1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

PROPRIETARY NAME AND DOSAGE FORM

RINEX DIFFUCAPS (capsule)

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

RINEX DIFFUCAPS is available without a doctor's prescription, for you to treat a mild illness. Nevertheless you still need to use RINEX DIFFUCAPS carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share RINEX DIFFUCAPS 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 5 to 7 days.

WHAT RINEX DIFFUCAPS CONTAINS

The active substances are:

Each RINEX DIFFUCAPS capsule contains:

Chlorphenamine maleate	12 mg
Phenylpropanolamine hydrochloride	30 mg
Phenylephrine hydrochloride	20 mg

The other ingredients are:

Colour FD & C Blue No. 2 (C.I. No. 73015), erythrosine (C.I. No. 45430), gelatin, lactose monohydrate, maize starch, povidone, shellac, stearic acid, sucrose, sunset yellow (C.I. No 15985), talc.

Contains sugar: Sucrose 159,15 mg, lactose monohydrate 6,00 mg

WHAT RINEX DIFFUCAPS IS USED FOR

RINEX DIFFUCAPS is used for

- The symptomatic relief of blocked nose due to the common cold and flu, hay fever (inflammation of the nasal passages), allergic rhinitis (inflammation of the nasal passages), other allergies affecting the nasal passages and the throat, or associated with sinusitis (inflammation of the sinuses).
- Relief of Eustachian tube (tube that runs from the middle ear to the nasal passages and throat) congestion as an adjunct to treatment of middle ear infection.

BEFORE YOU TAKE RINEX DIFFUCAPS

Do not take RINEX DIFFUCAPS

- If you are allergic (hypersensitive) to any of the ingredients contained in RINEX DIFFUCAPS (see WHAT RINEX DIFFUCAPS CONTAINS).
- RINEX DIFFUCAPS should not be given during acute attacks of asthma.
- If you are on treatment with a monoamine oxidase inhibitor for depression, or within two weeks of stopping treatment with the monoamine oxidase inhibitor.
- If you are pregnant or breastfeeding, as safety has not been established. Phenylephrine hydrochloride, one of the active ingredients in RINEX DIFFUCAPS, is best avoided in pregnancy, because it may cause contraction of the uterus and constriction of blood vessels, with the possibility of decreasing oxygen supply to the foetus.

- If you suffer with hypertension (high blood pressure), hyperthyroidism (overactive thyroid gland) or cardiovascular disease, such as ischaemic heart disease (less oxygen supply to the heart).
- RINEX DIFFUCAPS must not be used in children under twelve years of age.

Take special care with RINEX DIFFUCAPS

- RINEX DIFFUCAPS should not be taken for more than seven days. After 5 to 7 days, tolerance may occur and the product loses effect. If symptoms do not improve, or are accompanied by fever, consult a doctor.
- Exceeding the recommended dosage may result in nervousness, dizziness, sleeplessness, tremulousness or cardiac dysrhythmia (irregular heartbeat).
- If you have any of the following conditions:
  - Occlusive vascular disease including arteriosclerosis (hardening of the arteries) and aneurysms (abnormal widening of a portion of a blood vessel).
  - Closed-angle glaucoma (increased pressure in the eye).
  - Phaechromocytoma (a tumour of the adrenal gland).
- RINEX DIFFUCAPS may cause severely high blood pressure which may lead to intracranial haemorrhage (bleeding in the brain).
- If you exceed the recommended dose; as an increased risk of serious adverse events such as hypertensive crisis and haemorrhagic stroke have been associated with higher than normal doses.
- If you have cardiovascular disease, hypertension or hyperthyroidism (see Do not take RINEX DIFFUCAPS).
- If you have diabetes, glaucoma or prostatic enlargement as RINEX DIFFUCAPS may aggravate such conditions.
- If you have angina pectoris (severe chest pain due to a lack of oxygen supply), as

RINEX DIFFUCAPS may cause angina pain (chest pain).

Taking RINEX DIFFUCAPS with food and drink

RINEX DIFFUCAPS may be taken with or without food and drink.

Pregnancy and breastfeeding

Do not use RINEX DIFFUCAPS if you are pregnant or breastfeeding.

Phenylephrine hydrochloride, one of the actives ingredients in RINEX DIFFUCAPS, is best avoided in pregnancy, because it may cause contraction of the uterus and constriction of blood vessels, with the possibility of decreasing oxygen supply to the foetus.
Always tell your healthcare provider if you are taking any other medicine. If you are pregnant or breastfeeding your baby, please consult your healthcare provider for advice before taking RINEX DIFFUCAPS.

Driving and using machinery

RINEX DIFFUCAPS may lead to drowsiness and impaired concentration, which may be aggravated by the simultaneous intake of alcohol or other central nervous system depressants. Do not drive vehicles, climb dangerous heights or operate dangerous machinery, as impaired decision making could lead to accidents.

Important information about some of the ingredients in RINEX DIFFUCAPS

RINEX DIFFUCAPS contains lactose and sucrose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance

should not take RINEX DIFFUCAPS. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking RINEX DIFFUCAPS.

Taking other medicines with RINEX DIFFUCAPS

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

The use of RINEX DIFFUCAPS together with the following medicines may cause undesirable effects:

- RINEX DIFFUCAPS taken together with cardiac glycosides, quinidine or tricyclic antidepressants may cause an increased risk of dysrhythmias.
- Take special care if you are on antihypertensive therapy as RINEX DIFFUCAPS may reverse the action of antihypertensive medication.
- Interactions are possible with reserpine, tricyclic antidepressants, digoxin and alpha-methyldopa.
- RINEX DIFFUCAPS may cause an abnormal heart rhythm in patients undergoing anaesthesia with halothane, or other halogenated anaesthetics.

HOW TO TAKE RINEX DIFFUCAPS

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

Always take RINEX DIFFUCAPS exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Dosage:

DO NOT EXCEED THE RECOMMENDED DOSE.

Adults and children 12 years and older: One capsule every 8 to 12 hours.

Do not chew the capsule or the content.

If you have the impression that the effect of RINEX DIFFUCAPS is too strong or too weak, talk to your doctor or pharmacist.

If you take more RINEX DIFFUCAPS 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.

If you forget to take RINEX DIFFUCAPS

If you miss a dose. Take the dose as soon as you remember, but do not take your next dose at the same time. Then go on as before. Do not take a double dose to make up for forgotten individual doses.

POSSIBLE SIDE EFFECTS

RINEX DIFFUCAPS can have side effects.

Not all side effects reported for RINEX DIFFUCAPS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking RINEX DIFFUCAPS, please consult your healthcare provider for advice.

If any of the following happens, stop taking RINEX DIFFUCAPS and tell your doctor immediately or go to the casualty department at your nearest hospital:

- An allergic reaction: swelling of the face, lips, tongue or throat, skin reactions such as an

itchy skin rash or skin that is red, flaky or peeling,

- narrowing of the airways causing difficulty breathing or swallowing.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to RINEX DIFFUCAPS. 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:

- Liver problems including yellowing of the skin or whites of the eyes (jaundice),
- palpitation, irregular or racing heartbeat.

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

Tell your doctor if you notice any of the following:

- Sedation ranging from slight drowsiness to deep sleep, inability to concentrate, unusual tiredness or weakness, blurred vision, headaches, dizziness, incoordination, ringing or buzzing in the ears, irritability, nightmares, excitement (especially in children), confusion (especially in the elderly),
- stomach or intestine disturbances such as feeling or being sick or diarrhoea, dry mouth, stomach pain, indigestion, loss of appetite,
- difficulty in passing water,
- low blood pressure,
- tight chest, thickening of phlegm,
- changes in the number and types of your blood cells. If you notice increased bruising, nosebleeds, sore throats, infections, excessive tiredness, breathlessness on exertion or abnormal paleness of the skin, you should tell your doctor who may want you to have a

blood test,

- twitching, muscular weakness,
- sensitivity to sunlight or artificial light (e.g. sun beds).

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

STORING AND DISPOSING OF RINEX DIFFUCAPS

Store at or below 25 °C, in a well-closed container.

Protect from light.

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).

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

PRESENTATION OF RINEX DIFFUCAPS

10 capsules are packed into clear, transparent, PVC blister strips with an aluminium backing.

The blister strips are packed into an outer cardboard carton with a leaflet.

IDENTIFICATION OF RINEX DIFFUCAPS

Transparent, hard gelatin capsule, with a clear body and orange cap containing blue and white pellets.

REGISTRATION NUMBER

N/5.8/67

NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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