PACKAGE LEAFLET : INFORMATION FOR THE USER

Urispas® 200mg 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. Do not pass it onto others. It may harm them, even if their symptoms are the same as yours.
- If any side effects get serious, or if you notice any side effects not in this leaflet, please tell your doctor or pharmacist.

The name of your medicine is Urispas® 200mg Film-coated Tablets but will be referred to as Urispas throughout this leaflet.

In this leaflet:

1. WHAT URISPAS IS AND WHAT IT IS USED FOR

Urispas 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 Urispas
- 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)

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)
- if you have any urinary infections

Taking other medicines
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 Urispas 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 200mg tablet three times a day.

Urispas should be taken 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 more than one dose to make up for a forgotten tablet.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Urispas 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:

Heart disorders:
Increased heart rate (tachycardia), sensation of heart pounding (palpitations)

Eye disorders:
Blurred vision, increased pressure in the eye (ocular tension)

Blood disorders:
Increase or decrease in the number of white blood cells

Gastrointestinal disorders:
Indigestion, diarrhoea, nausea, difficulty in swallowing (dysphagia), vomiting, dry mouth

Nervous system disorders:
Headache, dizziness, mental confusion, nervousness, vertigo, drowsiness

Skin disorders:
Itching, skin redness, rash, rapid swelling of the skin (angioedema, urticaria)

Urinary disorders:
Painful urination

Other:
Allergic reactions (hypersensitivity), tiredness, fever

Reporting 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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

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 take your tablets after the expiry date which is stated on the carton and blister label after 'Exp'. The expiry date refers to the last day of that month.

Do not store above 30˚C. Store in the original package in order to protect from light.

Remember if your doctor tells you to stop taking this medicine, return any unused tablets to your pharmacist for safe disposal. Only keep this medicine if your doctor tells you to.

If your tablets become discoloured or show any signs of deterioration, seek the advice of your pharmacist.

Medicines should not be disposed of via waste water 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 200mg flavoxate (as hydrochloride).

The other ingredients are: lactose, povidone, carboxymethylcellulose, talc, magnesium stearate, aerosol, avicel, sepifilm, 6000, titanium oxide and polyethylene glycol.

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 tablets.

Manufactured by: Recordati, S.p.A. Milan, Italy.

Procured from within the EU and repackaged by the Product Licence holder: B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK.

Urispas® 200mg Film-coated Tablets; PL No: 18799/2215 **POM**

Leaflet date: 15.06.2015

PACKAGE LEAFLET : INFORMATION FOR THE USER

Flavoxate hydrochloride 200mg Film-coated Tablets

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. Do not pass it onto others. It may harm them, even if their symptoms are the same as yours.
- If any side effects get serious, or if you notice any side effects not in this leaflet, please tell your doctor or pharmacist.

The name of your medicine is Flavoxate hydrochloride 200mg Film-coated Tablets but will be referred to as Flavoxate hydrochloride throughout this leaflet.

In this leaflet:

1. WHAT FLAVOXATE HYDROCHLORIDE IS AND WHAT IT IS USED FOR

Flavoxate hydrochloride belong to a group of medicines which relieve and prevent muscle spasms. Flavoxate hydrochloride contains an anti-spasmodic which works by inhibiting bladder contractions in the urinary tract in addition to reducing associated pain.

Flavoxate hydrochloride is used to treat muscle spasms of the urinary tract which may be a result of inflammation of the bladder, prostate gland or urethra.
Flavoxate hydrochloride 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 FLAVOXATE HYDROCHLORIDE

Do not take Flavoxate hydrochloride
- if you are allergic (hypersensitive) to flavoxate hydrochloride or any of the other ingredients of Flavoxate hydrochloride
- 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)

Flavoxate hydrochloride is not recommended for children under 12 years of age

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

Taking other medicines
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.

Flavoxate hydrochloride 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 Flavoxate hydrochloride.

Important information about some of the ingredients of Flavoxate hydrochloride
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 Flavoxate hydrochloride.

3. HOW TO TAKE FLAVOXATE HYDROCHLORIDE

Always take Flavoxate hydrochloride 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 200mg tablet three times a day.

Flavoxate hydrochloride should be taken whole with water.

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

If you forget to take Flavoxate hydrochloride
If you miss a dose do not worry, take the next dose at the usual time. Do not take more than one dose to make up for a forgotten tablet.

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