

PATIENT INFORMATION LEAFLET
FLOLOC CHEWS 5 mg & 10 mg chewable tablets

SCHEDULING STATUS:

S3

FLOLOC CHEWS 5 mg and 10 mg chewable tablets

Solifenacin succinate

Contains sugar:

FLOLOC CHEWS 5 mg: Lactose monohydrate 43 mg and mannitol 125 mg per tablet

FLOLOC CHEWS 10 mg: Lactose monohydrate 86 mg and mannitol 250 mg per tablet

Contains sweetener:

FLOLOC CHEWS 5 mg: sucralose 5 mg per tablet

FLOLOC CHEWS 10 mg: sucralose 10 mg per tablet

Read all of this leaflet carefully before you start taking FLOLOC CHEWS

- 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.
- FLOLOC CHEWS 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 FLOLOC CHEWS is and what it is used for.

2. What you need to know before you take FLOLOC CHEWS.
3. How to take FLOLOC CHEWS.
4. Possible side effects.
5. How to store FLOLOC CHEWS.
6. Contents of the pack and other information

1.What FLOLOC CHEWS is and what it is used for:

- FLOLOC CHEWS contains solifenacin succinate which belongs to a group of medicines called cholinolytics (anticholinergics).

FLOLOC CHEWS is used for the treatment of:

- Overactive bladder syndrome (Frequent feeling of needing to urinate)
- Symptoms of urinary urgency
- Frequent urination
- Urinary incontinence (Wetting yourself).

2. What you need to know before you take FLOLOC CHEWS

Do NOT take FLOLOC CHEWS:

- If you are hypersensitive (allergic) to solifenacin succinate or any of the other Ingredients of FLOLOC CHEWS (listed in section 6).
- If you suffer from urinary retention (Inability to completely or partially empty the bladder) .
- If you suffer from uncontrolled narrow angle glaucoma (high pressure in the eyes, with gradual loss of eyesight).
- If you suffer from myasthenia gravis (a muscle disease that causes weakness of the skeletal muscles).

- If you suffer from a severe gastro-intestinal condition called toxic megacolon (a complication associated with ulcerative colitis, a condition that affects the intestine).
- If you are currently undergoing hemodialysis.
- If you suffer from severe liver disease.
- If you suffer from severe kidney disease or moderate liver disease and are being treated with medicines that may decrease the removal of [PRODUCT NAME] from the body (e.g. ketoconazole). Please consult your doctor on this.
- If you suffer from a prolonged QT interval (dizziness, sudden fainting or feeling faint, shortness of breath or chest pains, lightheadedness that comes and goes, palpitations), either congenital (inherited or genetic) or acquired (triggered by some condition, medication or event)
- If you are pregnant and breastfeeding

Warnings and precautions:

Tell your doctor or healthcare professional before taking FLOLOC CHEWS

Special care should be taken with FLOLOC CHEWS:

- If you suffer from obstruction of the bladder or have difficulty passing urine resulting in retention of urine.
- If you have an obstruction of the digestive tract.
- If you have decreased movement of the digestive tract, affecting the passage and digestion of food.
- If you have severe kidney disease.
- If you have moderate liver disease.
- If you are currently taking medicines that may prevent or decrease the removal of FLOLOC CHEWS from the body.

- If you suffer from a hiatus hernia (when your stomach bulges up into your chest) or gastro-esophageal reflux (when acid leaks from the stomach up into the oesophagus) and/or are taking medicines that can aggravate these conditions.
- If you have autonomic neuropathy (a group of symptoms that occur when there is damage to the nerves that manage every day body functions).
- If you develop angioedema (skin allergy that results in swelling of the tissue just below the skin) with airway obstruction (difficulty breathing). Stop FLOLOC CHEWS and contact a doctor.
- If you develop anaphylactic reaction (a serious allergic reaction that is rapid in onset and may cause death). Stop FLOLOC CHEWS immediately and go to your nearest hospital.

Children and adolescents

FLOLOC CHEWS should not be used in children, as its safety and efficacy has not been established.

Other medicines and FLOLOC CHEWS:

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

If you are taking any of the following medicines, check with your doctor or pharmacist first before taking FLOLOC CHEWS.

- Medicines belonging to the same class as FLOLOC CHEWS (anticholinergic medicines) as the effect and side effects of both medicines may be enhanced. An interval of approximately one week should be allowed after stopping treatment with FLOLOC CHEWS before starting other anticholinergic medicines.

- Medicines belonging to a different class which has the opposite effect of FLOLOC CHEWS (cholinergic receptor agonists), as they can reduce the effect of FLOLOC CHEWS.
- FLOLOC CHEWS can reduce the effect of medicines that stimulate the movement of the digestive tract e.g. metoclopramide.
- Medicines that decrease the removal of FLOLOC CHEWS from the body e.g. ketoconazole.

FLOLOC CHEWS with food and drink:

FLOLOC CHEWS can be taken with or without food.

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 this medicine.

- You should not take FLOLOC CHEWS if you are pregnant.
- You should not take FLOLOC CHEWS if you are breastfeeding your baby.

Driving and using machines:

- FLOLOC CHEWS may make you feel drowsy and sleepy as well as cause blurred vision. Therefore, if you are taking
- FLOLOC CHEWS you should not drive, use any machines or perform any tasks that require you to be mentally alert.

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

FLOLOC CHEWS contains mannitol and may have a laxative effect.

- FLOLOC CHEWS contains 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 FLOLOC CHEWS:

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

Always take FLOLOC CHEWS exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose of FLOLOC CHEWS is 5 mg once daily. If required, your doctor may increase the dose to 10 mg once daily.

Your doctor will tell you how long your treatment with FLOLOC CHEWS will last. Do not stop treatment early. If you have the impression that FLOLOC CHEWS is too strong or weak, tell your doctor or pharmacist.

If you take more FLOLOC CHEWS than you should:

In the event of an overdose you may experience any of the side effects listed below.

- Headache
- Dry mouth
- Dizziness
- Drowsiness

- Blurred vision

In the event of an overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison center.

If you forget to take FLOLOC CHEWS:

Do not take a double dose to make up for the forgotten individual doses.

Take FLOLOC CHEWS as soon as you remember. Do not take more than one dose daily.

4 . Possible side effects:

FLOLOC CHEWS can have side effects.

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

If any of the following happens, stop taking FLOLOC CHEWS 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
- Rash, pruritis (When the skin becomes red, inflamed and itchy making you want to scratch it constantly),
- Hives (Also known as urticaria, which is swollen, pale, red bumps that appear on the skin suddenly).

These are all very serious side effects. If you have them, you may have had a serious reaction to FLOLOC CHEWS. 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:

- Urinary tract infection or cystitis (inflammation of the bladder)
- Irregular heartbeat, palpitations
- If you go for a liver function test and your result is abnormal.
- Sudden heart problems, which can include an irregular heart rate, chest pain etc.
- If you are passing less urine than is normal for you.

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

Tell your doctor if you notice the following:

Frequent side effects:

- Blurred vision
- Dry mouth
- Constipation
- Nausea
- Heart burn
- Abdominal pain.

Less frequent side effects:

- Hallucinations and confusional state
- Strong desire for sleep
- Distortion of the sense of taste
- Dizziness
- Headache
- Dry eyes
- Nasal dryness

- Gastro-oesophageal reflux disease (stomach acid leaking into oesophagus)
- Dry throat
- Faecal impaction
- Obstruction in the colon (intestine)
- Vomiting
- Dry skin
- Difficulty urinating
- Fatigue
- Peripheral oedema (swelling of the tissues of the lower limbs)

Side effects where the frequency is unknown:

- Decreased appetite
- Hyperkalaemia (High potassium levels in the blood)
- Delirium (Difficulty in being able to think, remember, sleep and pay attention)
- Glaucoma (Increased pressure in the eyes)
- Dysphonia (difficulty in speaking)
- Lack of movement in the intestines
- Abdominal discomfort
- Exfoliative dermatitis (reddening and scaling of the skin)
- Muscle weakness
- Renal impairment

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 or 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 FLOLOC CHEWS.

5. How to store FLOLOC CHEWS:

Store all medicines out of reach of children.

Do not store above 30 °C.

Store in the original package.

There are no special storage instructions for FLOLOC CHEWS.

Do not use after the expiry date stated on the packaging material.

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:

The active substance in FLOLOC CHEWS is Solifenacin succinate 5 mg or 10 mg.

The other ingredients are: Croscarmellose sodium, lactose monohydrate, magnesium stearate, maize starch (partially pregelatinised) mannitol, microcrystalline cellulose, purified water, strawberry flavor vanilla and sucralose.

What FLOLOC CHEWS looks like and contents of the pack:

FLOLOC CHEWS 5 and 10 are chewable tablets.

FLOLOC CHEWS 5 are white to off white, round, flat tablets with “5” engraved on one side.

FLOLOC CHEWS 10 are white to off white, round, flat tablets with “10” engraved on one side.

FLOLOC CHEWS 5 mg and 10 mg chewable tablets are packed in Aluminium / Aluminium blisters which are packed into cardboard boxes.

Holder of Certificate of Registration:

CIPLA MEDPRO (PTY) LTD.

Building 9, Parc du Cap

Mispel Street

Bellville

7530

RSA

Registration number:

FLOLOC CHEWS 5: 53/5.4/0052

FLOLOC CHEWS 10: 53/5.4/0053