# PATIENT INFORMATION LEAFLET

## SCHEDULING STATUS

S2

## BLADURIL, 200 mg film-coated tablets

## Flavoxate hydrochloride

## Contains sugar (lactose monohydrate): 64 mg

**Read all of this leaflet carefully before you start taking BLADURIL**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- BLADURIL has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

**What is in this leaflet**



## 1. What BLADURIL is and what it is used for

BLADURIL contains flavoxate hydrochloride. It is a non-specific, direct-acting, smooth muscle relaxant. BLADURIL is therefore an anti-spasmodic which works by inhibiting contractions in the urinary tract, thereby reducing urinary symptoms and associated pain.

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

## 2. What you need to know before you take BLADURIL

**Do not take BLADURIL:**

- if you are hypersensitive (allergic) to flavoxate hydrochloride or any of the other ingredients of BLADURIL listed in section 6.
- if you have a history of, suffer from or think you may have a blockage of the stomach, bowel, or urinary tract; or if you suffer from bleeding from the stomach or bowel.
- if you have an inability to swallow (achalasia).
- If you are or think that you might be pregnant or if you are breastfeeding.
- if you suffer from urinary retention (the inability to empty the bladder completely).
- if you have glaucoma (increased pressure of the fluid inside the eye).
- If you have a muscle disorder called myasthenia gravis (disorder causing weakness in the skeletal muscles).

BLADURIL is not recommended for use in children under 12 years of age.

**Warnings and precautions**

**Take special care with BLADURIL:**

- If you have kidney problems.
- if you think you may have glaucoma (increased pressure of the fluid inside the eye).
- if you have serious, uncontrolled disorders that is causing a blockage of the lower urinary tract.
- if you feel drowsy, you should wait longer before taking your next dosage. See also “Driving and using machines”.

**Children**

Do not give your child BLADURIL, as the safety and efficacy of BLADURIL in children (aged < 12 years) have not been established.

**Other medicines and BLADURIL**

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

No interaction studies have been performed on BLADURIL. Please consult your doctor, pharmacist or other health care provider for advice.

**Pregnancy and breastfeeding**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking BLADURIL. Do not take BLADURIL during pregnancy or breastfeeding.

**Driving and using machines:**

It is not always possible to predict to what extent BLADURIL may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which BLADURIL affects them.

BLADURIL may cause drowsiness, blurred vision and dizziness which can affect your ability to drive a vehicle and use machines.

**BLADURIL contains lactose monohydrate**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking BLADURIL.

## 3. How to take BLADURIL

Do not share medicines prescribed for you with any other person. Always take BLADURIL exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is one tablet three times a day for as long as is required.

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

If you have the impression that the effect of BLADURIL is too strong or too weak, tell your doctor or pharmacist.

**If you take more BLADURIL than you should**

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

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

**If you forget to take BLADURIL:**

If you miss a dose, take it as soon as possible. However, if it is almost time for the next dose, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for forgotten individual doses.

## 4. Possible side effects

BLADURIL can have side effects.

Not all side effects reported for BLADURIL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BLADURIL, please consult your health care provider for advice.

If any of the following happens, tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to BLADURIL. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Less frequent side effects:

- palpitations (rapid irregular action of the heart).
- tachycardia (increased rate of heartbeat).

Side effects with an unknown frequency:

- yellowing of the skin and eyes (also called jaundice), liver disorders, abnormal liver enzyme levels.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor as soon as possible if you notice any of the following:

Frequent

- Nausea

Less frequent:

- blood disorders (increased or decreased white blood cell count).
- drowsiness, dizziness, headache, confusion (especially if you are elderly), nervousness, sleepiness, sensation of whirling and loss of balance (vertigo).
- blurred vision, visual impairment, eye disorders (disturbances in eye accommodation), increased eye tension.

- diarrhoea, dry mouth, dyspepsia (heartburn, indigestion), dysphagia (difficulty swallowing) and vomiting.
- urticaria (allergic skin rash), itch (pruritus) and other dermatoses (diseases of the skin).
- dysuria (painful or difficult urination), inability to completely empty the bladder.
- fatigue (unusual weakness or tiredness), and fever.

Side effects with an unknown frequency:

- feeling confused.
- glaucoma (increased pressure of the fluid inside the eye).
- redness of the skin.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

**Reporting of side effects**

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the 6.04 Adverse Drug Reaction Reporting Form, found online under SAHPRA"s publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of BLADURIL.

## 5. How to store BLADURIL

- Do not store above 30 °C.
- Protect from moisture and light.
- Keep the blister strips in the outer carton.
- Store all medicines out of reach of children.

Return all unused medicine to your pharmacist.

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

## 6. Contents of the pack and other information

### What BLADURIL contains

The active substance is flavoxate hydrochloride.

The other ingredients are:

Tablet Core

Lactose monohydrate, magnesium stearate, microcrystalline cellulose (Avicel PH-102), povidone (Polyvinylpyrollidone K30), sodium starch glycolate (Type A), talc.

Coating

Macrogol 6000, magnesium stearate, Sepifilm® (coating consisting of: hypromellose, macrogol stearate, microcrystalline cellulose), titanium dioxide (CI 77891).

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

White, homogeneous film-coated tablets with “F200” embossed.

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.

Not all pack sizes may be marketed.

### Holder of Certificate of Registration

Adcock Ingram Limited

1 New Road,

Erand Gardens,

Midrand, 1685

South Africa

0860 ADCOCK (232625)

### This leaflet was last revised in

10 May 2022

## Registration number

56 0136