PATIENT INFORMATION LEAFLET

Read this entire leaflet carefully because it contains important information. This medicine is available without a doctor's prescription, for you to treat a mild illness. Nevertheless you still need to use URISPAS 200 carefully to get the best results.
Keep this leaflet as you may need to read it again. Ask your pharmacist if you need more information or advice. You must see a doctor if your symptoms worsen or do not improve while taking this medicine.

SCHEDULING STATUS:

S2

NAME OF THE MEDICINE:

URISPAS 200 (Flavoxate hydrochloride)

1. WHAT URISPAS 200 CONTAINS:

The active ingredient in **URISPAS 200** is flavoxate hydrochloride 200 mg.

The tablets contain lactose monohydrate 64 mg as a sugar.

The other ingredients contained are hypromellose, macrogol 6000, macrogol stearate, magnesium stearate, microcrystalline cellulose, povidone, purified water, sodium starch glycollate, talc, and titanium dioxide (E171).

2. WHAT URISPAS 200 IS USED FOR:

The active ingredient flavoxate hydrochloride is a non-specific, direct acting, smooth muscle relaxant.

URISPAS 200 is used for its antispasmodic (preventing or relieving spasms) action in urological disorders (disorders of or relating to urinary tract.)

3. BEFORE YOU TAKE URISPAS 200:

Do not take URISPAS 200:

- If you are allergic to flavoxate hydrochloride or any of the other ingredients in the preparation.
- If you have a condition which causes a blockage of the stomach, bowel or urinary tract or if you suffer from bleeding from the stomach or bowel.
- Is not recommended for use in children under 12 years of age.

Take special care with URISPAS 200:

In the event of drowsiness, blurred vision or vertigo (dizziness), patients should not drive or operate a motor vehicle or machinery.

Pregnancy and breastfeeding:

Safety in pregnancy and breastfeeding has not been established.

If you are pregnant or breastfeeding your baby while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

Taking other medicines with URISPAS 200:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **URISPAS 200** with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

4. HOW TO TAKE URISPAS 200:

Adults - One tablet three times a day for as long as is required.

If you take more URISPAS 200 than you should (an overdose):

The most likely symptoms of overdose are blurred vision, dry mouth, drowsiness and diarrhoea or constipation. Treatment by your doctor or healthcare professional is symptomatic and supportive. Do not share your medicines with other people.

5. POSSIBLE SIDE EFFECTS

URISPAS 200 can have side effects.

Blood and lymphatic disorders:

Less frequent: Eosinophilia (increased number of a certain type of white blood cells in blood) and leukopenia (too few white blood cells).

Cardiac disorders:

Less frequent: Palpitations (rapid irregular action of heart) and tachycardia (increased rate of heart beat).

Eye disorders:

Less frequent: Blurred vision, disturbances in eye accommodation and increased ocular (eye) tension.

Gastrointestinal disorders:

Less frequent: Diarrhoea, dry mouth, dyspepsia (heartburn; indigestion), dysphagia (difficulty in swallowing), nausea and vomiting.

General disorders:

Less frequent: Fatigue (tiredness) and hyperpyrexia (abnormally high body temperature).

Immune system disorders:

Less frequent:

Angioedema (development of a raised mark on the skin caused by many allergic reactions).

Nervous system disorders:

Less frequent: Drowsiness, dizziness, headache, mental confusion (especially in the elderly), nervousness and vertigo (dizziness).

Renal and urinary disorders:

Less frequent: Dysuria (painful or difficult urination).

Skin and* subcutaneous *tissue disorders:

Less frequent: Urticaria (allergic skin rash) and other dermatoses (diseases of the skin).

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

6. STORING AND DISPOSING OF URISPAS 200:

Store below 25 °C. Protect from moisture. Keep the blister strips in the outer carton.

Keep all medicines out of the reach and sight of children.

Do not use the medicine after the expiry date stated on the container.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets)

7. PRESENTATION OF URISPAS 200:

Cartons of 15 tablets: Each carton contains 1 blister strip containing 15 tablets.

Cartons of 90 tablets: Each carton contains 6 blister strips containing 15 tablets per blister strip.

8. IDENTIFICATION OF URISPAS 200:

White, film-coated tablets embossed with “F 200”.

9. REGISTRATION NUMBER:

29/18/0428

10. NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Adcock Ingram Limited

1 New Road

Erand Gardens

Midrand, 1685, RSA

Private Bag X69

Bryanston, 2021, RSA

www.adcock.co.za

11. DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET:

11 April 2008