

1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

FLOSPASM 200mg film-coated tablet

Flavoxate hydrochloride

Contains sugar: Lactose monohydrate 64 mg

Read all of this leaflet carefully because it contains important information for you

FLOSPASM is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use FLOSPASM carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share FLOSPASM with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after a few days.

What is in this leaflet:

1. What FLOSPASM is and what it is used for
2. What you need to know before you take FLOSPASM
3. How to take FLOSPASM
4. Possible side effects
5. How to store FLOSPASM
6. Contents of the pack and other information

1. What FLOSPASM is and what it is used for

FLOSPASM belongs to a group of medicines which relieve and prevent muscle spasms.

FLOSPASM works by stopping contractions in the urinary tract and bladder caused by disorders of the urinary tract.

2. What you need to know before you take FLOSPASM

Do not take FLOSPASM:

- If you are hypersensitive (allergic) to flavoxate hydrochloride or any of the other ingredients of FLOSPASM.
- If you have any type of blockage in your stomach or bowel or any type of disease that may cause blockage or affects the normal passage of food.
- If you have a muscular inability to swallow (achalasia).
- If you have bleeding in your stomach or gut.
- If you have problems with blockages in your bladder or urinary tract or are unable to completely empty your bladder (urinary retention).
- If you have increased pressure in the eye caused by glaucoma.
- If you have myasthenia gravis which causes weakness of the muscles.
- If the child is under the age of 12 years.
- If you are pregnant or breastfeeding your baby.

Warnings and precautions

Take special care with FLOSPASM:

- if you have kidney problems or any type of bladder and/or kidney problems.
- if you ever feel drowsy after taking FLOSPASM as you may need to discuss this with your healthcare provider.

Children

FLOSPASM should not be used in children under 12 years of age.

Other medicines and FLOSPASM

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

FLOSPASM with food

FLOSPASM should be taken after a meal in order to prevent nausea.

Pregnancy, breastfeeding and fertility

You should not take FLOSPASM if you are pregnant or breastfeeding your baby.

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking FLOSPASM.

Driving and using machines

FLOSPASM is expected to influence your ability to drive. You should not drive, use machinery or perform any tasks that require concentration until you are certain that FLOSPASM does not adversely affect your ability to do so safely (see section 4 Possible side effects).

It is not always possible to predict to what extent FLOSPASM 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 FLOSPASM affects them.

FLOSPASM contains lactose monohydrate

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

3. How to take FLOSPASM

Do not share medicines prescribed for you with any other person.

Always take FLOSPASM exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

The usual dose of FLOSPASM in adults is one tablet (200 mg) three times per day by mouth for as long as required.

This means a daily maximum of three tablets (600 mg) per day.

FLOSPASM should be taken after a meal to prevent nausea.

If you take more FLOSPASM than you should

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

Overdosage with FLOSPASM can cause blurred vision, dry mouth, sleepiness and diarrhoea or constipation.

4. Possible side effects

FLOSPASM can have side effects.

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

If any of the following happens, stop taking FLOSPASM and 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 (hypersensitivity, anaphylactic reaction, anaphylactic shock),
- rash (urticaria, dermatoses, angioedema,) or itching (pruritus),
- fainting.

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Signs of recurrent infections such as fever, cough or sore throat.
- Changes in the way your heart beats, for example, if you notice it beating faster or slower.
- Yellowing of the skin and whites of the eyes (jaundice), dark urine and tiredness which may be symptoms of liver problems.
- Not being able to fully empty your bladder (urinary retention), painful or difficult urination.
- Pain in your eye with nausea and sudden visual disturbance as these may be symptoms of glaucoma (increased pressure in your eye).

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Nausea.

Less frequent side effects:

- Sleepiness, drowsiness, dizziness, headache, spinning sensation;
- impairment in your vision, blurred vision, disturbances in the way that your eye focuses;
- vomiting, dry mouth, indigestion/heartburn, diarrhoea, difficulty in swallowing;
- confusion (especially in the elderly), nervousness;
- tiredness, fever.

Side effects with an unknown frequency

- 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 FLOSPASM.

5. How to store FLOSPASM

Store all medicines out of reach of children.

Store at or below 25 °C.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

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 FLOSPASM contains

The active substance is 200 mg flavoxate hydrochloride.

The other ingredients are anatase titanium dioxide (E171), hypromellose (E464), lactose monohydrate, magnesium stearate, macrogol, macrogol stearate, povidone, microcrystalline cellulose (E460), sodium starch glycolate.

What FLOSPASM looks like and contents of the pack

FLOSPASM is a white to off white, round, film-coated tablet with "D 93" on one side and plain on the other side.

PVC/PVDC/Aluminium or PVC/PE/Aluminium blisters with either 10 or 15 tablets per blister strip.

Pack size of 10 tablets consists of 1 blister strip of 10 tablets in a carton.

Pack size of 15 tablets consists of 1 blister strip of 15 tablets in a carton.

Pack size of 90 tablets consists of 9 blister strips of 10 tablets or 6 blister strips of 15 tablets in a carton.



Not all pack sizes may be marketed.

HOLDER OF THE CERTIFICATE OF REGISTRATION

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Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

<https://www.sahpra.org.za/pi-pil-repository/>

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

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