Package leaflet: Information for the user

Flotros 20mg film-coated tablets

Trospium chloride

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 Flotros 20mg film-coated tablets are and what they are used for

Flotros 20mg film-coated tablets are a medicine that relaxes the muscles of the bladder.

Flotros 20mg film-coated tablets are used in patients with a compelling need to urinate (urgency) accompanied by involuntary urine loss (urge incontinence) and/or frequent urination and need to urinate in patients with an overactive bladder (due to unknown causes or neurological disease).

2. What you need to know before you take Flotros 20mg film-coated tablets

Do not take Flotros 20mg film-coated tablets:
- if you are allergic to trospium chloride or any of the other ingredients of this medicine (listed in section 6)
- if you suffer from urinary retention, i.e. blockage of the urinary tract
- if you have raised pressure in the eye (narrow angle glaucoma)
- if you have a fast, irregular heartbeat (tachycardic arrhythmia)
- if you have myasthenia gravis, a disorder that causes muscle fatigue
- if you suffer from severe inflammation of the gut (intestines), e.g. severe ulcerative colitis or Crohn's disease
- if you have a severe gastro-intestinal condition, such as toxic megacolon

Warnings and precautions
Talk to your doctor or pharmacist before taking Flotros 20mg film-coated tablets
- if you have an obstruction in your gut, e.g. a narrowing of the exit from your stomach (pyloric stenosis)
- if you have difficulties in passing urine and/or a poor stream of urine
- if you suffer from neuropathy, i.e. nerve damage
- if you have any heart conditions, such as coronary artery disease or congestive heart failure
- if you have a hiatus hernia or heartburn
- if you have an overactive thyroid gland

Patients with liver problems
If you have severe liver disease, you should not take Flotros 20mg film-coated tablets.
If you have mild to moderate liver disease, please talk to your doctor.

Patients with kidney problems
If you have kidney problems, please talk to your doctor. Your doctor may have to adjust the dose of Flotros 20mg film-coated tablets (see Section 3: "How to take Flotros 20mg film-coated tablets").

Children
Do not give Flotros 20mg film-coated tablets to children under the age of 12.

Other medicines and Flotros 20mg film-coated tablets
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Talk to your doctor if you are taking one of the following medicines:
- amantadine (used for the treatment of Parkinson's disease)
- certain medicines used to treat depression called tricyclic antidepressants (e.g. imipramine or amitriptyline)
- medicines to treat asthma, which may accelerate your heart beat (e.g. salbutamol)
- medicines used to treat nausea and vomiting (e.g. metoclopramide or domperidone)
- medicines used to affect secretion of digestive juices
- medicines that contain guar, colestyramine, or colestipol
- medicines that contain quinidine or disopyramide (used to treat heart rhythm problems)
- medicines used to treat allergies (antihistamines)

Flotros 20mg film-coated tablets with food, drink and alcohol
During the use of Flotros 20mg film-coated tablets you should not drink alcohol, if possible.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
There is insufficient data on the use of trospium chloride in humans during pregnancy and breast-feeding.

It is unknown whether trospium chloride is excreted in human breast milk. Your doctor will decide whether or not you should stop breast-feeding while taking Flotros 20mg film-coated tablets.

Driving and using machines
This medicine may cause blurred vision. If you experience this, do not drive or use any tools or machines.

Flotros 20mg film-coated tablets contain lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Flotros 20mg film-coated tablets
Always take Flotros 20mg film-coated tablets exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:
1 film-coated tablet twice daily (equal to a daily total of 40mg trospium chloride)

The maximum daily dose is 40mg trospium chloride.

In patients with severe kidney problems, the recommended dosage is 1 film-coated tablet daily or 1 film-coated tablet every other day (equal to a total of 20mg trospium chloride either daily or every other day).

The tablet should be swallowed whole with a glass of water. It should be taken before meals, on an empty stomach.

Duration of use

The length of your treatment is determined by your doctor. The need to continue treatment should be evaluated every 3 to 6 months.

If you take more Flotros 20mg film-coated tablets than you should
If you have taken too many Flotros 20mg film-coated tablets you should contact your doctor or go to the nearest hospital emergency department immediately.

If you forget to take Flotros 20mg film-coated tablets
If you forget to take a tablet, take your next tablet as soon as you remember. Do not take a double dose to make up for a forgotten dose.

If you stop taking Flotros 20mg film-coated tablets
Your symptoms may return if you stop taking Flotros 20mg film-coated tablets before told to do so by your doctor. Therefore, you should take Flotros 20mg film-coated tablets for as long as prescribed by your doctor. Please consult your doctor if you wish to stop treatment.

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.

The following side effects are important and will require immediate action if you experience them. You should stop taking Flotros 20mg film-coated tablets and see your doctor immediately if the following symptoms occur:

Rare: may affect up to 1 in 1000 people
- **inability to empty the bladder**

Very rare: may affect up to 1 in 10,000 people
- **swelling of the face, tongue and windpipe, which can cause difficulty in breathing**

Not known: cannot be estimated from the available data
- **a sudden allergic reaction with shortness of breath, rash, wheezing and sudden dizziness**
- **life-threatening hypersensitivity reactions with extensive detachment of the skin and/or mucous membranes**

Other side effects

Very common: may affect more than 1 in 10 people
- dry mouth

Common: may affect up to 1 in 10 people
- indigestion, constipation, abdominal pain, nausea

Uncommon: may affect up to 1 in 100 people
- wind (flatulence), diarrhoea
- headache
- fast heart beat
- chest pain

Rare: may affect up to 1 in 1000 people
- dizziness
- inability to (completely) empty the bladder
- blurred vision
- skin rash
- muscle pain, joint pain

Other possible side effects, whose frequency is not known
- fast and irregular heart beat
- breathing difficulties (dyspnoea)
- pruritus, nettle rash (urticaria)
- changes in blood test results used to monitor the liver (measured by your doctor)
- weakness
- hallucinations, confusion, agitation (these adverse effects occurred mostly in elderly patients and can be facilitated by neurological diseases and/or concomitant intake of other anticholinergic drugs)

Reporting of side effects in the UK
If you get any side effects, talk to your doctor or 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 website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

Reporting of side effects in Ireland
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; e-mail: medsafety@hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Flotros 20mg film-coated tablets
Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister and on the carton after "EXP". The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater 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 Flotros 20mg film-coated tablets contain
The active substance is trospium chloride 20mg

The other ingredients are:
Tablet core: silica, colloidal anhydrous; lactose monohydrate; cellulose, microcrystalline; sodium starch glycolate (Type A); povidone K 25; magnesium stearate.
Tablet film: hypromellose; cellulose, microcrystalline; stearic acid (Ph. Eur.); titanium dioxide (E171).

What Flotros 20mg film-coated tablets look like and contents of the pack
Flotros 20mg film-coated tablets are round, white-coloured, film-coated tablets available in packs of 10, 20, 30, 50, 60 and 100 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder
Dr. Pfleger Arzneimittel GmbH, Dr.-Robert-Pfleger-Straße 12, 96052 Bamberg, Germany

Manufacturer
Dr. R. Pfleger Chemische Fabrik GmbH, Dr.-Robert-Pfleger-Straße 12, D-96052 Bamberg

This medicinal product is authorised in the member states of the EEA under the following names:

Austria:	Trospiumchlorid Pfleger 20mg
Denmark:	Trospiumchlorid Alternova
Finland:	Trospium Verman 20mg tabletti, kalvopäällysteinen
Germany:	Spasmex 20mg Filmtabletten
Ireland:	Flotros 20mg film-coated tablets
United Kingdom:	Flotros 20mg film-coated tablets

This leaflet was last revised in 03/2019.