PATIENT INFORMATION LEAFLET

EFFERFLU C COLD & FLU

SCHEDULING STATUS:

S2

EFFERFLU C COLD & FLU Effervescent tablets

Paracetamol, chlorphenamine maleate and sodium ascorbate as vitamin C

EFFERFLU C COLD & FLU contains sugar alcohol, sorbitol 212 mg per tablet.

EFFERFLU C COLD & FLU contains aspartame 40 mg

EFFERFLU C COLD & FLU contains 314 mg sodium per tablet

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

EFFERFLU C COLD & FLU is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use EFFERFLU C COLD & FLU carefully to get the best results from it. Keep this leaflet. You may need to read it again.

1. Do not share EFFERFLU C COLD & FLU with any other person.
2. Ask your healthcare provider or pharmacist if you need more information or advice.
3. You must see a doctor if your symptoms worsen or do not improve after 7 days.

What is in this leaflet

1. What EFFERFLU C COLD & FLU is and what it is used for
2. What you need to know before you take EFFERFLU C COLD & FLU
3. How to take EFFERFLU C COLD & FLU
4. Possible side effects
5. How to store EFFERFLU C COLD & FLU
6. Contents of the pack and other information

1. What EFFERFLU C COLD & FLU is and what it is used for

EFFERFLU C COLD & FLU contains the following active ingredients: paracetamol, sodium ascorbate

equivalent to vitamin C and chlorphenamine maleate.

EFFERFLU C COLD & FLU is indicated for symptomatic relief of runny nose, sneezing, sore throat, headache and generalized aching due to colds and flu.

2. What you need to know before you take EFFERFLU C COLD & FLU

Do not take EFFERFLU C COLD & FLU:

- if you are hypersensitive (allergic) to paracetamol, vitamin C, chlorphenamine maleate or to any of the ingredients of EFFERFLU C COLD & FLU (see section 6)
- if you have severe liver disease
- if you have any disease of the heart and blood vessels
- if you suffer from epilepsy
- do not use EFFERFLU C COLD & FLU in children under the age of 12 years
- if you are sensitive to any antihistamines
- if you are receiving monoamine oxidase inhibitor (MAOI) 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 suffer with acute attacks of asthma
- if you are pregnant or breastfeeding, as safety and efficacy have not been established.

Warnings and precautions

Take special care with EFFERFLU C COLD & FLU:

- do not use in combination with any other medicines containing paracetamol as it may lead to an overdose. Paracetamol overdose may cause liver failure, which may require liver transplant and may lead to death

- if you have an enlargement of the prostate, as it may cause problems when urinating, increased pressure in the eye (narrow angle glaucoma), a lung disorder which makes breathing difficult (emphysema) or persistent inflammation of the lungs (chronic bronchitis), asthma, passing less urine than is normal (urinary retention), heart disease, porphyria
- EFFERFLU C COLD & FLU should not be taken by elderly patients who suffer with confusion
- if you experience side effects including hyper mental and physical excitability which deviates from normal, irregular heartbeat, tremors, convulsions or seizures (fits) whilst taking this medicine (especially in children and the elderly)
- EFFERFLU C COLD & FLU may enhance the symptoms of nervousness and the inability to sleep in elderly people and children
- EFFERFLU C COLD & FLU may increase the symptoms in the elderly people which are especially susceptible to dry mouth, urinary retention, sedation, dizziness, confusion and low blood pressure
- if you drink any alcohol or take any central nervous system depressants (sedatives) such as sleeping tablets other pain tablets while taking EFFERFLU C COLD & FLU as drowsiness and impaired concentration may worsen
- take special care if you have liver or kidney problems. Too much of this medicine may cause severe liver damage
- if you experience severe skin reactions, painful large areas of blistering and peeling skin or fever and swelling of the face, treatment with EFFERFLU C COLD & FLU should be discontinued and medical advice sought immediately
- if you require any laboratory skin tests you will need to stop taking this medicine a few days before, as EFFERFLU C COLD & FLU may affect the results
- tell your doctor if the pain or fever persists or gets worse at the recommended dosage, if new symptoms occur or if redness and swelling persist, as these could be signs of a more serious condition

- if you have low levels of glutathione due to metabolic deficiencies, such as if you are severely malnourished, anorexic, have a low body mass index, have alcohol induced dehydration or have sepsis (when bacteria and their toxins circulate in the blood leading to organ damage)
- if you are taking a medicine containing flucloxacillin, as the use of paracetamol may increase the risk of metabolic acidosis (when acids build up in your body, especially in patients with kidney conditions and diabetes)
- do not use EFFERFLU C COLD & FLU continuously for more than 7 days without consulting your doctor.

EFFERFLU C COLD & FLU contains paracetamol which may be fatal in overdosage. In the event of overdosage or suspected overdose and notwithstanding the fact that the person may produce or show no symptoms, the nearest doctor, hospital or poison centre must be contacted immediately.

Other medicines and EFFERFLU C COLD & FLU

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

- Patients sensitive to another antihistamine (medicine used to treat allergies) may be sensitive to EFFERFLU C COLD & FLU (see Do not take EFFERFLU C COLD & FLU)
- EFFERFLU C COLD & FLU 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 (see Warnings and precautions).

Paracetamol

- if you are currently taking any medicine which is poisonous to the liver (e.g. phenytoin, carbamazepine or barbiturates, used to treat seizures (fits) or mood disorders), then the simultaneous use of EFFERFLU C COLD & FLU will increase the poisoning of your liver

- simultaneous use of enzyme inducing medicines (examples are anti-epileptics, oral contraceptives and rifampin) with EFFERFLU C COLD & FLU may decrease liver health and possibly decrease the healing effects of EFFERFLU C COLD & FLU
- metoclopramide (which is used to relieve symptoms such as nausea, vomiting, heartburn, loss of appetite, and feeling of fullness that lasts long after meals) may accelerate the absorption of EFFERFLU C COLD & FLU
- cholestyramine (used for removing bile acid from the body) – absorption of EFFERFLU C COLD & FLU is reduced if given within one hour of cholestyramine
- prolonged concurrent use of EFFERFLU C COLD & FLU with salicylates (aspirin) increases the risk of adverse kidney problems
- the simultaneous use of probenecid (Benemid) might cause an overdose of the EFFERFLU C COLD & FLU
- prolonged concurrent use of EFFERFLU C COLD & FLU with warfarin (used to prevent blood clots from forming) may increase the risk of bleeding
- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (high anion gap metabolic acidosis) that must have urgent treatment and which may occur particularly in case of severe kidney damage, sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), malnutrition, chronic alcoholism, and if the maximum daily doses of paracetamol are used
- medicines to treat tuberculosis (isoniazid) may increase the risk of liver problems.

Certain blood sugar and/or urine test results may be affected whilst taking EFFERFLU C COLDS & FLU.

Chlorphenamine maleate

- chlorphenamine maleate may enhance the sedating effects of certain medicines used to calm you or to help you sleep.

These substances include alcohol, barbiturates, hypnotics (sleep inducing drugs), opioid analgesics (such as codeine), anxiolytic sedatives (used for treatment of anxiety), belladonna (a herbal medicine) and antipsychotics (used to increase mental health)

- simultaneous use of monoamine oxidase (MAO) inhibitors (medicines used for mental disorders) with EFFERFLU C COLD & FLU may prolong and intensify the sedative effect of chlorphenamine maleate. Concurrent use is not recommended. Care should be taken when tricyclic antidepressants and maprotiline (which are used in the treatment of depression), guanethidine (for treatment of blood pressure), reserpine (lowers blood pressure), methyldopa (reduction of blood pressure), atropine (used in serious allergic response) are taken concomitantly
- if chlorphenamine maleate is used simultaneously with medications which can cause damage to the ear (examples of these damages are hearing loss, ringing in the ear, dizziness or sensation of whirling or balance disorders), the symptoms may be masked
- chlorphenamine may increase the risk of phenytoin poisoning.

Chlorphenamine maleate may suppress positive skin test results for allergies and should be stopped several days before the test.

Vitamin C

- vitamin C should not be given for the first month after starting treatment with desferrioxamine (a medicine used as an antidote to treat iron poisoning or overload) due to increased iron poisoning
- large doses of vitamin C may increase hormone levels in women taking oral contraceptives
- simultaneous use of vitamin C and fluphenazine (used for the treatment of mental problems) may reduce the effect of the fluphenazine
- may interact with warfarin (a medicine used to treat and prevent blood clots).

EFFERFLU C COLD & FLU with food, drink and alcohol

EFFERFLU C COLD & FLU may be taken with or without food.

Do not drink alcohol while you are taking EFFERFLU C COLD & FLU.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, 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 EFFERFLU C COLD & FLU.

The safety of EFFERFLU C COLD & FLU during pregnancy and breastfeeding has not been established and should therefore not be taken (see Do not take EFFERFLU C COLD & FLU).

Driving and using machines

EFFERFLU C COLD & FLU may make you dizzy, drowsy, give you blurred vision and impair your concentration. If you start treatment with EFFERFLU C COLD & FLU, do not drive your vehicle or operate machinery or perform hazardous tasks where loss of concentration could lead to accidents. Simultaneous intake of alcohol or other nervous system depressants, such as sleeping tablets, pain tablets and tablets for anxiety will worsen your drowsiness.

It is not always possible to predict to what extent EFFERFLU C COLD & FLU 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 EFFERFLU C COLD & FLU affects them.

EFFERFLU C COLD & FLU contains

Sorbitol

EFFERFLU C COLD & FLU contains the sugar alcohol, sorbitol.

Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take this medicine.

Aspartame

EFFERFLU C COLD & FLU 40 mg aspartame in each effervescent tablet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

Sodium

EFFERFLU C COLD & FLU contains 314 mg sodium (main component of cooking/table salt) in each effervescent tablet. This is equivalent to 15,7 % of the recommended maximum daily dietary intake of sodium for an adult.

3. How to take EFFERFLU C COLD & FLU

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

Always take EFFERFLU C COLD & FLU exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you. Check with your doctor, pharmacist or nurse if you are not sure.

DO NOT EXCEED THE RECOMMENDED DOSE.

Adults and children over 12 years:

The usual dose is one effervescent tablet every 8 hours if necessary. Dissolve one tablet in a glass of water and drink the content immediately, once the whole tablet has dissolved.

Consult a doctor if no relief is obtained from the recommended dosage.

Do not use EFFERFLU C COLD & FLU continuously for more than 7 days without consulting your doctor.

Children:

These tablets should not be used in children below the age of 12 years.

If you take more EFFERFLU C COLD & FLU than you should

Prompt treatment is essential.

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

Symptoms of overdose may include:

- chronic liver disease, kidney failure
- diarrhoea, loss of appetite, nausea or vomiting
- unhealthy, pale appearance
- stomach cramps and pain
- increased sweating
- unsteadiness and severe drowsiness
- dryness of throat, nose and mouth
- severe redness of face and shortness of breath
- convulsions, fast and irregular heartbeat
- hyper excitement
- hallucinations
- the loss of full control of bodily movements
- abnormal muscle contraction causing involuntary writhing movements.

If you forget to take EFFERFLU C COLD & FLU

If you forget to take EFFERFLU C COLD & FLU, take as soon as you remember. If it is almost time for your next dose, wait until then. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

EFFERFLU C COLD & FLU can have side effects.

Not all side effects reported for EFFERFLU C COLD & FLU are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using EFFERFLU C COLD & FLU, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop using EFFERFLU C COLD & FLU 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 swallowing or breathing
- rash or itching
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to EFFERFLU C COLD & FLU. 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:

- skin reactions which can be life-threatening and are characterised by redness, inflamed or swollen skin, blisters, hives, itching and sometimes peeling or pain (see Take special care with EFFERFLU C COLDS & FLU)
- high blood pressure, tightness of the chest, tingling, heaviness and weakness of the hands
- change in the way your heart beats, for example, if you notice it beating faster
- difficulty breathing

- change in urine colour or decrease in amount of urine or difficulty in passing urine, colic of the kidneys, failure of kidney function
- serious blood disorders including agranulocytosis (an acute condition involving a severe and dangerous lowered white blood cell count with symptoms such as recurrent infections including fever or sore throats, ulcers or white spots on lips or in mouth)
- convulsions or seizures, hallucinations, loss of full control of bodily movements, confusion
- yellowing of the skin or whites of the eyes, or urine getting darker and stools paler, fatigue, weakness, malaise, loss of appetite, nausea or vomiting caused by liver problems (signs of hepatitis, jaundice, liver problems or liver failure)
- inflammation of the pancreas, which causes severe or sharp pain in lower back and/or side of abdomen (pancreatitis)
- kidney failure (less urine than is normal for you), renal colic (acute, intense pain in your back or lower stomach area, spreading to your back or groin, nausea).

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:

- drowsiness, dizziness, increased sweating, tremor, nervousness, sleeplessness or headache, physical or mental weariness, lack of energy, feeling or state of intense excitement and happiness, sleepiness
- flatulence or wind, diarrhoea, nausea, vomiting, dryness of mouth nose or throat and loss of appetite, constipation.

Less frequent side effects:

- various blood disorders which can only be detected by means of testing of the blood, such as neutropenia (low white blood cell count), reduction in platelets (which are important for blood clotting), bleeding into the tissues, bruising, and slow blood clotting after injury

(thrombocytopenia), anaemia (low red blood cell count), pancytopenia (bone marrow disorder)

- hypoglycaemia (abnormally low level of glucose in your blood)
- tremor
- blurred vision or double vision
- oedema (build-up of fluid in the body's tissue, a type of swelling)
- ringing or buzzing in the ears
- stomach pain, bleeding
- thickening of mucous
- reduced bile and liver function
- redness, peeling and blistering skin disorder, skin rash
- clumsiness, fatigue and swelling of legs, feet or hands
- severe, unexpected reaction to a medicine, which affects several organ systems at the same time
- mucous membrane and skin disorder
- skin reaction characterised by pustules, swelling under the skin, dry itchy skin, hives
- swelling of lymph nodes
- a general feeling of discomfort, illness, or unease, sedation
- overdose and poisoning.

The following side effects have been reported but the frequency for them to occur is not known:

- itchy, dry skin or a rash on swollen, reddened skin (dermatitis)
- depression
- tingling sensation (pins and needles)
- dryness of the respiratory passages
- pain in the upper abdomen, acid reflux
- sensitivity to sunlight, hair loss, sweating, fever with or without chills

- muscle cramps, muscle spasm, muscle pain
- increase in urination frequency
- red blood cell blood disorder (haemolysis)
- ringing or buzzing in the ears
- low 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. 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.

By reporting side effects, you can help provide more information on the safety of EFFERFLU C COLD & FLU. You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

5. How to store EFFERFLU C COLD & FLU

Store all medicines out of reach of children.

Store at or below 25 ºC in a dry place. Keep the tube tightly closed.

Do not use after the expiry date stated on the carton.

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 EFFERFLU C COLD & FLU contains

The active ingredients in each effervescent tablet are paracetamol 500 mg, sodium ascorbate equivalent to vitamin C 250 mg and chlorphenamine maleate 2 mg.

The other ingredients are

Anhydrous citric acid, aspartame, lemon flavour, orange flavour, povidone, simethicone, sodium carbonate anhydrous, sodium hydrogen carbonate and sorbitol.

EFFERFLU C COLD & FLU contains 212 mg of the sugar alcohol, sorbitol, per tablet.

EFFERFLU C COLD & FLU contains aspartame 40 mg.

What EFFERFLU C COLD & FLU looks like and contents of the pack

EFFERFLU C COLD & FLU is a white or almost white, round, flat tablet. It produces a slightly opalescent, colourless solution with a citrus flavour once dissolved in a glass of water.

EFFERFLU C COLD & FLU is available in white polypropylene tubes closed with a low-density polyethylene cap. Each tube contains 10, 12 or 20 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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