SCHEDULING STATUS: S2

PROPRIETARY NAMES, STRENGTHS AND PHARMACEUTICAL FORMS:

CINDRID 25 (tablets)

CINDRID 75 (capsules)

Read all of this leaflet carefully before you start taking CINDRID.

- Keep this leaflet. You may need to read it again.
- Do not share CINDRID with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if you need more information and advice.

1. WHAT CINDRID CONTAINS:

The active substance is cinnarizine.

Each Cindrid 25 tablet contains 25 mg cinnarizine.

Each Cindrid 75 capsule contains 75 mg cinnarizine.

The other ingredients are:

Each Cindrid 25 tablet contains: Aerosil (colloidal silicon dioxide), erythrosine aluminium lake, explotab (sodium starch glycolate), hydroxypropyl methylcellulose 2910 5cPs, indigo carmine aluminium lake (FD&C blue No. 2), lactose 200 mesh, magnesium stearate, maize starch, polyethylene glycol 400, purified talc, starch 1500, sucrose, sunset yellow FCF aluminium lake (FD&C yellow No. 6), titanium dioxide.

Each Cindrid 75 capsule contains: Erythrosin (CI 45430), explotab (sodium starch glycolate), gelatine, lactose DC, magnesium stearate, maize starch, sunset yellow FCF (CI 15985), talc, titanium dioxide (CI 77891), yellow iron oxide (CI 77492).

Each Cindrid 25 tablet contains sugar (lactose 81,00 mg and sucrose 19,00 mg).

Each Cindrid 75 capsule contains sugar (lactose 125,00 mg).

2. WHAT CINDRID IS USED FOR:

CINDRID is an antihistamine which is used:

- In the treatment of nausea and dizziness due to Ménière's disease and other disturbances of the middle ear.
- For the prevention and treatment of motion sickness (feeling sick when travelling by car, boat or aeroplane).

3. BEFORE YOU TAKE CINDRID:

Do not take CINDRID:

- If you are hypersensitive (allergic) to cinnarizine or any of the other ingredients in CINDRID.
- If you have porphyria (a hereditary blood disorder).
- If you have Parkinson's Disease.
- If you are pregnant or breastfeeding.

Take special care with CINDRID:

- If you suffer from liver or kidney problems.
- If you are elderly and affected by other antihistamines which usually cause fatigue and low blood pressure.
- CINDRID could affect your reaction to skin tests used to investigate allergies. If you have taken CINDRID within 4 days before a test, tell your doctor.

You may still be able to take CINDRID, but you should discuss this with your doctor first.

Taking CINDRID with food and drink:

The combined effect of CINDRID and alcohol may make you feel drowsy, therefore avoid alcohol while taking this medicine.

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.

CINDRID should not be used during pregnancy and breastfeeding.

Driving and using machinery:

CINDRID can make you feel drowsy. If this happens, do not drive or use any tools or machines.

Important information about some of the ingredients of CINDRID:

CINDRID 25 and 75 contains lactose. Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance should not take CINDRID.

CINDRID 25 contains sucrose. Patients with rare hereditary conditions such as fructose intolerance, glucose-galactose mal-absorption or sucrase-isomaltase insufficiency should not take CINDRID 25.

Lactose and sucrose may have an effect on the control of your blood sugar if you have diabetes mellitus.

Taking other medicines with CINDRID:

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

In particular tell your doctor or pharmacist if you are taking medicines to treat:

- Anxiety.

- Relax muscles.
- Mood or sleep disorders.
- Pain.
- Depression.

CINDRID could affect your reaction to skin tests used to investigate allergies. If you have taken CINDRID within 4 days before a test, tell your doctor.

4. HOW TO TAKE CINDRID:

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

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

The tablets and capsules should be swallowed whole with a glass of water.

The usual dose is one CINDRID 25 tablet three times a day orally for adults.

The dose can be increased to three CINDRID 25 tablets or one CINDRID 75 capsule three times a day orally.

For the prevention of motion sickness in adults the dose is one CINDRID 25 tablet orally one hour before departure followed by one CINDRID 25 orally tablet every 6 - 8 hours.

If you take more CINDRID 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.

Stop taking CINDRID at signs and symptoms of an overdose. These can be: changes in consciousness ranging from sleepiness to drowsiness and coma, vomiting, movement disorders, dry mouth, flushed face, and muscle weakness. Fits can occur in young children.

In adults, symptoms of drowsiness, coma, fits leading to respiratory failure and heart problems can occur.

If you forget to take CINDRID:

If you missed a dose, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose and continue to take the tablet at the usual time. Do not take a double dose to make up for the forgotten individual doses.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

5. POSSIBLE SIDE EFFECTS:

CINDRID can have side effects.

Not all side effects reported for CINDRID are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

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

- Swelling of your face, lips, mouth, tongue, eyes or throat (angioedema).
- Difficulty breathing, dizziness (severe hypersensitivity).
- Severe skin rash, blistering, itching or peeling of the skin.
- Dizziness or fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to CINDRID. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following side effects that have been reported frequently:

- Drowsiness.
- Increased weight.
- Nausea (feeling sick).
- Indigestion.

Tell your doctor if you notice any of the following side effects that have been reported less frequently:

- Lack of energy, tiredness.
- Vomiting (being sick).
- Stomach pain.
- Excessive sweating.
- Skin rash with patches of spots, red or pinkish skin sometimes with mouth sores.
- Headache.
- Dry mouth.

Tell your doctor if you notice any of the following side effects that have been reported where the frequency is not known:

- Movement disorders including trembling and shaking of the hands and fingers, uncontrollable twitching or twisting movements or restless legs.
- Yellowing of the skin and eyes, also called jaundice.
- Muscle stiffness.

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

6. STORING AND DISPOSING OF CINDRID:

- **STORE ALL MEDICINES OUT OF REACH OF CHILDREN.**

- Store at or below 25 °C. Protect from light.
- Do not use after the expiry date printed on the label or carton.
- Return all unused medicine to your pharmacist.

7. PRESENTATION OF CINDRID:

Cindrid 25: Amber glass bottles and securitainers of 100, 250 or 500 tablets and blister strips tristar foil for multiple-unit packs and aluminium laminated foil of 10, 100, 250 or 500 tablets.

Cindrid 75: Securitainers of 30 and 100 and amber glass bottles of 10 capsules in 50 mℓ bottles and 100 capsules in 100 mℓ bottles.

Blister strips: PVC, Tristar foil and aluminium laminated foil of 30, 60,100 or 500 capsules.

Not all pack sizes may be marketed.

8. IDENTIFICATION OF CINDRID:

Cindrid 25: Round, flat, pale orange topink, slightly mottled tablet with bevel-edges and a score on one side.

Cindrid 75: Opaque yellow body/orange cap, size 2 capsule containing white powder.

9. REGISTRATION NUMBERS:

Cindrid 25: U/5.7.2/8

Cindrid 75: U/5.7.2/9

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

Sandoz (Pty) Ltd[1]

Waterfall 5-Ir

Magwa Crescent West

Waterfall City

Jukskei View

2090

11. DATE OF PUBLICATION:

Date of registration: 08 March 1988

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[1] Company Reg No: 1990/001979/07