

**PATIENT INFORMATION LEAFLET
EFFERFLU-C COLD & FLU**

SCHEDULING STATUS:

Ⓢ2

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

EFFERFLU-C COLD & FLU effervescent tablets.

Please read this leaflet carefully before taking **EFFERFLU-C COLD & FLU** effervescent tablets because it contains important information for you. This medicine is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use **EFFERFLU-C COLD & FLU** effervescent tablets carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share **EFFERFLU-C COLD & FLU** with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 10 days.

1. WHAT EFFERFLU-C COLD & FLU CONTAINS:**Active ingredients:**

Chlorphenamine maleate	2 mg
Paracetamol	500 mg
Sodium ascorbate equivalent to Vitamin C	250 mg

Inactive ingredients:

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

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

2. WHAT EFFERFLU-C COLD & FLU 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.

**PATIENT INFORMATION LEAFLET
EFFERFLU-C COLD & FLU**

3. 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 any of the other ingredients (See “**WHAT EFFERFLU-C COLD & FLU CONTAINS**”).
- If you have severe liver disease.
- If you suffer from epilepsy.
- Do not use **EFFERFLU-C COLD & FLU** in children under the age of 12 years.

Take special care with EFFERFLU-C COLD & FLU:

- Take **EFFERFLU-C COLD & FLU** exactly as this leaflet instructs you to.
- Do not increase the dosage.
- Take special care if you have liver or kidney problems. Too much of this medicine may cause severe liver damage.
- Take special care if you suffer from alcohol dependence.
- 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 10 days without consulting your doctor.

Take special care if you are suffering from:

- an enlargement of the prostate as it may cause problems when urinating.
- narrow angle glaucoma
- emphysema or chronic bronchitis
- porphyria
- hyper mental and physical excitability which deviates from normal
- may enhance the symptoms of nervousness and the inability to sleep in elderly people and children.
- may increase the symptoms in the elderly people which are especially susceptible to dry mouth, urinary retention, sedation dizziness, confusion and low blood pressure.

PATIENT INFORMATION LEAFLET
EFFERFLU-C COLD & FLU

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.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

Driving and using machinery:

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.

Important information of some of the ingredients of EFFERFLU-C COLD & FLU:

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

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

Using other medicines with EFFERFLU-C COLD & FLU:

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

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.

PATIENT INFORMATION LEAFLET
EFFERFLU-C COLD & FLU

- Simultaneous use of enzyme inducing medicines (examples are anti-epileptics, oral contraceptives and rifampin) with **EFFERFLU-C COLD & FLU** may increase the risk of liver unhealthiness and a possible decrease in 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), and antipsychotics (used to increase mental health).
- Simultaneous use of MAO inhibitors (medicines used for mental disorders) **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

PATIENT INFORMATION LEAFLET EFFERFLU-C COLD & FLU

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 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).

4. HOW TO USE EFFERFLU-C COLD & FLU:

DO NOT EXCEED THE RECOMMENDED DOSE.

- Always use **EFFERFLU-C COLD & FLU** exactly as this leaflet instructs you to.
- You should check with your pharmacist if you are unsure.
- 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.
- Do not use **EFFERFLU-C COLD & FLU** continuously for more than 10 days without consulting your doctor.

Use in children:

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

If you use more **EFFERFLU-C COLD & FLU** than you should:

Prompt treatment is essential.

PATIENT INFORMATION LEAFLET EFFERFLU-C COLD & FLU

In event of overdosage, 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.

In the event of overdosage, you may experience the following:

- 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 use EFFERFLU-C COLD & FLU:

- If you miss a dose of **EFFERFLU-C COLD & FLU**, take it as soon as you remember.
- Do not take two doses together.
- If it is almost time for your next dose, wait until then.

5. 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 doctor, pharmacist or other healthcare professional for advice.

**PATIENT INFORMATION LEAFLET
EFFERFLU-C COLD & FLU**

If any of the following happens, stop taking EFFERFLU-C COLD & FLU and tell your doctor or go to the casualty at your nearest hospital:

- swelling of the hands, feet ankles, face, lips mouth or throat, which may cause difficulty in swallowing or breathing.
- fainting.
- hives, itching, skin rash.
- yellow eyes or skin, also called jaundice.

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 hospitalization.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- chest pain
- angina
- change in the way your heart beats, for example, if you notice it beating faster,
- difficulty in breathing
- signs of recurrent infections such as fever or sore throats
- change in urine colour or decrease in amount of urine or difficulty in passing urine, colic of the kidneys, failure of kidney function,
- Ulcers or white spots on lips or in mouth.
- Serious blood disorders

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

If you experience the following side effects, continue the medication and consult your doctor only if they continue or are bothersome:

- stomach pains, severe or sharp pain in lower back and/or side or abdomen
- flatulence or wind, diarrhoea, nausea, vomiting, dryness of mouth nose or throat and loss of appetite

**PATIENT INFORMATION LEAFLET
EFFERFLU-C COLD & FLU**

- dizziness, drowsiness, increased sweating, convulsions or seizures, tremor, nervousness, sleeplessness or headache
- blurred vision or double vision
- unusual tiredness or weakness
- light-headedness
- dry cough
- muscle cramps
- fever with or without chills.
- Hair loss and sweating
- Reduced bile and liver function.
- Clumsiness, fatigue and swelling of legs, feet or hands.
- Various blood disorders which can only be detected by means of testing of the blood
- Depression
- Kidney stones

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

6. STORING AND DISPOSING OF EFFERFLU-C COLD & FLU

- Store your tablets in the pack that they came in
- Do not put it in another container
- Store the tablets at or below 25 °C
- Store the tablets in a dry place and keep the tube tightly closed
- The EXPIRY date is marked on the pack. Do not use the tablets after the expiry date has elapsed
- Return all unused medicines to your pharmacist
- Do not dispose of unused medicines in drains and sewerage systems (e.g. toilets)
- **STORE ALL MEDICINES OUT OF REACH OF CHILDREN**