

Patient Information Leaflet for FAMUCAPS

SCHEDULING STATUS

Schedule 2

PROPRIETARY NAME AND DOSAGE FORM

FAMUCAPS capsules

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 take **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.

1. WHAT FAMUCAPS CONTAINS

Each capsule contains:

Chlorpheniramine maleate	2 mg
Phenylephrine hydrochloride	5 mg
Paracetamol	300 mg

The other ingredients are gelatine capsule, lactose monohydrate, magnesium stearate, maize starch.

Contains sugar: lactose monohydrate.

2. WHAT FAMUCAPS IS USED FOR

FAMUCAPS is used for the symptomatic relief of sinusitis, rhinitis (runny nose) and allergic conditions of the respiratory tract, hay fever and influenza (flu-like symptoms).

3. BEFORE YOU TAKE FAMUCAPS

Do not take FAMUCAPS:

- If you are hypersensitive (allergic) to chlorpheniramine maleate, phenylephrine hydrochloride, paracetamol or any of the other ingredients in **FAMUCAPS** (see **WHAT FAMUCAPS CONTAINS**).
- If you are pregnant or breastfeeding your baby.
- If you have any disease of the heart and/or blood vessels.
- If you suffer from high blood pressure.
- If you suffer from an overactive thyroid gland.
- If you are receiving a monoamine oxidase inhibitor (antidepressant treatment), or if you stopped this treatment less than 14 days ago.
- If your child is under the age of 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.

Take special care with FAMUCAPS:

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.

- If you have liver or kidney problems, paracetamol must be taken under supervision of your doctor.
- If you suffer from epilepsy.
- If you have angle-closure glaucoma (where the pressure of the fluid inside your eye ball is increased).
- If your prostate gland is enlarged (prostate hypertrophy).

- If you have any heart disorder (including severe ischaemic heart disease), abnormal heart rhythm, or any condition that affects your circulatory system (occlusive vascular disease).
- If you suffer from any respiratory disorder (bronchitis, bronchiectasis or asthma).
- 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.

Taking FAMUCAPS with food and drink:

FAMUCAPS can be taken with or without food.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **FAMUCAPS**.

Driving and using machinery:

FAMUCAPS can cause dizziness and sleepiness. Do not drive a vehicle or operate any tools or machines, particularly at the beginning of the treatment, as dizziness could lead to accidents.

Important information about some of the ingredients of FAMUCAPS

FAMUCAPS contains lactose, 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**.

Taking other medicines with FAMUCAPS

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

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

- Barbiturates (used to treat anxiety and seizures/fits).

- Hypnotics (used to treat sleep disorders).
- Opioid analgesics (used to treat severe pain).
- Anxiolytic sedatives (used to treat anxiety).
- Antipsychotics (used to treat schizophrenia).
- Atropine (used before eye examinations in order to treat certain eye conditions).
- Antidepressants (used to treat mood disorders) known as monoamine oxidase inhibitors (MAOIs) or tricyclic antidepressants.
- Aminoglycoside antibiotic (used to treat bacterial infections).
- Thyroid hormones (used to treat an over- or underactive thyroid gland).
- Cardiac glycosides (used to treat heart failure and abnormal heart rhythms).
- Antihypertensive agents (used to treat high blood pressure).
- Hepatic enzyme inducers (e.g. phenytoin, carbamazepine or barbiturates, used to treat seizures or mood disorders).

4. 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 under 6 years.

If you take more FAMUCAPS than you should

Prompt treatment is essential.

In the event of overdosage, consult your doctor or pharmacist immediately. 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 dosage at the usual time.

5. 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 doctor, pharmacist or other healthcare professional 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 the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in breathing or swallowing.
- Rash, 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:

Frequent:

- Tightness of the chest, difficulty breathing.

Less frequent:

- Seizures (fits).

Frequency unknown:

- 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).

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:

- Dizziness, sleepiness, central nervous system depression (decreased rate of breathing, decreased heart rate, leading to loss of consciousness or coma), difficulty to concentrate, reduction of physical movement.
- Anxiety, fear, restlessness, confusion, psychiatric disorders, irritability, headache.
- Blurred vision.
- Thickened respiratory tract secretions.
- Dry mouth, constipation, heartburn, nausea, vomiting.
- Difficult or painful urination.
- Unusual weakness or tiredness.
- Anorexia (weight loss).

Less frequent:

- Agranulocytosis (severe reduction of the number or absence of white blood cells, which makes infections more likely), leucopenia (reduction in number of white blood cells), haemolytic anaemia (illness, resulting from the destruction of red blood cells), thrombocytopenia (low blood platelet count), pancytopenia (severe reduction in blood cells), neutropenia (lack of white blood cells).
- Loss of appetite.
- Tingling or numbness of the hands or feet (pins and needles), uncontrollable or unusual movements, shaking or tremors, sleeping problems, tingling or weakness of the hands.
- Buzzing or ringing sound in the ears.
- Low blood pressure (dizziness or light-headedness).
- Diarrhoea, stomach pain.

- Cholestasis (where bile cannot flow to the liver), hepatitis (liver disease with yellowing of the skin or eyes and dark coloured urine), liver problems.
- Abdominal pain caused by kidney stones (renal colic), kidney problems, high levels of white blood cells in the urine (pyuria).
- Increased sweating, hair loss (temporary).
- Muscle pain, muscle weakness, muscle contractions.

Frequency unknown:

- Blood dyscrasias (low levels of red or white blood cell or blood platelet count).
- Depressed or elevated mood, nightmares.
- Dilated pupils.
- Indigestion, increased salivation.
- Increased sensitivity of the skin to sunlight.
- Difficulty passing urine.
- Erection of the hair of the skin (goose bumps).
- Low potassium levels in the blood, high blood sugar levels in the blood, build-up of lactic acid levels in the blood.
- High blood pressure, constriction of the blood vessels leading to poor blood circulation.

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

6. STORING AND DISPOSING OF FAMUCAPS

Store at or below 25 °C in a cool, dry place.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

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).

7. PRESENTATION OF FAMUCAPS

White polypropylene securitainer with a white polyethylene push-on lid, pack size: 20 capsules.

Or

2 litre white polypropylene securitainer lined with a plastic bag with a white polypropylene push-on lid, pack size: 1 000 capsules.

8. IDENTIFICATION OF FAMUCAPS

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

9. REGISTRATION NUMBER

G1235 (Act 101/1965)

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Brunel Laboratoria (Pty) Ltd

1 Van Tonder Street

Sunderland Ridge

Centurion

11. DATE OF PUBLICATION

14 December 1979