Front



CILNIDIPINE TABLETS

COMPOSITION
CINCO S(Clinidipine Tablets 5 mg)
Each If im coated tablet contains:
Clinidipine
Excipents
Colour: [ren oxide red & Titanium dioxide

CNOD 10(Clinidipine Tablets 10 mg)
Each film coated tablet contains:
Clinidipine
Excipients
Q.s.
Cobur: Iron oxide red, Lake sunset yellow FCF & Titanium
Dioxida

5.0mg q.s.

DOSAGE FORM: Film Coated Tablets

Print Comes taignes

DESCREPTOR:

Clandigines described 0.14(2-mithboyethyl), 0.9-((E)-Shenyl prop Zenyl [2, 8 dimethyl 4.4-(2-nittophenyl)1.4dibydoyyldnes-3.5-lacathoodise. 1.4-dibyto-2.6-dimethyl1.4dibydoyyldnes-3.5-dischoodise. 1.4-dibyto-2.6-dimethyl1.4dibydoyyldnes-3.5-dischoodise. 1.4-dibyto-2.6-dimethyl1.4dibydoyyldnes-3.5-dischoodise.
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Cincol 10 (Childighias Tablets 10mg)
Hydroxyncry (Cellables, Mediano), Hydroxyncry (Cellables, Mediano), Mayasaum Alamnometas Icata,
Dechtormarhum, Mediano), Mayasaum Alamnometas Icata,
Mediano, Mediano, Mediano, Mediano, Mediano, Mediano,
Croscarmellose Sodum, Hydrometase Pathelatin, Talc,
Magnesium Stansin, Hustaced St. (Cel-40140 Aznage (Host)
Prop Ji Netty) Cellabase Hydrometase. Pelyerhytere Gyrod, Talc,
Tharman Dzocki alea Zunder Viden. (Leponog Jelczoch)

CLINICAL PARTICULARS

NOTORIOUS EFFECTS OF EXCIPIENTS

NOTOROUS EFFECTS OF EXCHAENTS

Dichleromethane should be lented or pharmacountical products because of their inherent loansity. PDEs (Pormissiple Daily Exposure) are given to the sensette O. Ingidity, and Exposure) are given to the sensette O. Ingidity, and Dichleromethan-inhalmeted evidence of a corrisogenic effect.

Lacksone monitory letter & Avenier nections to better are talged, attributed to lactice interference, which occurs in individuals with a dictionary of the interference, which occurs in individuals with a dictionary of the interference in the control of the

take this medicine.² Isopropylational is about twice as toxic as athraical and should therefore not be administered orally isopropyl about of also has an unpleasant teste, Symptoms of isopropyl about of bodyl are similar to those for otherand coopyl that isopropyl about of has no initial suptrior action and gastriat writing are more prominent. Detail combally may be useful as

rapid screen test to identify patients at risk of complications from ingestion of isopropy electrol. The lethel and dose is estimated to be about 120–250 mL although toxic symptoms may be produced by 20 mL.

be about 100-200 m. albough box symptoms may be produced be the pramarcalism of south in proper placed may be used in small, also quantities in capsular of stablet manifoliating; That: Table is not become dispersional politication and is therefore regarded as an essentially norboxic makeful. Albough label. But been estimatedly interestiguide for list produced to the properties of the properties of the produced and in terrocalism forwards in the produced and produced and inconsulative. Nevere, the contensional with aboution to produce should have been albour the produced and produced produced and in pharmocautical production, Also, long-own tools offsets of bits contensional production, Also, long-own tools offsets of bits contensional production, and the production of the productio

POSOLOGY AND METHOD OF ADMINISTRATION
Adults: 5-10 mg once a day after breakfast. The dosage may be adjusted according to the patient's age and symptoms. The dose can be increased up to 20 mg once a day, if a sufficient response does not appear.

Severe Hypertension: 10-20 mg once a day for oral use after breakfast.

Administration: For oral use,

CONTRAINDICATIONS

CONTRAINDICATIONS

(Use in preparate) Vehicle in or to any of the exciplents of Cinod.

Use in preparate, Pregnant women or women having possibilities of being pregnant, Cinod should not be ediministered to pregnant women or women having possibilities of being pregnant, it has been reported that childrane predongs the gestation period and delivery similar named opportments (in risk).

SPECIAL WARNINGS AND PRECAUTIONS FOR USE

SPECIAL WARNINGS AND PRECAUTIONS FOR USE
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Patients with serious hepsite dysfunction, (the planta
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notices established (no direct experience).

Use in the elsely-Childipine should be administered carefully under close observation of the patient's condition, tabling such measures as starting with a lover dose (e.g., 5 mg); It is generally avoided in the elsely-Childipine should be accordant to the control of the starting should be accordant to the st

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION Clinidipne is, chiefly metabolized by the drug-metabolizing enzyme CYP2A4 and in part by CYP2C19.

Care to be taken with Combinion

Drugs having a hypotensive action	Blood pressure is likely to excessively decrease.	It has been considered to enhance the additive or synergistically.
Digoxin	increase the blood	Mechanism is not fully understood but is thought to be due to digoxin renal and extra-renal disarance is reduced.

discontinuation of Clinidipine, should be taken.

Other Adverse Reactions: If any of the following adverse reactions occur, appropriate measures should be taken depending on the symptoms.

Liver	AST (GOT), ALT (GPT), LDH, elevated, such as Al-P	
kidne y	Rise of creatinine urea nitrogen, urinary protein positive, urinary sediment positive	
Neur opsy chiatr ic	Headache, heaviness of the head, dizziness, lightheadedness, stiff neck, drowsiness, insomnia, hand tremors, forget things, numbness	
atory	Hot flushes, palpitations, hot flashes, abnormal decreased blood gressure, chest pain, increased decreased blood gressure, chest pain, increased cardiotheratic ratio, tachycardia, attroventricular block, cold sensation, premature contraction, bradycardia	
tive	Nausea, vomiting, abdominal pain, constipation, abdominal distension, dry mouth, gingival hyperplasia, heartburn, diarrhea	
Hype rsens itivity	Rash, redness, itching, photosensitivity disease	
blood	The number of white blood cells, neutrophils, hemoglobin, red blood cell count, hematocrit, eosinophils, fluctuation of lymphocyte	
Other	Edema (face, lower limbs, etc.), general malaise, trequent urination, etwards estum cholesterol, CK (CPK): uric acid-variation of serum K: serum P, weekness, musculus gastronemius spesificity, dry around the eyes, the eyes of hyperemia irritation, abnormal taste, urine sugar positive, change of feating blood glucose, total protein, serum Ca - CRP, cough, tilonius irritation, serum Ca - CRP, cough,	

expression mechanism of which is unclear, components contained in grapefruit juice is considered to inhibit the CYP344 in drug metabolism enzymes of this drug.

calcium antagor

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antagonists are thought to increase the clearance.

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Perspannery Utreast feedings Feetility
Use in pregnancy Pregnant income or excess in an image possibilities
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Azole antifungal agent this drug is likely to rise. Azole antifungal agent sepents litraconazole misconazole, etc.

Azole antifungal agent is considered to inhibit considered to inhibit misconazole, etc.

It has been confirmed that the blood concentration of this drug is increased.

were observed, such as discontinuing administration of the regulation or the drug the dose of digoxin depending on the condition and take appropriate measures

The action of the other calcium antagonists (nifedipine, etc.) is enhanced have been reported.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

The symptoms e.g., diaziness may occur because of the hypotensive action from Clinidipine. Give warning against engaging in hazardous activities requiring alertness e.g., working at a height, operating machinery or driving motor vehicles.

UNDESIRABLE EFFECTS

UNDESPARALE FFECTS
Adversa naccione, including abnormalities in bisioratory data, were observed in 414 (6,055); of 5,055 potities in the investigations at the time of approval and the post mandrell.
Climically Significant Adversa Reactions:
Hapaile: Ophirution and Jaundos accompanies with regular Cyphirution and Jaundos accompanies with regular Cyphirution and Jaundos accompanies with respect for the post of th

Overdosage of Clinidipine may cause excessive reduction in blood pressure. If reduction in blood pressure is remarkable, appropriate measures e.g., Ithing lower extremities, fluid therapy and administration of vasopressors should be taken.

and administration or vasopressors should be taken.

Hemodialytical removal of Chindipine is not effective because of its high rate of protein-binding.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic Properties Mechanism of Action

Mechanism of Action

Experimental Cales suggest that clinidiphies blinds to the dilydropinidre binding sizes of the L-lyap vallage dependent experiments and size of the L-lyap vallage dependent experiments of the cliniciphies considerated that the cliniciphies considerate model material exists with the change of the cliniciphies considered bine as hypothesis exists.

Chicatiphie in binding considerate that the considerate action.

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medicinion.

Pharmacokinetic When a single does of citriogine is - 10-or participate is - 1

Date 22-06-2021 Artist :SPC Product : Cinod Actual Size : 280 x 210 mm Ref artwork :----Colour : Black

Country : Anglo Africa



Back

the administration and there was no existence of the accumulation, the pharmacolineties of Cheldrighen have disk been evoluted in placets with impaired and function (serime been evoluted in placets with impaired and function (serime) and the placets of the plac

PHARMACEUTICAL PARTICULARS Incompatibilities: Not applicable

Special precautions for storage: Not Applicable Storage Condition: Store below 30°C.

Shelf life:2 years.

10 tablets in Alu-Alu blister pack, 3 such blister in a printed carton along with Pack Insert.

MANUFACTURING AUTHORISATON HOLDER AND

Manufacturing Authorization Holder	Manufacturer
Ajanta Pharma Limited Ajanta House, Charkop Kandivil (West) Mumbai - 400 067, India Tel: +91-22-8808 1000 Fax: (0081) 22-69061200/ 300 Email: info@ajantapharma.com	Ajanta Pharma Limited Mirza-Palashbari Road Village Kokihar, Kamrup (R), Guwahati, Assam - 781128, India.

LAST REVISION DATE: June, 2021

CINOD

CILNIDIPINE TABLETS PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully before you start taking this

- nedicine because itentions to ensure perfore you start taking this needicine 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.

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 styou get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not fisted in this leaflet.

Distribution Category: Prescription Only Medicine or POM What is in this leaflet?

- What Cinod Tablets are and what they are used for

1. What Cinnot Tabelles are and what they are used for 2. What type under to revolute the Cinnot Tabelles 3. Here to lake Cinnot Tabelles 3. Here to lake Cinnot Tabelles 3. Here to lake Cinnot Tabelles 4. Here to lake Cinnot Tabelles 4. Here to lake Cinnot Tabelles 4. Here to control tabelles 4. Here to control tabelles 4. Here to group of meditiones caled calculars arrangements be active substance childrights which believes to a group of meditiones caled calculars arrangements and discrease in a Bod of meditiones the calcular mit on calcular the cost in tabelles (1) and the calcular the calcula

- Have heart failure due to a heart attack;
 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. Beware of over-the-counter medicines and dietary supplements as well as other prescription medicines.)

Warnings & Precautions

Talk to your doctor before taking Cined Tablets You should inform you doctor if you have or have had any of the following conditions

- Recent heart attack

Use in children and adolescents:

Cincol 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 Cilnidipine

Taking other medicines and clinicipine. Please tell your doctor or pharmacist if you are taking or have recently taken other medicines, including medicines obtained without a prescription. Clinicipine may affect or be affected by other medicines, such as:

- **Returning affect or on affected by other medicines, such as:

 *ketoconazole, thraconazole (antifungel medicines used to treat
 thrush and ringworm)

 **Itonavir, Indinavir, neffinavir (antivirals used in treatment of HIV
 infections)

rifampicin, erythromycin, clarithromycin (antibiotics)

- cimebiline (H2 antagonist)
Clinidipine 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 haspital for any reason, tell them that you are taking Clinidipine Tablets.

Taking Cilnidipine 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 Clintidipine, which can cause an unpredictable increase in its blood pressure lowering effect.

on predictable increase in a broot pressure rowering elect. The safety of Cliridipine 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 Cliridipine Tablets.

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

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

Driving and using machine

Taking Childipine Tablets may affect your ability to drive or use machinery because Clinidipine could cause side effects such as dizziness, headaches, nausea or tiredness, all of which could affect your ability to concentrate. 3. How to use CINOD

Smallow 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 how offen to take them. If you are still not zure, ask your pharmacist or doctor. The usual doses are described below. Adults

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

Blooky
As for audits (one limp labels a day). Your doctor will closely nonline your response to any increase in the doce.

Ryou take more Clorif abels than you assoluted goodless, or if you take a called have been a secure of your thirty and the control of your thirty and the control of your thirty and the called has earlied any of the stables, continuely you make the pollution of your thirty and you will be control or you make the days of earlier will not be then you make you make you make you make you make the your thirty than you will be controlled to your high did above the your thirty than you will be controlled to your high did above the your thirty than you could lesse consciousness.

consciousness.
If you forget to take Clinod Tablets
If you forget to take a tablet, take one as soon as you remember,
unless it is nearly time to take the next one. Never take two doses
together. Take the remaining doses at the correct time.
If you stop taking Clinod Tablets

n you stop taking Cinod Tablets Take this medicine for as long as your doctor tells you to, as you may become unwell if you sto, 4. Possible side effects Like all medicines, clinidipine can cause side effects, although not everybody gate them.

everytody gets them. The most commonly reported adverse reactions include headache, dull headache, dizziness on standing up, still shoulder, facial flushing, palpitation, sensation of heat, decreased blood pressure, neusee-vomitting, abdominel pain, rest, profiness, lich, photosensitivity, adoma (facel/limbs), general majaise and frequent utrainals.

If any of these symptoms occur, consult with your doctor or phermacist. The symptoms described below are rarely seen as initial symptoms of the adverse reactions indicated in brackets.

general malaise, loss of appetite, yellow discoloration of the skin and the white of eyes [liver dysfunction, jaundice]

nose bleeding, gum bleeding, subcutaneous bleeding in [imbs [decreased platelets]

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

this medicane. Consult with your doctor or pharmacist if you notice any symptoms of concern other than those listed above. of concern other than thos 5. How to store CINOD

5. How to store CINOD

Do not use the tablets after the end of the expiry month (use-by 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 via wastewater or household.

6. Contents of the pack and other information What CINOD contains:

What CNOD contains:
Active substances are:
CINOD 5 (Clinidipine Tablets 5 mg)
Each film coated tablet contains:
Clinidipine
Excipients
q.s.
Colour, Iron oxide red & Titanium dioxide

CINOD 10(Clinidipine Tablets 10 mg)
Each film coated tablet contains:
Clinidipine 10,0mg
Excipents 9,5
Colour Iron oxide red, Lake sunset yellow FCF & Titanium

List of Excipents:
Clinod 5 (Gilndipine Tablets 5mg)
Hypcromilisos Phihalate, Polyethylene Glycol, Dichloromethane
(Meth ylene Chloride), Methanol, Magnesium
Aluminometalilicate, Lactose Monohydrate, Microcystaline
Cellulose, Creammillose Sodium, Hydrocystypol cellulose,
Lon Olde Sicovit, Tatic, Wagnesium Stearate, Instancet Sol IC23 White, Isopropy/Apochici.

Cinod 10 (Cilnidipine Tablets 10mg)

Cinco 10 (Clindipine Tables 100) (Clindipine Tables 10

Geodesia Sanz or one side and plant or other side.

Cinod 10 (Clinidipine Tablets 10mg)

Light cange to orange coloured, circular, biconvex, film coated tablets with breakline on one side and plain on other side. 10 tablets in Alu-Alu blister pack, 3 such blister in a printed carton along with Pack Insert.

MANUFACTURING AUTHORISATON HOLDER AND MANUFACTURER

MANUFACTURER
Manufacturer
Holder
Apertal Pharmas Lumined
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Apertal Pharmas Lumined
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For any information about this medicinal product, please contact the Manufacturing Authorisation Holder.

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