PATIENT INFORMATION LEAFLET FOR FAMUCAPS

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S2

FAMUCAPS, hard capsules
2 mg chlorphenamine maleate, 5 mg phenylephrine hydrochloride and 300 mg paracetamol
Contains sugar: 52 mg lactose monohydrate per capsule

Read all of this leaflet carefully because it contains important information for you.
FAMUCAPS is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use FAMUCAPS carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share FAMUCAPS with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

What is in this leaflet

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

1. What FAMUCAPS is and what it is used for
FAMUCAPS contains the following active ingredients: chlorphenamine maleate, phenylephrine hydrochloride and paracetamol.

FAMUCAPS is used for the symptomatic relief of:
- Sinusitis (feeling of tension or fullness in the nose, cheeks and behind your eyes, sometimes with a throbbing ache).
- Rhinitis (runny nose) and allergic conditions of the respiratory tract.
- Hay fever and influenza (flu-like symptoms).

2. What you need to know before you take FAMUCAPS
Do not take FAMUCAPS:
- if you are hypersensitive (allergic) to chlorphenamine maleate, phenylephrine hydrochloride, paracetamol or any of the other ingredients of FAMUCAPS (listed in section 6);
- if you have kidney problems;
- if you are pregnant or breastfeeding your baby;
- if you have any disease that affects your heart;
- if you suffer from epilepsy (fits or seizures);
- if you suffer from high blood pressure;
- if you suffer from an overactive thyroid gland;
- if you suffer from a tumour of the adrenal gland, which is located near the kidney (phaeochromocytoma);
- if you have abnormally high pressure in your eye (glaucoma);
- if you are taking other medicine used to treat a cold or flu;
- if you are taking tricyclic antidepressants, used to treat depression;
- if you are taking beta blocking medicines, used to reduce blood pressure;
- if you are receiving a monoamine oxidase inhibitor (antidepressant treatment), or if you stopped this treatment less than 10 days ago;
- if your child is younger than 6 years;
- if you have liver problems or are an alcoholic;
- if you suffer from diabetes mellitus, as you may experience an increase in your blood sugar levels.

Warnings and precautions

FAMUCAPS contains paracetamol which may be fatal in overdose. In the event of overdose or suspected overdose, even if the person does not show any symptoms of overdose, the nearest doctor, hospital or poison centre must be contacted immediately. Doses higher than the recommended dose can damage your liver.

Take special care with FAMUCAPS:

- If you have liver or kidney problems, paracetamol must be taken under supervision of your doctor;
- do not use in combination with any other medicines containing paracetamol as it may lead to an overdose. Paracetamol overdose may cause liver failure, which may require liver transplant and may lead to death;
- do not use in combination with other medicines that may cause sedation, as this may lead to an increase in sedative effects;
- if your prostate gland is enlarged (prostate hypertrophy);
- if you suffer from any respiratory disorder (bronchitis, bronchiectasis (coughing up thickened mucus and shortness of breath), emphysema (shortness of breath, with a cough) or asthma (difficulty breathing, chest pain, cough and wheezing));
- if you have a condition called porphyria;
- if you have low levels of glutathione due to metabolic deficiencies;
- if you have any disease that affects your blood vessels;
- if you are unusually or excessively excitable (increased energy, restlessness and nervousness);
- if you are an elderly patient and may sometimes be confused;
- if you have problems to empty your bladder completely (urinary retention);
- if you have problems with your gastric outflow (pyloroduodenal obstruction);
- if you have not received any relief from your symptoms with the recommended dosage for more than 10 days;
- if you develop any skin adverse reactions, such as toxic epidermal necrolysis (TEN), Steven-Johnson syndrome (SJS), acute generalised exanthematous pustulosis (AGEP), drug rash with eosinophilia and systemic symptoms (DRESS) or drug-induced hypersensitivity syndrome (DIHS) and fixed drug eruptions (FDE), treatment with FAMUCAPS must immediately be discontinued. These reactions can be life-threatening and can be characterised by redness, inflamed or swollen skin, blisters, hives, itching and sometimes peeling or pain. Should you experience any of these symptoms, contact your health care provider immediately.

Children
FAMUCAPS should not be used in children younger than 6 years.

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

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- Metoclopramide or domperidone (used to treat nausea);
- Colestyramine (used to lower high cholesterol levels in your blood);
- Barbiturates (used to treat anxiety and seizures/fits);
- Hypnotics (used to treat sleep disorders);
- Anxiolytic sedatives (used to treat anxiety);
- Atropine (used before eye examinations in order to treat certain eye conditions);
- Antidepressants (used to treat mood disorders) known as monoamine oxidase inhibitors (MAOIs), tricyclic antidepressants or maprotiline;
- Sympathomimetic amines (e.g. phentermine, ephedrine, pseudoephedrine, used to treat ischaemic heart disease complicated by heart failure and shock);
- Cardiac glycosides (used to treat heart failure and abnormal heart rhythms);
- Ergot alkaloids (e.g. ergotamine, methysergide, used to treat migraine and cluster headaches);
- Warfarin and other coumarins (used to prevent the formation of blood clots);
- Antihypertensive medicines (used to treat high blood pressure);
- Hepatic enzyme inducers (e.g. phenytoin, carbamazepine or barbiturates, used to treat seizures or mood disorders).

FAMUCAPS with food and drink
You should not drink alcohol while you are taking FAMUCAPS.

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 FAMUCAPS.

Driving and using machines
FAMUCAPS can cause blurred vision, impaired concentration, dizziness and sleepiness. This applies particularly when taken in combination with alcohol. Do not drive a vehicle or operate any tools or machines, as dizziness and impairment of concentration could lead to accidents.

FAMUCAPS contains lactose monohydrate, Sunset Yellow (E110) and Ponceau 4R (E124)
FAMUCAPS contains lactose monohydrate, which is a type of sugar. If you have been told by your doctor that you cannot tolerate or digest some sugars (you have an intolerance to some sugars), talk to your doctor before taking FAMUCAPS.

FAMUCAPS contains Sunset Yellow (E110) and Ponceau 4R (E124) (colourants), which may cause allergic reactions.

3. How to take FAMUCAPS

DO NOT EXCEED THE RECOMMENDED DOSE.
Adults: 2 capsules 3 times a day.
Children (6 – 12 years): 1 capsule 3 times a day.
Not recommended for children younger than 6 years.
Do not use continuously for more than 10 days without consulting your doctor.

If you take more FAMUCAPS than you should
Prompt treatment is essential.
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. A delay in starting treatment may mean that the antidote is given too late to be effective.
FAMUCAPS contains paracetamol, which is very harmful when taken in high amounts.

If you forget to take FAMUCAPS
If you or your child forget to take a dose, take it as soon as you remember.
Do not take a double or larger dose to make up for the forgotten individual doses. Continue to take the next dose at the usual time.

4. Possible side effects

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

If any of the following happens, stop taking FAMUCAPS and tell your doctor immediately or go to the casualty department at your nearest hospital:
- swelling of your hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in breathing or swallowing;
- rash or itching;
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to FAMUCAPS. 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:
- tightness of your chest, difficulty breathing, shortness of breath;
- seizures (fits);
- cerebral haemorrhage (an emergency condition in which a ruptured blood vessel causes bleeding inside the brain, which may be characterised by a sudden tingling, numbness or paralysis of the face, arm or leg, particularly on one side of the body, confusion, dizziness, visual disturbances, difficulty walking or speaking);

- frequent infections, such as fever, severe chills, sore throat or mouth ulcers;
- bleeding or bruising more easily than normal;
- tiredness, headaches, being short of breath when exercising, dizziness, looking pale;
- palpitations (the sensation that your heart has skipped a beat or added an extra beat), irregular heartbeat, fast heartbeat (tachycardia);
- chest pain (angina), a sudden, unexpected loss of heart function, decreased heart rate (bradycardia);
- build-up of fluid in the lungs characterised by breathlessness, which may be severe and usually worsens when laying down;
- kidney problems (build-up of fluid in your body causing swelling in your legs, ankles or feet, difficulty to urinate, lower back pain);
- liver problems (with yellowing of your skin or eyes and dark coloured urine);
- skin reactions such as toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome (SJS), acute generalised exanthematous pustulosis (AGEP), drug rash with eosinophilia and systemic symptoms (DRESS) or drug-induced hypersensitivity syndrome (DIHS) and fixed drug eruptions (FDE). These reactions can be life-threatening and are characterised by redness, inflamed or swollen skin, blisters, hives, itching and sometimes peeling or pain (see Take special care with FAMUCAPS).

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

Tell your doctor as soon as possible if you notice any of the following:
Frequent:
- nervousness;
- headache, dizziness, inability to sleep;
- nausea, vomiting, diarrhoea;
- sleepiness, drowsiness, difficulty to concentrate;
- high blood pressure.

Frequency unknown:
- reduced or loss of appetite;
- change in metabolism including a change in the sugar (glucose) levels in your blood;
- anxiety, fear, restlessness, confusion, psychiatric disorders, irritability, hallucinations;
- shaking or tremors;
- flushing;
- difficulty passing urine or emptying your bladder;
- painful urination;
- blurred vision;
- buzzing or ringing sound in your ears;
- low blood pressure (dizziness or light-headedness);
- thickened respiratory tract secretions (mucus);
- dry mouth, stomach pain, constipation, heartburn;
- increased sensitivity of your skin to sunlight;
- muscle spasm, unusual muscle tone causing distortion of the body, unsteadiness when walking, muscle weakness;
- fatigue, medicine-induced fever, dryness of the nose;
- inflammation of the pancreas;
- stomach pain caused by kidney stones (renal colic);
- high levels of white blood cells in your urine (pyuria);
- dilated pupils, build-up of pressure in your eye (acute angle-closure glaucoma);
- depressed or elevated mood, nightmares;
- increased energy, particularly in children;
- weakness.

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 FAMUCAPS.

5. How to store FAMUCAPS

- Store at or below 25 °C. Protect from moisture.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use 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).

6. Contents of the pack and other information

What FAMUCAPS contains

Each hard capsule contains:

Chlorphenamine maleate	2 mg
Phenylephrine hydrochloride	5 mg
Paracetamol	300 mg

The other ingredients are: Brilliant Blue (E133), gelatine, lactose monohydrate, magnesium stearate, maize starch, Ponceau 4R (E124), Sunset Yellow (E110), titanium dioxide (E171).

What FAMUCAPS looks like and contents of the pack

Size 0 gelatine capsules with a brown cap and opaque white body, containing a uniform white powder.

FAMUCAPS hard capsules are packed into white polypropylene securitainer with a white polyethylene push-on lid (pack size: 20 capsules) or 2,5 litre white polypropylene securitainer lined with a plastic bag with a white polypropylene push-on lid (pack size: 1 000 capsules).

Holder of Certificate of Registration

Brunel Laboratoria (Pty) Ltd
1 Van Tonder Street
Sunderland Ridge
Centurion
Tel: 012 666 8994
info@brunel.co.za

This leaflet was last revised

27 October 2023

Registration number

G1235 (Act 101/1965)

Date of registration

14 December 1979 (Act 101/1965)

famcPIL-1K