

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

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EFFERFLU C COLD & FLU Effervescent tablets

Paracetamol, Chlorphenamine maleate and Ascorbic acid as Vitamin C

EFFERFLU C COLD AND FLU contains 21,10 mg sorbitol 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 mild illness associated with colds and flus.

- Keep this leaflet. You may need to read it again.
- Do not share EFFERFLU C COLD & FLU 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 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
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1. What EFFERFLU C COLD & FLU is and what it is used for

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 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 are pregnant or breastfeeding, as safety and efficacy have not been established



Warnings and precautions

Take special care with EFFERFLU C COLD & FLU:

- 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) or porphyria.
- if you have hyper mental and physical excitability which deviates from normal.
- 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 AND FLU should be discontinued.

- 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.
- 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 overdose. In the event of overdose 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 health care 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).

Paracetamol:



- If you are currently taking any medicine which is poisonous to the liver, 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.

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 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.

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).



Pregnancy, breastfeeding 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 health care provider for advice before taking this medicine.

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 drowsy 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.

Patients with rare hereditary problems of fructose intolerance should not take this medicine.

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 overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. Take this leaflet and any remaining tablets with you, so that the doctor knows what you have taken.

Symptoms of overdose may include:

- 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 taking EFFERFLU C COLD & FLU, please consult your health care provider for advice.

If any of the following happens, stop taking 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
- hives, itching, skin rash

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:



- 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)

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
- 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)
- dizziness, increased sweating, tremor, nervousness, sleeplessness or headache, physical or mental weariness; lack of energy, feeling or state of intense excitement and happiness
- blurred vision or double vision
- ringing or buzzing in the ears
- 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 of lymph nodes



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)

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 “**6.04 Adverse Drug 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 EFFERFLU C COLD & FLU.



5. How to store EFFERFLU C COLD & FLU

Store all medicines out of reach of children.

Store at or below 25 °C 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 21,10 mg of the sugar alcohol, sorbitol, per tablet.

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.



Holder of Certificate of Registration

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This leaflet was last revised in

04 June 2024

Registration number

RSA S2 A39/5.8/0451

NAM NS1 07/5.8/0167

BOT S3 BOT1302449

