Package Leaflet: Information for the User

Urispas® 200mg Film-coated Tablets
Flavoxate hydrochloride 200mg Film-coated Tablets

(flavoxate hydrochloride)

Your medicine is known by the above names, but will be referred to as Urispas® throughout this leaflet.

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 URISPAS® IS AND WHAT IT IS USED FOR

What Urispas® is

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.

What Urispas® is used for

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. WHAT YOU NEED TO KNOW BEFORE YOU TAKE URISPAS®

Do not take Urispas®

- If you are allergic to flavoxate hydrochloride or any of the other ingredients of this medicine (listed in section 6);
- If you have a gastrointestinal disease that affects the normal passage of food (obstruction);
- If you have an gastro-intestinal bleeding
- If you have a muscular inability to swallow (achalasia)
- If you are not able to completely empty your bladder (urinary retention)
- If you are being treated for an eye disease called glaucoma
- If you have a disease which causes general weakness and fatigability of the muscles (myasthenia gravis)

Warnings and precautions

Talk to your doctor or pharmacist before taking Urispas®:
- If you have impaired kidney function.

Children

Urispas® should not be used in children younger than 12 years of age.

Other medicines and Urispas®

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Pregnancy, breast-feeding and fertility

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.

The safety of this medicine in pregnancy and lactation has not been established. If you are pregnant or breast-feeding this medicine is not recommended.

Driving and using machines

Do not drive or operate machinery if you experience somnolence or blurred vision whilst taking Urispas®.

Urispas® contains lactose

If you have been told by your doctor or pharmacist that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Urispas contains sodium

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

3. HOW TO TAKE URISPAS®

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

The recommended dose is one 200 mg film-coated tablet three times a day, by oral administration.

Do not break the tablet but swallow it whole, preferably with a glass of water.

The tablets should be taken after a meal in order to prevent nausea.

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.

If you stop taking Urispas®

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.

If any of the **below** side effects get serious, or if you notice any side effects not listed below, please tell your doctor or pharmacist:

Common *(may affect up to 1 in 10 people)*

Nausea

Uncommon *(may affect up to 1 in 100 people)*

Somnolence

Visual impairment

Vomiting, dry mouth, gastric pain and upset stomach (dyspepsia)

Rash

Rare *(may affect up to 1 in 1,000 people)*

Hives, pruritus

Inability to completely empty the bladder (urinary retention)

Fatigue

Not known *(frequency cannot be estimated from the available data)*

Hypersensitivity, anaphylactic reaction, anaphylactic shock

Confusional state

Glaucoma

Fast or irregular heartbeats (called palpitations)

Yellowing of the skin and eyes (Jaundice), liver disorders, abnormal results of liver function tests (hepatic enzyme abnormal)

Redness of the skin (Erythema).

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 at: 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 URISPAS®

- Keep out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.
- Do not store above 30˚C.
- In order to protect your medicine from light, keep the blister strips in the outer carton.
- If the tablets become discoloured or show any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.
- Medicines should not be disposed of via wastewater or household waste. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Urispas® contains

The active substance is flavoxate hydrochloride.

Each tablet contains 200 mg flavoxate hydrochloride.

The other ingredients are: Lactose, povidone (E1201), carboxymethylcellulose (E466), talc (E533b), magnesium stearate (E572), colloidal silica (E551), cellulose microcrystalline (E460), hydroxypropylmethylcellulose, polyethylene glycol 300, titanium dioxide (E171) and polyethylene glycol 6000.

What Urispas® looks like and contents of the pack

Urispas® are white, round film-coated tablets which are plain on both sides.

They are available in blister strips containing 60 and 90 tablets.

Manufactured by Recordati Industria Chimica e Farmaceutica S.p.A., Via Matteo Civitali 1, 20148 Milan, Italy.

Procured from within the EU and repackaged by the Product Licence Holder Beachcourse Ltd., Unit 2-3, Townsend Industrial Estate, Waxlow Road, London, NW10 7NU.

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