Package leaflet: Information for the user

Urispas 200 mg film-coated tablets
(flavoxate hydrochloride)

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 200mg 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 effects 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 or 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 has told you. Check with your doctor or pharmacist if you are not sure.
The recommended dose is one 200mg tablet three times a day, by oral administration.
Do not break the tablet but swallow it whole with 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 disorder, 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance,
Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie;
E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Urispas

Keep this medicine out of the sight and reach of children.
Do not store above 30°C.
Keep the blister strips in the outer carton in order to protect from light.
Do not use this medicine after the expiry date which is stated on the carton and blister. The expiry date refers to the last day of that month.
Do not use this medicine if you notice that it is damaged or the pack has been tampered with.
Do not throw away any medicines via waste water or household waste. Ask your pharmacist how to throw away medicines you no longer use. 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 film-coated tablet contains flavoxate hydrochloride 200 mg.
- The other ingredients are:
  Lactose monohydrate, sodium starch glycolate, povidone, talc, magnesium stearate, cellulose microcrystalline, hypromellose, macrogol 6000, macrogol stearate, magnesium stearate, titanium dioxide.

What Urispas looks like and contents of the pack
Urispas are white, film-coated tablets with ‘F 200’ embossed.
They are available in PVC/aluminium foil blister packed in cartons in packs of 6, 90, 100, 250 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation holder
Recordati Ireland Limited
Raheens East, Ringaskiddy Co. Cork, Ireland

Manufacturer
RECORDATI Industria Chimica e Farmaceutica S.p.A.
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This leaflet was last revised in