

### 1.3.2 PATIENT INFORMATION LEAFLET

#### SCHEDULING STATUS

**S2**

#### PROPRIETARY NAME AND DOSAGE FORM

#### FLUSIN S EFFERVESCENT

Effervescent tablets

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

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

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 7 days.

#### WHAT FLUSIN S EFFERVESCENT CONTAINS

Each tablet of FLUSIN S EFFERVESCENT contains the following active substances:

Pseudoephedrine hydrochloride	50 mg
Chlorphenamine maleate	4 mg
Paracetamol	500 mg
Vitamin C	330 mg

The other ingredients are:

Aspartame, citric acid anhydrous, colloidal silicon dioxide, ginger flavour 77903-31, light liquid paraffin, polyethylene glycol, sodium bicarbonate, sodium carbonate anhydrous.

Contains sweetener: Aspartame 60,0 mg

### **WHAT FLUSIN S EFFERVESCENT IS USED FOR**

FLUSIN S EFFERVESCENT is used to relieve the symptoms of colds and flu in adults and children 12 years or older.

### **BEFORE YOU TAKE FLUSIN S EFFERVESCENT**

- Be aware that overstimulation, nervousness and sleeplessness may occur in some children and in the elderly.
- Be aware that elderly patients are especially prone to dizziness, drowsiness, confusion, low blood pressure as well as dry mouth and an inability to urinate.

### **Do not use FLUSIN S EFFERVESCENT**

- If you are hypersensitive (allergic) to chlorphenamine maleate, pseudoephedrine hydrochloride, paracetamol or vitamin C.
- If you have any disease of the heart and blood vessels.
- If you are pregnant or breastfeeding.
- For a child under the age of 12 years old.
- If you are sensitive to any antihistamines.
- If you are receiving monoamine oxidase inhibitor antidepressant treatment, or if you stopped this treatment less than 14 days ago.
- If you are about to have surgery and will need a general anaesthetic; as halothane or other halogenated anaesthetics may bring about an uncoordinated rapid heartbeat (ventricular fibrillation).
- If you have liver disease.
- If you are suffering from inflammation of the liver or alcoholism, or recovering from any

form of liver disease.

### **Take special care with FLUSIN S EFFERVESCENT**

- If you drink any alcohol or take any central nervous system depressants (sedatives) such as sleeping tablets other pain tablets while taking FLUSIN S EFFERVESCENT as drowsiness and impaired concentration may be made worse.
- If you have prostate problems, increased pressure in the eye (narrow angle glaucoma), a lung disorder which makes breathing difficult (emphysema) or persistent inflammation of the lungs (chronic bronchitis) or porphyria.
- If you have a stomach disorder or recurrent fits.
- If you have high blood pressure, an overactive thyroid, sugar diabetes, stomach ulcer or a tumour of the adrenal gland (phaeochromocytoma).
- If you are taking antidepressant medicines; as you may experience certain side effects such as tremor, slurred speech and movement disorders as well as side effects such as dry mouth, forgetfulness and confusion, light headedness and mental clouding, constipation and blurred vision.
- If you exceed the recommended dose you may develop severe liver damage.
- If you exceed the recommended dosage it may cause nervousness, dizziness, sleeplessness, tremulousness or a heart rate disorder.
- After 5 to 7 days FLUSIN S EFFERVESCENT may lose its effect. If symptoms do not improve, or are accompanied by a fever, contact your doctor.

### **Pregnancy and breastfeeding**

You should not take FLUSIN S EFFERVESCENT if you are pregnant or breastfeeding your baby.

Always tell your healthcare provider if you are taking any other medicine. If you are pregnant

or breastfeeding your baby, please consult your healthcare provider for advice before taking FLUSIN S EFFERVESCENT.

### **Driving and using machinery**

Do not drive or operate any tools or machines particularly at the beginning of the treatment as loss of concentration could lead to accidents.

### **Taking other medicines with FLUSIN S EFFERVESCENT**

Always tell your healthcare provider if you are taking any other medicines. (This includes complementary or traditional medicines).

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

- Antihistamines (medicines used to treat allergies).
- Antidepressant medicines (used to treat mood disorders) known as monoamine oxidase inhibitors (MAOI).
- Medicines that are harmful to the liver or affect liver enzymes (e.g. isoniazid).
- Metoclopramide (used to treat nausea and vomiting).

### **HOW TO TAKE FLUSIN S EFFERVESCENT**

Always take FLUSIN S EFFERVESCENT exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

#### **Adults and children over 12 years of age:**

Take one tablet every 6 hours if necessary.

Place one tablet in a glass of warm water and allow to dissolve. Drink the contents immediately once the whole tablet has dissolved.

If you find that FLUSIN S EFFERVESCENT is too strong or too weak, talk to your doctor or pharmacist.

Do not use continuously for more than 7 days without consulting your doctor.

**If you take more FLUSIN S EFFERVESCENT than you should prompt treatment is essential.**

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

FLUSIN S EFFERVESCENT contains paracetamol, which is very harmful when taken in high amounts.

#### **If you forget to take FLUSIN S EFFERVESCENT**

If you miss a dose, just resume the usual schedule when your next dose is due. Do not take a double dose to make up for forgotten individual doses.

#### **POSSIBLE SIDE EFFECTS**

FLUSIN S EFFERVESCENT can have side effects.

Not all side effects reported for FLUSIN S EFFERVESCENT are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking FLUSIN S EFFERVESCENT, please consult your doctor, pharmacist or other healthcare provider for advice.

**If any of the following happens, stop taking FLUSIN S EFFERVESCENT and tell your**

**doctor immediately or go to the casualty department at your nearest hospital:**

- Allergic reactions including rash, swelling of the face, lips, tongue, and/or throat which may cause difficulty in breathing or swallowing.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to FLUSIN S EFFERVESCENT. 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:**

- Rapid or uneven heart beat;
- rise in blood pressure;
- slurred speech and difficulty in movement with muscle spasms and muscle pain;
- seizures (fits).

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

**Tell your doctor or pharmacist if you notice the following:**

The following side effects have been frequently reported:

- Inability to sleep, feeling anxious, restlessness.

The following side effects have been reported less frequently:

- Dizziness, drowsiness, tiredness, tremor;
- headache;
- nausea, vomiting;
- loss of appetite, constipation;
- difficulty and pain in passing urine.

The following side effects have been reported with a frequency unknown:

- Confusion, hallucinations, irritability;
- depression;
- blurred vision, ringing in the ears;
- diarrhoea, stomach pain.

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

### **STORING AND DISPOSING OF FLUSIN S EFFERVESCENT**

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

Keep tube tightly closed.

Keep in original packaging until required for use.

Do not store in a bathroom.

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).

**STORE ALL MEDICINES OUT OF REACH OF CHILDREN.**

### **PRESENTATION OF FLUSIN S EFFERVESCENT**

12 tablets are packed in aluminium tubes, seamless with lacquered inner and outer surfaces with a low density polyethylene press-on white cap with a spiral tablet stabilizer, with drier cavity with self indicating silica gel drier and then packed in an outer cardboard carton.

### **IDENTIFICATION OF FLUSIN S EFFERVESCENT**

Round biplane tablet, off-white with a pink tinge and a rough surface, with clean edges and a

sweet ginger smell. Produces a slightly pink, clear solution with a sweet ginger taste.

**REGISTRATION NUMBER**

30/5.8/0001

**NAME BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE  
CERTIFICATE OF REGISTRATION**

PHARMACARE LIMITED

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