Patient Information Leaflet

SCHEDULING STATUS

S2

FLUSTAT® SYRUP

Each 20 ml contains:

Phenylpropanolamine hydrochloride 25 mg

Dextromethorphan hydrobromide 15 mg

Paracetamol 500 mg

Preservative: Nipastat 0,08 % m/v

Alcohol 14,8 % v/v

Contains Sugar: Sucrose 4,0 g per 20 ml

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

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

- Keep this leaflet. You may need to read it again.
- Do not share FLUSTAT® SYRUP 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

6. Contents of the pack and other information

1. WHAT FLUSTAT® SYRUP IS USED FOR

FLUSTAT® SYRUP is recommended for the relief of the symptoms associated with colds and influenza such as headache, minor aches and pains and coughing.

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

Do not take FLUSTAT® SYRUP:

- if you are allergic to any of the active or inactive ingredients of FLUSTAT® SYRUP (listed in section 6). 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 asthma;
- if you are sensitive to drugs which stimulate the bodies rapid involuntary response;
- if you have any liver issues;
- if you have any heart problems;
- if you have high blood pressure;
- if you have an overactive thyroid;
- if you have the tendency to be easily and excessively excited;
- if you have a tumour of the adrenal gland;
- 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® SYRUP

- if you have difficulty urinating;
- if you are taking medications which have the ability to cause the loss of sensation (anaesthetics);
- if you are taking medication to treat depression;

- if you are taking antihypertensive medication (e.g. guanethidine, reserpine and methyldopa);
- if you have diabetes.
- 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® SYRUP are not recommended for children under the age of 6 years.

Other medicines and FLUSTAT® SYRUP

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:

- if you are taking medication to treat depression

Using FLUSTAT® SYRUP with food and drink:

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

Do not take this mediation with alcohol.

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® SYRUP should not be used in pregnancy.

Driving and using machines

You may experience side effects such as dizziness, headaches and drowsiness.

It is not always possible to predict to what extent FLUSTAT® SYRUP 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 FLUSTAT® SYRUP affects them.

FLUSTAT® SYRUP contains

Sucrose: If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Liquid sorbitol non crystallising: patients with hereditary fructose intolerance (HFI) should not take/be given FLUSTAT® SYRUP.

Small amounts of ethanol (alcohol): less than 100 mg per dose.

Sodium: This medicine contains 31 mg sodium (main component of cooking/table salt) in each 20 ml dosage. This is equivalent to 1,55 % of the recommended maximum daily dietary intake of sodium for an adult.

3. HOW TO TAKE FLUSTAT® SYRUP

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

Always take FLUSTAT® SYRUP 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.

Over 12 years: 20 ml every four hours up to four times daily.

Children 6-12 years: 10 ml every four hours up to four 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® SYRUP than you should

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

- Irregular pulse rate and respiration, paleness, nauseas, vomiting, abdominal pain and disorientation/confusion.

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® SYRUP

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® SYRUP

If you are unsure when to stop using FLUSTAT® SYRUP, 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® SYRUP** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **FLUSTAT® SYRUP**, please consult your health care provider for advice.

If any of the following happen, you should stop taking **FLUSTAT® SYRUP** 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.

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® SYRUP**. 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
- 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 r ash, 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:

<u>Frequency unknown side effects:</u>

- mental confusion
- dizziness

- headache
- tremor
- anxiety
- restlessness
- difficulty sleeping (insomnia)
- drowsiness
- muscle weakness
- nausea
- vomiting
- excitation
- diarrhoea
- enlargement of the prostate gland
- increased blood pressure

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® SYRUP**

5. HOW TO STORE FLUSTAT® SYRUP

Store all medicines out of reach of children

- Store at or below 25 ºC, in a cool, dark place.
- 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® SYRUP CONTAINS

Each 20 ml contains:

Phenylpropanolamine hydrochloride 25 mg

Dextromethorphan hydrobromide 15 mg

Paracetamol 500 mg

Preservative: Nipastat 0,08 % *m/v*

Alcohol 14,8 % *v/v*

Contains Sugar: Sucrose 4,0 g per 20 ml

The other ingredients are:

Alcohol 96 %, castor sugar (sucrose), citric acid monohydrate, cherry menthol liquid, nipastat, propylene glycol, purified water, sodium saccharin, sodium citrate, sorbitol solution 70 % w/w, sunset yellow dye.

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

A clear orange-red liquid, with a fruity flavour.

100 ml and 200 ml containers.

Holder of Certificate of Registration

Ranbaxy Pharmaceuticals (Pty) Ltd

14 Lautre Road,

Stormill, Ext. 1,

Roodepoort,

1724

This leaflet was last revised in

30 September 2023

Registration Number

28/5.8/0231 (S.A.)

NS1 04/5.8/1619 (Namibia)

PMPB/PL4/23 (Malawi) (100 ml)