

Back

the administration and there was no evidence of the accumulation. The pharmacokinetics of Cilindipine have also been evaluated in patients with impaired renal function (serum creatinine: 1.5-3.1 mg/dL) following a single oral dose of 10 mg in the hypertensive patients and no significant differences were found in the pharmacokinetic profile of Cilindipine compared with that in patients with normal renal function. Repeated oral administration of Cilindipine at a dose of 10 mg once a day for 7 days in patients with impaired renal function caused no differences in the pharmacokinetic profile compared with that in patients with normal renal function.

Metabolism and Excretion: From the metabolites identified in the plasma and urine of healthy male volunteers, it is considered that the major route of cilindipine metabolism is demethylation of the methoxyethyl group followed by hydrolysis of the cinnaril ester and oxidation of the dihydropyridine ring. It is considered that CYP3A4 is mainly involved and CYP3C19 is partly involved in the demethylation of the methoxyethyl group. In vitro, the calcium channel blocking action of the metabolite with the demethylated methoxyethyl group was only 1/100 of that of the parent compound (in rabbits). When a single oral dose of cilindipine 10 mg was repeatedly administered to healthy male volunteers once a day for 7 days, no unchanged compound of cilindipine but 5.7% of the dose was excreted in the urine as metabolites. (The approved administration of Cilindipine is orally once a day after breakfast.) An in vitro experiment showed that cilindipine was 95.3% bound to human serum protein.

PRECLINICAL SAFETY DATA

There is no information on Cilindipine. However, high doses of other calcium channel blockers have been tolerated in rats and dogs without toxic effects. Preclinical data, in other calcium channel blockers, based on studies in the rat and dog, revealed special hazards for humans for teratogenicity or embryotoxicity.

PHARMACEUTICAL PARTICULARS

Incompatibilities: Nil specific data

Special precautions for storage: Not Applicable

Storage Condition: Store below 30°C.

Shelf life: 2 years.

Nature and contents of container

10 tablets in Al₂O₃ blister pack, 3 such blisters in a printed carton along with leaflet.

| MANUFACTURING AUTHORITY | HOLDER AND MANUFACTURER |
|---|---|
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VERISON N-00

LAST REVISION DATE: June, 2021

CINOD

CILINDIPINE TABLETS

PATIENT INFORMATION LEAFLET

Read all of the leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

Distribution Category: Prescription Only Medicine or POM

What is this leaflet for?

1. What Cinod Tablets are and what they are used for
2. What you need to know before you take Cinod Tablets
3. How to take Cinod Tablets
4. Possible side effects
5. How to store Cinod Tablets

1. What Cinod is and what it is used for

Cinod Tablets contains the active substance cilindipine, which belongs to a group of medicines called calcium antagonists. This medicine blocks the calcium channel to suppress inflow of calcium into cells, leading to expansion of blood vessels and decrease in blood pressure. It also reduces the release of noradrenaline from sympathetic nerve terminals, leading to suppression of increased heart rate.

It is usually used to treat high blood pressure (hypertension).

2. What you need to know before you take Cinod Tablets

Do not take Cinod Tablets if:

- You have ever had an allergic reaction to cilindipine or any of the ingredients in the tablet, or to any other calcium antagonists. An allergic reaction may include a rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue;
- You have very low blood pressure (hypotension) so that you feel faint or dizzy;
- You have cardiac shock (a condition where your heart cannot pump enough blood for your body's needs);
- You have heart failure due to a heart attack;
- You have narrowing of the heart valve of the aorta (aortic stenosis);
- If you are pregnant or breastfeeding;
- If you are taking any other medicinal products. (Some medicines may interact to enhance or diminish medicinal effects. Review of over-the-counter medicines and dietary supplements as well as other prescription medicines.)

Warnings & Precautions

Talk to your doctor before taking Cinod Tablets

You should inform your doctor if you have or have had any of the following conditions:

- Liver disease;
- You are elderly and your dose needs to be increased;
- Recent heart attack;
- Heart failure;

Use in children and adolescents:

Cinod Tablets are not recommended for use in children and adolescents below 18 years of age, because there are only limited data on the safety and efficacy in this population.

Taking other medicines and Cilindipine

Please tell your doctor or pharmacist if you are taking or have recently taken other medicines, including medicines obtained without a prescription.

Cilindipine may affect or be affected by other medicines, such as:

- nitroglycerine, isosorbazide (anti-anginal medicines used to treat chest pain, angina pectoris)
- nitroglycerin, nitroglycerin (antidotes used in treatment of HIV infections)
- rifampicin, erythromycin, clarithromycin (antibiotics)
- cimetidine (H2 antagonist)

Cilindipine may lower your blood pressure even more if you are already taking other medicines to treat your high blood pressure. If you see another doctor or go into hospital for any reason, tell them that you are taking Cilindipine Tablets.

Taking Cilindipine Tablets with food and drink

You should not drink grapefruit juice or eat grapefruit while taking this medicine. Grapefruit and grapefruit juice can lead to an increase in the blood levels of Cilindipine, which can cause an unpredictable increase in its blood pressure lowering effect.

Pregnancy

The safety of Cilindipine in human pregnancy has not been established. If you think you might be pregnant, or are planning to get pregnant, you must tell your doctor before you take Cilindipine Tablets.

Breast-feeding

It is not known whether Cilindipine is passed into breast milk. If you are breastfeeding or about to start breastfeeding you must tell your doctor before taking Cilindipine Tablets.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Taking Cilindipine Tablets may affect your ability to drive or use machinery because Cilindipine could cause side effects such as dizziness, lightheadedness, nausea or tiredness, all of which could affect your ability to concentrate.

3. How to use CINOD

Swallow these tablets with a glass of water at the same time each day. Follow your doctor's instructions. Check the pharmacy label to see how many tablets to take and when to take them. If you are still not sure, ask your pharmacist or doctor. The usual doses are described below.

Adults

Take 5 to 10 mg of the active ingredient at a time, once a day after breakfast. Your doctor may increase the dose to one 20mg tablet once a day. However, the dosage may be adjusted according to the age or symptoms. If its effect is insufficient

Elderly

As for adults (one 5mg tablet a day), Your doctor will closely monitor your response to any increase in the dose.

If you take more Cinod Tablets than you should

If you (or someone else) swallow a lot of tablets all together, or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately. Take your medication and the packaging with you to the doctor or casualty department. If you have taken an overdose, you may appear flushed (your skin will look red), or you may feel dizzy or faint. If blood pressure drops it seems enough shock can occur. Your skin could feel cool or clammy and you could lose consciousness.

If you forget to take Cinod Tablets

If you forget to take a tablet, take one as soon as you remember. If it is too close to the next one, skip the one you forgot to take together. Take the remaining doses at the correct time.

If you stop taking Cinod Tablets

Take this medicine for as long as your doctor tells you to, as you may become unwell if you stop.

4. Possible side effects

Like all medicines, cilindipine can cause side effects, although not everybody gets them.

The most commonly reported adverse reactions include headache, dull headache, dizziness on standing up, stiff shoulders, facial flushing, palpitation, sensation of heat, decreased blood pressure, nausea/vomiting, abdominal pain, rash, redness, itch, photosensitivity, edema (swelling), general malaise and frequent urination.

If any of these symptoms occur, consult with your doctor or pharmacist.

The symptoms described below are rarely seen as initial symptoms of the adverse reactions indicated in this leaflet.

If any of these symptoms occur, stop taking this medicine and see your doctor immediately.

- general malaise: loss of appetite, yellow discoloration of the skin and the whites of eyes (liver dysfunction, jaundice)
- nose bleeding, gum bleeding, subcutaneous bleeding in limbs (increased platelets)

The above symptoms do not describe all the adverse reactions to this medicine.

Consult with your doctor or pharmacist if you notice any symptoms of concern other than those listed above.

5. How to store CINOD

- Do not use the tablets after the end of the expiry month (see expiry date shown on the product packaging).
- Do not store the tablets above 30°C.
- Store in the original package.

KEEP THIS MEDICINE OUT OF THE SIGHT AND REACH OF CHILDREN

Medicines should not be disposed of with wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What CINOD contains:

Active substances are:

CINOD 5 (Cilindipine Tablets 5mg)

Each film-coated tablet contains:

Cilindipine 5.0mg

Excipients 9.5mg

Colour: Iron oxide red & Titanium dioxide

CINOD 10 (Cilindipine Tablets 10mg)

Each film-coated tablet contains:

Cilindipine 10.0mg

Excipients 9.5mg

Colour: Iron oxide red, Lake sunset yellow FCF & Titanium Dioxide

List of Excipients:

Cinod 5 (Cilindipine Tablets 5mg)

Hydroxypropyl Cellulose, Polyethylene Glycol, Iron Oxide SiO₂, Dicalcium Phosphate, Methanol, Magnesium Aluminium silicate, Lactose Monohydrate, Microcrystalline Cellulose, Croscarmellose Sodium, Hypromellose, Povidone, Talc, Magnesium Stearate, Indazole Salt (C-104) Orange (Hydroxy Propyl Methyl Cellulose, Hydroxypropyl Cellulose, Titanium Dioxide Lake Sunset Yellow, Isopropyl Alcohol).

What CINOD looks like and contents of the pack

Cinod 5 (Cilindipine Tablets 5mg)

Reddish brown colored, capsule-shaped, film-coated tablets debossed S/C10 on one side and plain on other side.

Cinod 10 (Cilindipine Tablets 10mg)

Light orange to orange colored, circular, biconvex, film-coated tablets with beveling on one side and plain on other side. 10 tablets in Al₂O₃ blister pack, 3 such blisters in a printed carton along with leaflet.

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For any information about this medicinal product, please contact the Manufacturing Authorisation Holder.

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