Package leaflet: Information for the user Clonidine HCl CF 0.025 mg, film-coated tablets
Clonidine HCl CF 0.150 mg, tablets
Clonidine hydrochloride

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

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

What is Clonidine HCl CF and what is it used for?

1. When should you not use this medicine or be extra careful?
1. How should you take this medicine?
2. Possible side effects
3. How should you store this medicine?
4. Contents of the pack and other information
5. What is Clonidine HCl CF and what is it used for?

1. Clonidine HCl CF belongs to the group of blood pressure-lowering medicines.

Clonidine HCl CF belongs to the group of blood pressure-lowering medicines.

This medicine is used:

- for all forms of high blood pressure
- to prevent a migraine attack
- for hot flashes during menopause
- to combat withdrawal symptoms after stopping the use of opiates, such as morphine and heroin

2. When should you not use this medicine or be extra careful with it?

When should you not use this medicine?

- You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6.
- You have a low heart rate due to severe arrhythmias (sick sinus syndrome, second or third degree AV block).
- You are simultaneously using other blood pressure-lowering drugs and drugs with an adverse effect on heart rhythm.
- You have or have had kidney dysfunction, in case of withdrawal symptoms, treatment with clonidine should not take place.

- You have or have had low blood pressure, in case of withdrawal symptoms, treatment with clonidine should not take place.

When should you be extra careful with this medicine?

You should use this medicine with caution if you suffer from:
- arrhythmias
- poor circulation in the brain or limbs
- depression
- certain nervous system disorders
- constipation
- impaired kidney function
- heart failure or severe conditions of the blood vessels that supply your heart with blood.

Clonidine HCl CF has no effect on high blood pressure caused by a tumor of the adrenal medulla (pheochromocytoma).

You should never independently stop the treatment directly, but discuss this with your doctor. Your doctor will then gradually reduce the dosage over a few days. If you abruptly stop the treatment, you may experience restlessness, nervousness, palpitations, tremors (tremor), a rapid increase in blood pressure, nausea, and headache.

If you wear contact lenses, there is a chance that treatment with Clonidine HCl CF may cause a decrease in tear production.

Contact your doctor if any of the above warnings apply to you, or have applied in the past.

Are you using any other medicines?
Are you using any other medicines besides Clonidine HCl CF, have you done so recently, or is there a possibility that you will use other medicines in the near future? Then tell your doctor or pharmacist. This also applies to medicines for which you do not need a prescription.

When you use this medicine simultaneously with any of the following medicines, the effect of one of the medicines may be influenced:
- antihypertensive agents
- agents affecting heart rate (beta-blockers, cardiac glycosides)
- certain vasodilators (phentolamine and tolazoline)
- certain medicines for depression (tricyclic antidepressants and neuroleptics).

The effect of sedatives, sleeping pills, and agents that suppress the nervous system is enhanced by Clonidine HCl CF.

What should you pay attention to with food, drink, and alcohol?
The effect of alcohol is enhanced by Clonidine HCl CF. The effect of this medicine is not influenced by food.

Pregnancy and breastfeeding

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medicine.
There is insufficient data on the use of this medicine during pregnancy in humans to assess the potential harm.
Clonidine crosses the placenta and can lower the heart rate of the unborn child. After birth, a temporary increase in blood pressure may occur in the newborn. Therefore, use this medicine during pregnancy only after consulting your doctor.

Clonidine is excreted in breast milk. Therefore, breastfeeding while using this medicine is not recommended.

Driving ability and the use of machines
Due to the possible occurrence of side effects such as dizziness or drowsiness, this medication may reduce reaction speed. Take this into account when participating in traffic and operating machines.

Clonidine HCl CF contains lactose
If your doctor has informed you that you cannot tolerate certain sugars, contact your doctor before taking this medicine.

Clonidine HCl CF contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, which means it is essentially 'sodium-free'.

3. How do you take this medicine?

Always use this medicine exactly as your doctor or pharmacist has told you. Are you unsure about the correct use? Then contact your doctor or pharmacist.

The recommended dosage for adults (including the elderly) is:

Increased blood pressure:
The dosage of clonidine will be determined personally by your doctor based on the effect and tolerability of the medicine. The initial dosage is three times 0.075 mg. This dosage can later be decreased or increased depending on your response to this medicine. In normal cases, the dosage will not exceed 0.450 mg per day. In some cases, a higher dosage may be necessary. The adjustment is then usually done in a hospital.
The maximum daily dosage in those cases is 1.8 mg per day.

To prevent a migraine attack:
The initial dosage is 0.025 mg once a day. This dosage can be gradually increased after 2 weeks to a maximum of 0.050 mg twice a day. In exceptional cases, dosages of 0.075 mg twice a day can be given.

For hot flashes during menopause:

The initial dosage is 0.050 to 0.075 mg twice a day. The dosages should preferably be taken every 12 hours. If the treatment does not provide sufficient effect after 3 to 4 weeks, the treatment should be discontinued.

To combat withdrawal symptoms after stopping the use of opiates such as morphine and heroin: The initial dosage is 0.2 to 0.5 mg per day, divided into 2 to 4 doses. This dosage can then be increased by 0.1 to 0.3 mg per day to a maximum of 1.2 mg per day based on the effect and blood pressure of the user. After about 7 days, the treatment can be gradually discontinued over a period of 2 to 3 days.

The dosage of clonidine should not be suddenly increased or decreased. To prevent sudden rises and falls in blood pressure, the dosage of clonidine should be gradually and in small steps changed. To reduce the occurrence of side effects, it is advisable to have your pulse and blood pressure regularly measured by your doctor.

In patients with impaired kidney function, the doctor will adjust the dosage and close monitoring will take place.

Use in children
Clonidine HCl CF is not suitable for use in children.

Have you taken too much of this medicine?:
If you have taken too much of this medicine, you may experience constricted pupils, drowsiness, slow heart rate, low blood pressure, hypothermia, coma, or respiratory arrest. Contact your doctor or pharmacist immediately.

Have you forgotten to take this medicine?
If you quickly realize that you have missed a dose, you can still take it. However, if it is almost time for the next dose, you can skip the missed dose and continue with the next one. Do not take a double dose to make up for a forgotten dose.

If you stop taking this medicine
You may experience restlessness, nervousness, palpitations, tremors (tremor), a rapid increase in blood pressure, nausea, and headache. Always consult your doctor before stopping this medicine. Your doctor will then gradually reduce the dosage over a few days.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everyone gets them.

Very common (occurs in more than 1 in 10 users):
- dizziness
- drowsiness
- sleepiness (sedation)

- drop in blood pressure due to, for example, standing up quickly from a sitting or lying position, sometimes accompanied by dizziness (orthostatic hypotension)
- dry mouth

Common (occurs in less than 1 in 10 users):
- (severe) depression
- sleep disorders
- headache
- nausea
- constipation
- vomiting
- pain in the salivary glands
- a persistent or recurrent inability to achieve or maintain an erection sufficient for sexual activity (erectile dysfunction)
- fatigue

Sometimes (occur in less than 1 in 100 users):
- perceptual disorders
- perceptions of things that are not there (hallucinations)
- nightmares
- sensation of crawling, itching, or tingling without cause (paresthesia)
- slowed heart rate due to a decreased contraction frequency of the atria of the heart (sinus bradycardia)
- paleness of fingers and/or toes (Raynaud's disease)
- skin rash
- itching (pruritus)
- skin rash with severe itching and formation of welts (hives or urticaria)
- malaise

Rarely (occur in less than 1 in 1000 users):
- development of abnormal breast tissue in men (gynecomastia)
- reduced production of tear fluid
- certain conduction disorder of the heart, leading to arrhythmias (AV block)
- dry nose
- apparent obstruction of the large intestine
- hair loss
- elevated blood glucose levels detected via a laboratory test

Not known (cannot be determined from the available data):
- confusion
- reduced libido
- vision problems (accommodation disorders)
- a heart condition where the heart rate is exceptionally slowed (bradyarrhythmia).

Reporting side effects
If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands

Pharmacovigilance Centre Lareb, website: www.lareb.nl. By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. How to store this medicine?

Keep out of the sight and reach of children.
Store below 25°C

Do not use this medicine after the expiry date. This can be found on the blister pack, the box, and the tablet container after "EXP" or "Do not use after". It includes a month and a year. The last day of that month is the expiry date.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. They will then be destroyed responsibly and will not enter the environment.

6. Contents of the package and other information What substances are in this medicine?

The active substance in this medicine is clonidine hydrochloride.
Clonidine HCl CF 0.025 mg film-coated tablet: each tablet contains 0.025 mg clonidine hydrochloride. Clonidine HCl CF 0.150 mg tablet: each tablet contains 0.150 mg clonidine hydrochloride.

The other ingredients in this medicine are calcium hydrogen phosphate dihydrate (E341), lactose monohydrate, maize starch, sodium carboxymethyl starch (E466), povidone (E1201), magnesium stearate (E470b), anhydrous colloidal silica (E551).
The 0.025 mg film-coated tablets also contain hydroxypropyl methylcellulose (E 464), propylene glycol (E1520), titanium dioxide (E 171), talc (E553b), and indigotine (E 132).

What does Clonidine HCl CF look like and what is in a package?
Clonidine HCl CF 0.025 mg film-coated tablets are blue, round film-coated tablets with a diameter of 6 mm. The tablets may have the inscription "0.025".
Clonidine HCl CF 0.150 mg tablets are white to almost white, round tablets with a diameter of 8 mm. The tablet has a score line on one side and may have the inscription "0.150" on the other side.

Clonidine HCl CF tablets are available in a PP tablet container with a PE lid containing 30, 50, 100, 150, 200, 250, 500, 1000, 2000, 2500, or 5000 tablets and with 10 tablets in a PVC/Al blister pack, multiples of 10 in a cardboard box.

Not all pack sizes mentioned are marketed.

Marketing authorization holder and manufacturer
Marketing authorization holder Centrafarm B.V.
Van de Reijtstraat 31-E
4814 NE Breda
Netherlands

Manufacturer
Centrafarm Services B.V. Van de Reijtstraat 31-E 4814 NE Breda Netherlands

Registered under:
RVG 56917 Clonidine HCl CF 0.025 mg, film-coated tablets RVG 56919 Clonidine HCl CF 0.150 mg, tablets

This leaflet was last approved in September 2023.