

1 <sup>a</sup> BOZZA (31/07/2018)		LINEA GAMMA 3			
RECORDATI LEAFLET (f.ill.)	URISPAS 200 mg - tablets		GUEST (cliente)		COUNTRY (nazione)
			RECORDATI		IRELAND
ISSUE DATE (data creazione)		SIZE (formato)	CODE (codice)	PROOF-READING (revisione)	
31/07/2018		150 x 279,40	41894815	A	
		PHARMACODE (Laetus)	INVERSE PHARMACODE (Laetus inverso)	WORK N. (n. lavoro)	
		390	480	2475	
1 COLOUR (1 colore)		BLACK	FRONT (fronte)		
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Package leaflet: Information for the user

## Urispas<sup>®</sup> 200mg 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
2. What you need to know before you take Urispas
3. How to take Urispas
4. Possible side effects
5. How to store Urispas
6. Contents of the pack and other information

#### 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 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

##### Taking 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.

#### 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.

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#### 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)

#### 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](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto: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, titanium dioxide (E171)



##### What Urispas looks like and contents of the pack

Urispas are white, film-coated tablets with 'F 200' printed on one side.

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.

Via M. Civitali 1 - 20148 Milan, Italy

This leaflet was last revised in April 2018.

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