1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

FLUSIN S EFFERVESCENT

50 mg/ 4 mg/ 500 mg/ 330 mg tablets

pseudoephedrine hydrochloride, chlorphenamine maleate, paracetamol, vitamin C

Contains sweetener: Aspartame 60,0 mg

Sugar free

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.
- Do not share FLUSIN S EFFERVESCENT with any other person.
- Ask your healthcare provider or 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 is in this leaflet

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

1. What FLUSIN S EFFERVESCENT is and what it is used for

FLUSIN S EFFERVESCENT belongs to a group of medicines called analgesics and antipyretics.

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

2. What you need to know before you take FLUSIN S EFFERVESCENT

Do not take FLUSIN S EFFERVESCENT:

- If you are hypersensitive (allergic) to chlorphenamine maleate, pseudoephedrine hydrochloride, paracetamol or vitamin C or any of the other ingredients of FLUSIN S EFFERVESCENT (listed in section 6).
- If you have any disease of the heart and blood vessels (angina, ischaemic heart disease, peripheral vascular disease, dysrhythmia or tachycardia).
- If you are pregnant or breastfeeding.
- For a child under the age of 12 years old.
- If you are sensitive to any antihistamines (medicines used to treat symptoms of allergies).
- If you are receiving monoamine oxidase inhibitor antidepressant treatment, or if you stopped this treatment less than 14 days ago.
- If you suffer from severe liver disease, inflammation of the liver or if you are recovering from any form of liver disease.
- If you suffer from severe kidney disease.
- 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 suffer from high blood pressure (hypertension), or if you take a certain medicine called beta blockers to lower your blood pressure you should not take

FLUSIN S EFFERVESCENT.

- If you have an overactive thyroid (hyperthyroidism).
- If you have a tumour in your adrenal gland (phaeochromocytoma).
- If you suffer from closed angle glaucoma, a condition where your pupil changes and becomes too big (dilated) too quickly and pressure is raised in your eye.
- If you have too much oxalate in your urine (hyperoxaluria).
- If you suffer from diabetes mellitus (a condition where your blood glucose levels are too high).

Warnings and precautions

FLUSIN S EFFERVESCENT contains paracetamol which may be fatal in overdose. In the event of overdosage or suspected overdose and notwithstanding the fact that the person may be asymptomatic, the nearest doctor, hospital or Poison Centre must be contacted immediately.

FLUSIN S EFFERVESCENT may lead to drowsiness and impaired concentration, which may be aggravated by simultaneous intake of alcohol or other central nervous system depressants e.g. sedatives and tranquilizers. Caution should be used when driving a motor vehicle or operating machinery or performing potentially dangerous tasks, where loss of concentration may lead to accidents.

Take special care with FLUSIN S EFFERVESCENT:

- If you drink any alcohol or take any central nervous system depressants (sedatives) such as sleeping tablets or other pain tablets while taking FLUSIN S

EFFERVESCENT as drowsiness and impaired concentration may be made worse.

- If you have liver or kidney problems (see Do not take FLUSIN S EFFERVESCENT).
- If you have prostate problems, a lung disorder which makes breathing difficult (emphysema) or persistent inflammation of the lungs (chronic bronchitis, bronchial asthma) or porphyria (a rare disorders that result from a buildup of natural chemicals called porphyrins in the body).
- If you have a stomach disorder (blockage in the stomach known as pyloroduodenal obstruction) or recurrent fits (epilepsy).
- FLUSIN S EFFERVESCENT may affect certain skin test results and should be stopped several days before the test.
- If you suffer from difficulty in urinating.
- If you suffer from aneurysms (blown up or weakened area in a blood vessel).
- If you are malnourished (underfed), anorexic, have a low body mass index, are drinking large amounts of alcohol or have sepsis (your body's response to an infection).
- If you develop any skin adverse reaction, 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 FLUSIN S EFFERVESCENT must immediately be discontinued. These reactions can be life-threatening and are 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.
- If you experience sudden stomach ache or rectal bleeding, discontinue the use of FLUSIN S EFFERVESCENT and seek medical advice as these could be signs of ischaemic colitis (inflammation in the colon).
- If you experience loss of vision or difficulty seeing, discontinue the use of FLUSIN S

EFFERVESCENT and seek medical advice as this may be signs of ischaemic optic neuropathy (when blood does not flow properly to your eye's optic nerve).

- If you suffer from severe or uncontrolled high blood pressure or severe, acute or chronic kidney disease/failure you are at risk of developing posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS).

  PRES and RCVS can involve reduced blood supply (ischaemia) to the brain and may cause major and life-threatening complications in some cases. Common symptoms associated with PRES and RCVS include headache, nausea and seizures.
- 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 dosage, you may develop severe liver damage. You should not take any other medicines containing paracetamol whilst taking FLUSIN S EFFERVESCENT.
- If you exceed the recommended dosage, it may cause nervousness, dizziness, sleeplessness, tremulousness or a heart rate disorder.
- If you take too much ascorbic acid (vitamin C), one of the ingredients in FLUSIN S EFFERVESCENT your body may build up a tolerance. You should not take too much FLUSIN S EFFERVESCENT or for prolonged periods.
- Ascorbic acid (vitamin C) as contained in FLUSIN S EFFERVESCENT may interfere with serological tests (a laboratory test used to measure the presence and concentration of antibodies in the blood). You should inform your healthcare professional if you are taking FLUSIN S EFFERVESCENT and planned for a serological test.

- 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.
- 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.
- If you are taking an antibiotic called flucloxacillin with FLUSIN S EFFERVESCENT, as it may cause increased acid levels in your body especially if you have severe renal problems, severe reaction to infection (sepsis), malnutrition and other conditions that cause less glutathione to be produced by the body. Close monitoring is recommended.

Children and adolescents

There is no experience with FLUSIN S EFFERVESCENT in children younger than 12 years.

Other medicines and FLUSIN S EFFERVESCENT

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

Tell your doctor if you are taking any of the following:

- Phenytoin (medicines used to treat epilepsy).
- Belladonna (medicine used as a sedative, to stop bronchial spasms in asthma and whooping cough).
- Sedatives (medicine used to treat anxiety and sleep disorders) as FLUSIN S EFFERVESCENT may enhance the sedative effect.
- Antihistamines (medicines used to treat allergies).
- Antidepressant medicines (used to treat mood disorders) known as monoamine oxidase inhibitors (MAOI). (See section ‘Do not take FLUSIN S EFFERVESCENT).

- Cardiovascular medicine (medicine used to treat heart disease such as digoxin).
- Antihypertensives, alpha- and beta-blockers (medicines used to lower blood pressure e.g. guanethidine, reserpine, alpha-methyldopa). (See section 'Do not take FLUSIN S EFFERVESCENT).
- Tricyclic antidepressants (medicine used to treat depression e.g. amitriptyline, imipramine) as these may lead to an increase in certain side effects.
- Central Nervous System (CNS) stimulants (medicines such as sedatives (used to treat anxiety and sleep disorders), tranquilizers and hypnotics). These medicines may increase the effect of FLUSIN S EFFERVESCENT and lead to nervousness, irritability.
- Doxapram (medicine used as a respiratory stimulant) as these may lead to an increase in blood pressure.
- Ergot alkaloids (medicines used to treat severe headaches such a migraines).
- Appetite suppressants may increase the effects of FLUSIN S EFFERVESCENT.
- Oxytocin (medicine used to help start or continue labour and to control bleeding after childbirth).
- Isoniazid (medicine used to treat tuberculosis).
- Metoclopramide (used to treat nausea and vomiting).
- Probenecid (medicine used to treat chronic gout or gouty arthritis).
- Colestyramine (medicine used to lower high cholesterol levels in the blood).
- Nonsteroid anti-inflammatory drugs (NSAIDs) (medicine used to relieve pain, reduce inflammation, and bring down a high temperature such as ibuprofen, naproxen, aspirin and diclofenac).
- Zidovudine (medicine used in the treatment and management of HIV).
- Warfarin (medicine used to prevent blood clots).
- Flucloxacillin (an antibiotic used to treat skin infections).
- Amphetamine (used to treat attention deficit hyperactivity disorder (ADHD)).

- If you smoke or if you are taking any oral contraceptives.
- Iron supplements as this may increase the absorption of FLUSIN S EFFERVESCENT.
- Antacids (medicine used to treat heartburn or indigestion).
- Amygdalin (a complementary medicine used as anticancer therapy).
- Desferrioxamine (medicine used to remove excess iron from your body).
- Fluphenazine (medicine used to treat certain types of mental or mood disorders).

FLUSIN S EFFERVESCENT with alcohol

You should not consume alcohol while taking FLUSIN S EFFERVESCENT. This may lead to drowsiness, dizziness, blurred vision and impaired concentration.

Pregnancy, breastfeeding and fertility

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

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 taking this medicine.

Driving and using machines

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

FLUSIN S EFFERVESCENT may lead to drowsiness, dizziness, blurred vision and impaired concentration that may be aggravated by the simultaneous intake of alcohol or other central nervous system depressants which may interfere with your daily activities. You should

ensure that you do not engage in the above activities until you are aware of the measure to which FLUSIN S EFFERVESCENT affects you (see section 4).

FLUSIN S EFFERVESCENT contains aspartame

FLUSIN S EFFERVESCENT contains aspartame and should be avoided or restricted in patients with phenylketonuria (a rare inherited disorder that causes an amino acid called phenylalanine to build up in the body (phenylketonuria)).

3. How to take FLUSIN S EFFERVESCENT

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

Always take FLUSIN S EFFERVESCENT exactly as described in this leaflet or as your doctor, or pharmacist or nurse have told you. Check with your doctor, pharmacist or nurse if you are not sure.

The usual dose of FLUSIN S EFFERVESCENT is:

Adults and children over 12 years of age:

Take one tablet every 6 hours if necessary.

DO NOT EXCEED THE RECOMMENDED DOSE.

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

In the event of overdosage, consult your doctor or pharmacist. 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

Do not take a double dose to make up for forgotten individual doses.

If you have missed a dose of FLUSIN S EFFERVESCENT, take the dose that you have missed as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. If you have forgotten to take several doses, contact your doctor without delay.

4. 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 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:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting,
- blistering of the skin, mouth, eyes and genitals as these may be due to a serious allergic reaction known as Stevens-Johnson Syndrome (SJS). Severe Cutaneous

Adverse Reactions (SCARS) such as toxic epidermal necrolysis (TEN), Steven-Johnson syndrome (SJS), acute generalised exanthematous pustulosis (AGEP), Drug reaction with eosinophilia and systemic symptoms (DRESS)/Drug-induced hypersensitivity syndrome (DIHS) and fixed drug eruptions (FDE).

These are all very serious side effects. If you have them, you may have had a serious 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, slow or uneven heartbeats (tachycardia, bradycardia and dysrhythmias),
- pain in the chest with pressure heaviness and tightness (anginal pain, tightness of the chest),
- feeling in the chest that the heart is beating too fast (palpitations),
- sudden loss of heart function, breathing and consciousness (cardiac arrest),
- rise in blood pressure (hypertension),
- inflammation in your liver (hepatitis), including jaundice and liver dysfunction which can present as yellowing of the skin and eyes, dark urine and tiredness,
- blood disorders such as decrease in white blood cells (leucopenia, neutropenia and agranulocytosis), decrease in red blood cells (anaemia and haemolytic anaemia), decrease in most blood cells (pancytopenia) and a decrease in platelets (thrombocytopenia). The first symptoms may include fever, sore throat, surface mouth ulcers, flu-like symptoms, severe tiredness, nasal and skin bleeding or unexplained bruising,
- seeing or hearing things that are not really there (hallucination) and psychotic states,
- difficulty breathing (dyspnoea),

- inflammation of your pancreas, characterised by stomach pain, nausea and vomiting (pancreatitis),
- symptoms such as, but not limited to severe headache, weakness, tingling or numbness in the arms and legs, nausea, difficulty in speaking or understanding speech as this may be due to a bleed in the brain (cerebral haemorrhage),
- excess fluid in the lungs (pulmonary oedema) which causes difficulty breathing, chest pain and tiredness,
- restricted airflow to the lungs (bronchospasm) in those that are allergic to aspirin or other non-steroidal anti-inflammatory drugs (NSAIDS),
- slurred speech and difficulty in movement with muscle spasms and muscle pain,
- painful urination, blood in your urine, cloudy urine, fever as these may be due to a kidney stone is stuck in the urinary tract (renal colic),
- fits (convulsions/seizures).
- symptoms such as, but not limited to, nausea, vomiting, muscle cramps, loss of appetite, swelling of the feet and ankles, dry and itchy skin, shortness of breath as these may be due to a deterioration in kidney function (renal failure),
- if you experience visual disturbances, seizures, headaches and altered mentation this may be a sign of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS) a rare condition in which parts of the brain are affected by swelling, you should discontinue the use of FLUSIN S EFFERVESCENT and consult your healthcare professional.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Inability to fall asleep and staying asleep (insomnia), feeling anxious, restlessness,
- fear, confusion, irritability,
- involuntary quivering movement (tremor),
- dizziness,
- feeling weak, sweating,
- tolerance with dependence,
- slight drowsiness to deep sleep (sedation),
- excessive sleepiness, mental weariness, lack of energy (somnolence, lassitude, asthenia),
- inability to use different parts of the body efficiently (incoordination) or clumsy balance and limb movements (ataxia),
- blurred vision,
- nausea, dry mouth.

Less frequent side effects:

- Headache,
- vomiting,
- lesions in the mouth (mucosal lesions),
- itchy, raised, red or skin coloured bumps on the skin (urticaria, erythematous reactions, pruritus),
- loss of appetite, constipation,
- low levels of potassium in the blood (hypokalaemia),
- low blood pressure (hypotension),
- increased saliva in the mouth (hypersalivation),
- difficulty and pain in passing urine (urinary retention, micturition, dysuria),
- changes in blood sugar levels,

- nervousness, excitement and happiness (euphoria),
- nightmares,
- feeling tired (fatigue),
- abnormal sensation, feeling of pins and needles (paraesthesias),
- involuntary movements that you cannot control (extrapyramidal effects),
- ringing in the ears (tinnitus),
- thickening of mucous,
- when stomach acid irritates the food pipe lining (gastric reflux, dyspepsia),
- stomach pain, diarrhoea,
- pain in muscles or a group of muscles (myalgia),
- fever.

Side effects with an unknown frequency:

- Feeling of being threatened in some way (paranoid delusions),
- condition where blood does not flow properly to your eye's optic nerve, eventually causing lasting damage to this nerve (Ischaemic optic neuropathy),
- inflammation and injury of the large intestine (ischaemic colitis),
- an eating disorder where you don’t want to eat (anorexia),
- depression,
- heaviness and weakness of the hands, muscle spasms,
- dryness of the respiratory passages,
- rash due to sun exposure (photosensitivity), skin irritation and rashes (dermatitis),
- increase in body temperature caused by a medicine (drug fever),
- hair loss,
- involuntary (unintended) muscle contractions that cause slow repetitive movements or abnormal postures that can sometimes be painful (dystonia),

- frequent urination,
- increased blood flow to the skin (flushing),
- stomach cramps,
- kidney stones (formation of calcium oxalate calculi, increased urinary oxalate excretion),
- inability to stay still or sit still (psychomotor hyperactivity),
- increased transaminases in your blood which could mean that you have liver damage,
- white blood cells in the urine with no detection of bacteria (sterile pyuria),
- headache, nausea, vomiting, confusion, dizziness, feeling weak or tired, loss of appetite and increased heartbeat due to high acid levels in the body (metabolic acidosis or pyroglutamic aciduria).

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 188 088 / +27 (0)11 239-6200

By reporting side effects, you can help provide more information on the safety of FLUSIN S EFFERVESCENT.

5. How to store FLUSIN S EFFERVESCENT

Store all medicines out of reach of children.

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).

6. Contents of the pack and other information

What FLUSIN S EFFERVESCENT contains

The active substance is 50 mg pseudoephedrine hydrochloride, 4 mg chlorphenamine maleate, 500 mg paracetamol and 330 mg vitamin C.

The other ingredients are aspartame, citric acid anhydrous, colloidal silicon dioxide, ginger

flavour 77903-31, light liquid paraffin, polyethylene glycol 6000, sodium bicarbonate, sodium carbonate anhydrous.

Contains sweetener: Aspartame 60,0 mg

What FLUSIN S EFFERVESCENT looks like and contents of the pack

FLUSIN S EFFERVESCENT is a 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 ginger taste.

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.

Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912

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Registration number

30/5.8/0001

Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

Namibia: NS1 04/5.8/0470

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