

Patient Information Leaflet

SCHEDULING STATUS

S2

FLUSTAT[®] CAPSULES

Each capsule contains:-

Phenylephrine hydrochloride 5 mg

Chlorpheniramine maleate 2 mg

Paracetamol 300 mg

Ascorbic acid 75 mg

Caffeine 30 mg

Contains sugar: Lactose monohydrate 10,732 mg per capsule

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

FLUSTAT[®] CAPSULES is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use **FLUSTAT[®] CAPSULES** carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share **FLUSTAT[®] CAPSULES** with any other person.
- Ask your health care provider or 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 **FLUSTAT[®] CAPSULES** is and what it is used for
2. What you need to know before you take **FLUSTAT[®] CAPSULES**
3. How to take **FLUSTAT[®] CAPSULES**
4. Possible side effects

5. How to store **FLUSTAT® CAPSULES**
6. Contents of the pack and other information

1. WHAT FLUSTAT® CAPSULES IS USED FOR

FLUSTAT® CAPSULES are indicated for the relief of symptoms associated with colds and influenza such as nasal congestion, sniffing, headache, minor aches and pains.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE FLUSTAT® CAPSULES

Do not take FLUSTAT® CAPSULES:

- if you are allergic to any of the active or inactive ingredients of FLUSTAT® CAPSULES (symptoms of allergic reaction includes shortness of breath, wheezing or difficulty in breathing; swelling of the face, lips, tongue or other parts of the body, rash, itching or hives on the skin)
- if you have high blood pressure
- if you have disease of the heart and blood vessels
- if you have an overactive thyroid
- if you have recurrent fits
- if you are being treated with monoamine oxidase inhibitors or within 10 days of stopping such treatment
- if you have an enlarged prostate
- if you have problems with the digestive system
- if you have raised pressure in the eye
- if the patient is under 6 years of age.

Warnings and precautions

Take special care with FLUSTAT® CAPSULES

- if you suffer from liver or kidney disease
- if you suffer from overactive thyroid

- if you have diabetes
- if you have raised pressure in the eye
- if you have a history of peptic ulcers
- if you operate a vehicle or dangerous machinery
- if you suffer from life threatening skin reactions such as Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN).
- if you develop a red, scaly widespread rash with bumps under the skin and/or blisters mainly localized on the skin folds, trunk, and upper extremities accompanied by fever at the start of treatment (acute generalized exanthematous pustulosis).
- if you develop a skin rash, swelling of lymph nodes and increase of eosinophils (a type of white blood cells). This is known as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS).
- if you develop or have a history of Fixed Drug Eruptions (FDE) (may look like round or oval patches and swelling of the skin), blistering (hives), itching.

Children and adolescents

FLUSTAT® CAPSULES are not recommended for children under the age of 6 years.

Other medicines and FLUSTAT® CAPSULES

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

Care should be taken if you are taking:

- Antihypertensive medication (e.g. guanethidine, reserpine and methyldopa)

- Medications containing phenylpropanolamine (other flu preparations)
- Heart medication
- Antidepressants
- Barbiturates (used to treat fits)
- Hypnotics (sleep inducing drugs)
- Narcotic analgesics (pain medications containing codeine or morphine)
- Sedatives and tranquilisers
- Atropine (low heart rate medication)

Using FLUSTAT® CAPSULES with food and drink:

The use of **FLUSTAT® CAPSULES** with food and drink has not been established.

Pregnancy, breast-feeding and fertility

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 healthcare provider for advice before being taking this medicine.

FLUSTAT® CAPSULES should not be used in pregnancy.

Driving and using machines

Patients should be warned not to drive a motor vehicle, operate dangerous machinery or climb dangerous heights, as impaired decision making could lead to accidents.

FLUSTAT® CAPSULES contains lactose monohydrate

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 FLUSTAT® CAPSULES

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

Always take **FLUSTAT® CAPSULES** exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults: 2 capsules three times daily.

Children (6 - 12 years): 1 capsule three times daily.

Not recommended for children under the age of 6 years.

DO NOT EXCEED THE RECOMMENDED DOSE

Do not use continuously for more than 10 days without consulting your doctor.

If you take more FLUSTAT® CAPSULES than you should

If you notice the following symptoms, you may have taken more **FLUSTAT® CAPSULES** than you should:

- Muscle tremor, restlessness, ringing in the ears, irregularities with vision, irregular heartbeats, paleness, nausea, vomiting and abdominal pain.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control center.

If you forget to take FLUSTAT® CAPSULES

If you forget to take a dose, take it as soon as possible, unless it is almost time to take the next dose. Do not take a double dose to make up for forgotten individual doses.

If you stop taking FLUSTAT® CAPSULES

If you are unsure when to stop using **FLUSTAT® CAPSULES**, consult your doctor or pharmacist. Do not use continuously for more than 10 days without consulting

your doctor.

4. POSSIBLE SIDE EFFECTS

Not all side effects reported for **FLUSTAT® CAPSULES** are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking **FLUSTAT® CAPSULES**, please consult your health care provider for advice.

If any of the following happen, you should stop taking **FLUSTAT® CAPSULES** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Red skin rash or allergic skin reaction
- Sudden, life-threatening severe allergic reaction.
- Difficulty in breathing/shortness of breath

These are very serious side effects. If you have them you may have had a serious allergic reaction or other type of reaction to **FLUSTAT® CAPSULES**. 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:

- Chest pains
- Rapid irregular heart beat
- Tightness of chest and tingling
- Less urine than is normal for you
- skin rash or itching, which may include redness, hives (red itchy bumps), blisters, pustules or peeling of the skin (Toxic Epidermal Necrolysis) and bleeding in the lips, eyes, mouth, nose and genitals (Toxic Epidermal Necrolysis or Stevens-Johnson Syndrome),

- a red, scaly, widespread rash with bumps under the skin and blisters mainly localized on the skin folds, trunk, and upper extremities accompanied by fever at the initiation of treatment (Acute Generalised Exanthematous Pustulosis),
- a severe skin reaction known as DRESS syndrome can occur. Symptoms of DRESS include: skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cells),
- Fixed Drug Eruptions (FDE) (may look like round or oval patches of redness and swelling of the skin), blistering (hives), itching.

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

Tell your doctor if you notice any of the following:

Frequency unknown side effects:

- increased salivation
- lack of appetite
- fear and anxiety
- elation or depression
- nightmares
- irritability/restlessness
- tremors
- muscle twitching
- dizziness
- headache
- sedation
- insomnia
- blurred vision
- ringing in the ears
- increase/decrease in blood pressure

- nausea and vomiting
- diarrhoea
- constipation
- difficulty in the passing of urine
- inability to concentrate
- dry mouth
- weakness of hands

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 **FLUSTAT® CAPSULES**

5. HOW TO STORE FLUSTAT® CAPSULES

Store all medicines out of reach of children

- Store at or below 25 °C. Protect from light and moisture.
- Do not store in bathrooms in order to protect from light.
- Do not take medicine 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 FLUSTAT® CAPSULES CONTAINS

Each capsule contains:-

Phenylephrine hydrochloride 5 mg

Chlorpheniramine maleate 2 mg

Paracetamol 300 mg

Ascorbic acid 75 mg

Caffeine 30 mg

Contains sugar: Lactose monohydrate 10,732 mg per capsule

The other ingredients are:

Colloidal silicon dioxide (Aerosil 200), lactose 80 mesh, magnesium stearate, purified talc and sodium lauryl sulphate.

What FLUSTAT® CAPSULES looks like and the contents of the pack

A size 0 Capsule with a sky-blue cap and sky-blue body. The Name: Flustat® is printed in white on the body and cap.

Packs of 24, 100 and 1000 Capsules.

Patient ready packs of different pack sizes.

Holder of Certificate of Registration

Ranbaxy Pharmaceuticals (Pty) Ltd

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Stormill, Ext. 1,

Roodepoort,

1724

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S3	BOT 0500774 (Botswana) (1000's)
NS1	04/5.8/0990 (Namibia)
	P168/023 (Zambia) (24's, 1000's)