PATIENT INFORMATION LEAFLET for PARAGRIP C

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S2

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

PARAGRIP C effervescent tablets

Read all of this leaflet carefully before you start taking PARAGRIP C for you.

PARAGRIP C is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless you still need to use **PARAGRIP C** carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share **PARAGRIP C** with any other person.
- Ask you 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 PARAGRIP C CONTAINS

The active substances are paracetamol, sodium ascorbate equivalent to Vitamin C and chlorphenamine maleate.

Each effervescent tablet contains 2 mg Chlorphenamine maleate, 500 mg Paracetamol and 250 mg Sodium ascorbate equivalent to Vitamin C.

The other ingredients are anhydrous citric acid, aspartame, lemon flavour, orange and flavour, povidone, simethicone, sodium carbonate anhydrous, sodium hydrogen carbonate and sorbitol.

PARAGRIP C contains the sugar alcohol, sorbitol.

2. WHAT PARAGRIP C IS USED FOR

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

3. BEFORE YOU TAKE PARAGRIP C

Do not take PARAGRIP C:

- If you are hypersensitive (allergic) to paracetamol, Vitamin C, chlorphenamine maleate or any of the other ingredients (See **WHAT PARAGRIP C CONTAINS**).
- If you have severe liver disease.
- If you suffer from epilepsy.
- Do not use **PARAGRIP C** in children under the age of 12 years.
- Pregnancy and lactation (see **PREGNANCY AND LACTATION**)

Take special care with PARAGRIP C:

- Take **PARAGRIP C** 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 **PARAGRIP C** continuously for more than 10 days without consulting your doctor.
- If you are suffering from an enlargement of the prostate as it may cause problems when urinating.
- If you are suffering from narrow angle glaucoma.
- If you are suffering from emphysema or chronic bronchitis.

- If you are suffering from porphyria.
- If you are suffering from hyper mental and physical excitability which deviates from normal.
- As symptoms of nervousness and the inability to sleep may be enhanced, especially in elderly patients and children.
- As symptoms of susceptible to dry mouth, urinary retention, sedation dizziness, confusion and low blood pressure are especially increased in elderly patients.

PARAGRIP C 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.

Pregnancy and breastfeeding:

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

Driving and using machinery:

PARAGRIP C may make you drowsy and impair your concentration. If you start treatment with **PARAGRIP C**, 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 PARAGRIP C:

PARAGRIP C contains the sugar alcohol, sorbitol.

Patients with rare hereditary problems of fructose intolerance should not take **PARAGRIP C**.

Using other medicines with PARAGRIP C:

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

Paracetamol

- If you are currently taking any medicine which is poisonous to the Liver (such as isoniazid), then the simultaneous use of **PARAGRIP C** will increase the poisoning of your liver.
- Simultaneous use of enzyme inducing medicines (examples are anti-epileptics, oral contraceptives and rifampin) with **PARAGRIP C** may increase the risk of liver unhealthiness and a possible decrease in healing effects of **PARAGRIP C.**
- 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 **PARAGRIP C.**
- Cholestyramine (used for removing bile acid from the body) – absorption of **PARAGRIP C** is reduced if given within one hour of cholestyramine.
- Prolonged concurrent use of **PARAGRIP C** with salicylates (aspirin) increases the risk of adverse kidney problems.
- The simultaneous use of probenecid (Proben) might cause an overdose of the **PARAGRIP C**.

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) **PARAGRIP C** 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), monoamine oxidase inhibitors (used for mental disorder), 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 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 PARAGRIP C

Always take **PARAGRIP C** exactly as this leaflet instructs you to.

You should check with your doctor or 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 **PARAGRIP C** 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 PARAGRIP C than you should:

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

Prompt treatment is essential.

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, fever.
- 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 PARAGRIP C:

If you miss a dose of **PARAGRIP C**, 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

PARAGRIP C can have side effects. Not all side effects reported for **PARAGRIP C** are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking **PARAGRIP C**, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking PARAGRIP C and tell your doctor immediately 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 of 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 **PARAGRIP C.** 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.

Tell your doctor if you notice the following:

- 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.
- 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 cramp
- 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 PARAGRIP C

- 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.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date stated on the tube.
- Return all unused medicines to your pharmacist.

- Do not dispose of unused medicines in drains and sewerage systems (e.g. toilets).

7. PRESENTATION OF PARAGRIP C

PARAGRIP C is available in white polypropylene tubes closed with a low-density polyethylene cap. Each tube contains 10 or 12 tablets.

8. IDENTIFICATION OF PARAGRIP C

PARAGRIP C 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.

9. REGISTRATION NUMBER

A39/5.8/0450

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Unicorn Pharmaceuticals (Pty) Ltd
Corner of Searle and Pontac Street
Cape Town
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