HOW TO TAKE URISPAS®

Always take this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.
The recommended dose is one 200 mg tablet 3 to 4 times a day.
Do not break the tablet but swallow it whole with water.

If you take more Urispas® than you should
If you accidentally take too many Urispas® tablets, contact your doctor or hospital immediately.

If you forget to take Urispas®
If you miss a dose do not worry, take the next dose at the usual time. Do not take a double dose to make up for a forgotten tablet.

4. POSSIBLE SIDE EFFECTS

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

Very rare (may affect up to 1 in 10,000 people)
Heart disorders: Increased heart rate (tachycardia)
Eye disorders: Blurred vision, increased pressure in the eye (ocular tension)
Blood disorders: Increase in the number of white blood cells (eosinophilia)
Gastrointestinal disorders: Nausea, difficulty in swallowing (dysphagia), vomiting, dyspepsia, dry mouth, and, at high doses, constipation
Nervous system disorders: Headache, dizziness, mental confusion (especially in the elderly patients), nervousness, vertigo, drowsiness
Skin disorders: Itching, skin redness, rash, rapid swelling of the skin (angioedema, urticaria)
Urinary disorders: Painful urination (dysuria)
Other: Allergic reactions (hypersensitivity), tiredness, fever.

Not known: frequency cannot be estimated from the available data
Liver disorder, jaundice (yellowing of the skin or whites of the eyes), abnormal liver function test results

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE URISPAS®

Keep out of reach and sight of children.
Do not store above 30°C.
Store in the original package in order to protect from light.
Do not use Urispas® after the expiry date which is stated on the carton and the blister. The expiry date refers to the last day of that month.
Do not use Urispas® if you notice that it is damaged or the pack has been tampered with.
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 protect the environment.

6. FURTHER INFORMATION

What Urispas® contains
The active substance is flavoxate hydrochloride. Each film-coated tablet contains flavoxate hydrochloride 200 mg.
The other ingredients are:
Excipients: Croscarmellose sodium, microcrystalline cellulose, lactose, magnesium stearate, cab-o-sil, talc, povidone.
Coating: Carbowax 6000, sepifilm, magnesium stearate, titanium dioxide.

What Urispas® looks like and contents of the pack
Urispas® are white biconvex, film-coated tablets, plain on one side, engraved 'U 200' on the other.
They are available in PVC/aluminium foil blisters in packs of 30 tablets, each pack contains three blisters.

For more information about this medicinal product, please contact:
Algorithm SAL
Tel: +961-9-222050

To report any side effect:
Lebanon and all MENA countries
Algorithm SAL
Fax: +961-9-222141
Email: pharmacovigilance@blgx.net
Website: www.algorithm-lb.com

Also contact the relevant competent authority.

This is a medicament
- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

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