

Package leaflet: Information for the patient

Celiprolol Hydrochloride 200 mg Tablets Celiprolol Hydrochloride 400 mg Tablets

Read all of this 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, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness 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. See section 4.

What is in this leaflet:

1. What Celiprolol Hydrochloride is and what it is used for
2. What you need to know before you take Celiprolol Hydrochloride
3. How to take Celiprolol Hydrochloride
4. Possible side effects
5. How to store Celiprolol Hydrochloride
6. Contents of the pack and other information.

1. What Celiprolol Hydrochloride is and what it is used for

The name of your medicine is Celiprolol Hydrochloride 200 mg or 400 mg Tablets (called Celiprolol Hydrochloride throughout this leaflet).

Celiprolol Hydrochloride contains a medicine called celiprolol hydrochloride. This belongs to a group of medicines called beta-blockers. It works by slowing your heart rate or lowering your blood pressure. It is used to treat high blood pressure (hypertension).

2. What you need to know before you take Celiprolol Hydrochloride

Do not take Celiprolol Hydrochloride if you:

- are allergic to celiprolol hydrochloride or any of the ingredients of this medicine (listed in section 6). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- have suffered an allergic reaction to a beta-blocker (propranolol, sotalol, timolol etc.) in the past
- suffer from an irregular/very slow heartbeat (known as bradycardia) or low blood pressure (hypotension)
- suffer from heart failure which is not under control (heart failure is a condition in which your heart is not pumping blood as well as it should), have an abnormal heart rhythm, difficulty breathing and swollen ankles
- suffer from missed heart beats (heart block) or other heart problems or you suffer from hardened arteries
- have severe kidney problems
- have, or have had, episodes of asthma, wheezing or other severe breathing problems
- have a rare tumour called a phaeochromocytoma that is not being treated
- have abnormal levels of acid in your blood (metabolic acidosis), usually as a result of severe illness
- are already taking theophylline (an anti-asthma medicine).
- have late stage peripheral arterial occlusive disease or Raynaud's syndrome

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Celiprolol Hydrochloride.

Warnings and Precautions

Take special care and consult your doctor before taking Celiprolol Hydrochloride if you:

- have liver or kidney problems (please see Section 3, How to take Celiprolol Hydrochloride)
- have Prinzmetal's angina (chest pain while resting)
- have poor blood circulation e.g. Raynaud's, Burger's Disease. Symptoms of Raynaud's disease include fingers and toes changing colour when cold and tingling or painful on warming up. Your doctor will closely monitor you while taking this medicine.
- have inadequate circulation of blood through the coronary arteries.
- have ever had a skin condition known as psoriasis. Your doctor will stop this medicine if you have.
- have asthma or breathing problems due to long term lung problems (called bronchitis or emphysema)
- have a thyroid problem as the effects of an overactive thyroid gland (thyrotoxicosis) may be hidden by beta blocker medicine
- have a history of severe allergies, particularly to other medicines, including anaphylactic reactions
- need anti-allergic treatment eg. following a wasp or bee sting; your doctor may wish to interrupt your Celiprolol Hydrochloride treatment to prevent a possible allergic reaction.
- are diabetic. Patients with diabetes should be aware that the symptoms of low blood pressure (hypoglycaemia) may be hidden by beta blocker medicines
- have any heart failure that is under control with medication. Your doctor will give this medicine under strict medical surveillance
- have a slow or irregular heartbeat.

While taking Celiprolol Hydrochloride if you:

- have any heart problems and your doctor wants to stop this medicine, the dose should be gradually reduced over 1-2 weeks. At the same time, if necessary, any replacement therapy for prevention of anginal attacks may be considered by your doctor.

Children

Celiprolol Hydrochloride is not recommended for use in children.

Operations or anaesthetics

Tell your doctor or dentist if you are taking Celiprolol Hydrochloride if you are going to have an anaesthetic or an operation (including dental surgery).

Drug test in sport:

Celiprolol Hydrochloride may give a positive result if you have a blood or urine test to check for the presence of drugs.

Other medicines and Celiprolol Hydrochloride

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. This is because Celiprolol Hydrochloride can affect the way some other medicines work. Also, some other medicines can affect the way Celiprolol Hydrochloride works.

Care is needed if you are taking:

- medicine to treat an abnormal heart rhythm eg. Disopyramide, Quinidine, Amiodarone, Sotalol, Hydroquinidine, Ibutilide, Dafetilide, Propafenone
- other medicines to treat a heart condition, chest pain or high blood pressure eg. Verapamil, Diltiazem, Nifedipine, Digoxin, Digoxin, Alpha-methyl dopa, Guanfacine, Reserpine, Bepridil or Clonidine. If you are taking clonidine and Celiprolol Hydrochloride together, you must not stop taking clonidine unless the doctor tells you to do so. Your doctor would stop Celiprolol Hydrochloride many days before clonidine is discontinued

- vasodilators such as glyceryl trinitrate (commonly known as nitroglycerin), isosorbide mononitrate and isosorbide dinitrate, sodium nitroprusside etc. (used to treat hypertension, heart failure and angina)
- diuretics (“Water Tablets”) e.g. Chlorthalidone or Hydrochlorothiazide
- medicines used for treatment of mental depression known as monoamine oxidase inhibitors (MAOI) e.g. phenelzine, tranylcypromine, moclobemide and isocarboxazid.
- diabetic medicine e.g. insulin or oral anti-diabetic medicines (e.g. glibenclamide, metformin). Your blood sugar needs to be monitored closely
- noradrenaline or adrenaline (used for treatment of low blood pressure, heart failure, asthma or allergies). Noradrenaline and adrenaline are always given under medical supervision
- medicines used for asthma
- medicines used as anaesthetics
- medicines such as phenylephrine, pseudoephedrine, phenylpropanolamine (contained in cough medicine or nose and eye drops). These medicines may counteract the effect of Celiprolol Hydrochloride
- medicines used for treating mental illnesses such as barbiturates, phenothiazines (e.g. chlorpromazine, trifluoperazine), or most tricyclic antidepressants (e.g. imipramine, amitriptyline, clomipramine, desipramine).
- medicines used to relieve pain such as Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) e.g. ibuprofen, indomethacin
- mefloquine (medicine used for the prevention and treatment of malaria)
- if you develop shock or low blood pressure due to floctafenine (medicine used to treat pain), Celiprolol Hydrochloride may reduce the effectiveness of medicines used to treat these conditions
- medicines such as verapamil, erythromycin, clarithromycin, ciclosporin, quinidine, ketokonazole, itraconazole, rifampicin and St. John’s wort which may affect the amount of this medicine you absorb.
- fingolimod, used in treating multiple sclerosis. Your doctor may monitor the start of your treatment.

Celiprolol Hydrochloride with food and drink

If you take this medicine with food it may not work as well. Celiprolol Hydrochloride should be taken preferably first thing in the morning, one hour before food or 2 hours after it. **Do not** drink alcoholic beverages until you have discussed the affects with your doctor. Citrus juices increase the amount of Celiprolol Hydrochloride you absorb, so should be avoided while taking this medicine.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advise before taking this medicine.

If your doctor cannot find any safer alternative you may be given Celiprolol Hydrochloride. If you take Celiprolol Hydrochloride during pregnancy, you should tell your midwife. In the new born of the treated mother, activity of these kind of medicines remains for several days. The effects can include slow heart beat, heart failure or having trouble breathing. Therefore close monitoring of the neonate is recommended for the first 3 to 5 days of life.

If you are already taking Celiprolol Hydrochloride and have just found out you are pregnant, you should talk to your doctor immediately.

You should not breast-feed if you are taking Celiprolol Hydrochloride. If you are breast-feeding or planning to breast-feed you should talk to your doctor or pharmacist before taking this medicine.

Driving and using machines

While using this medicine you may feel dizziness, fatigue as well as potentiation of side effects such as shaking, headaches or visual disturbances. If this happens, do not drive or use any tools or machines.

3. How to take Celiprolol Hydrochloride

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- Swallow the tablets whole with a glass of water.
- Take the tablets preferably first thing in the morning, one hour before food or two hours after food.
- To help you remember to take your medicine, try to get into the habit of taking it at the same time each day, preferably first thing in the morning.

The recommended dose is:

Adults including the elderly – the recommended starting dose is 200 mg of Celiprolol Hydrochloride once a day. If needed after 2 to 4 weeks, your doctor will increase your dose to 400 mg once a day. The maximum dose is 400 mg once a day.

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

Adults with liver or kidney problems – if you have kidney problems, your doctor may give you a lower dose than stated above and increase it as needed. A reduction in dosage by half may be appropriate in patients with moderate impairment of kidney function (creatinine clearance in the range of 15-40 ml per minute). Celiprolol Hydrochloride is not recommended for patients with severely impaired kidney function (creatinine clearance less than 15 ml per minute). Use of low doses of Celiprolol Hydrochloride is recommended in patients with liver problems.

Children – Celiprolol Hydrochloride should not be given to children

Elderly – Your doctor may decide to lower your dose of Celiprolol Hydrochloride if necessary

If you take more Celiprolol Hydrochloride than you should

You may have symptoms such as slow heart beats, low blood pressure, feeling dizzy or weak, difficulty in breathing, wheezing or heart problems. Contact your doctor or go to the nearest hospital casualty department immediately. Take this leaflet or some tablets with you so your doctor will know what you have taken.

If you forget to take Celiprolol Hydrochloride

If you forget to take a dose, take it as soon as you remember, unless it is time for your next dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Celiprolol Hydrochloride

If you suddenly stop taking Celiprolol Hydrochloride your condition may worsen rapidly. Your doctor will reduce your dose slowly over a period of 7 to 10 days.

Take your tablets as directed and for as long as directed; do not stop them, even if you feel better, as otherwise the symptoms may return.

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

4. Possible side effects

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

Serious side effects

If any of the following happen, stop taking Celiprolol Hydrochloride and tell your doctor immediately, or go to the casualty department of your nearest hospital:

- Allergic reaction: a rash, swallowing or breathing problems, swelling of your face, lips, throat or tongue.

- You get flu like symptoms, swollen or painful joints, increased sensitivity to sunlight, hair loss, abdominal pain, anaemia. This may mean you have a condition called Systemic Lupus Erythematosus (SLE). These symptoms will usually go away after Celiprolol Hydrochloride has been stopped. These are very serious side effects. If you have them you may have had a serious allergic reaction to Celiprolol Hydrochloride. You may need urgent medical attention or hospitalization.

Tell your doctor immediately or go to the casualty department of your nearest hospital if you notice any of the following:

Common side effects (may affect up to 1 in 10 people)

- Dizziness or light headedness, weakness, or fainting especially when standing up from a lying position. These could be signs of low blood pressure.
- Skin rashes, excessive itching

Uncommon side effects (may affect up to 1 in 100 people)

- Pounding heartbeat
- Shortness of breath

Rare side effects (may affect up to 1 in 1,000 people)

- Worsening of previously existing heart failure with swelling of hands, ankles or feet and difficulty in breathing after exercise, cold and blue or purple colouration of hands and feet
- Lung disease with symptoms such as fever, chills, fatigue, breathlessness, chest tightness and cough, difficulty in breathing, inflammation of the lung, shortness of breath especially in patients with asthma or history of asthma
- Allergic skin reactions such as itching, flush, hives, unusual bleeding or bruising under the skin.

Not known: frequency cannot be estimated from the available data

- Worsening of previously diagnosed sugar diabetes (diabetes mellitus)
- Increased thirst, excessive urination, increased appetite, weight loss. This may be an undiagnosed case of sugar diabetes (diabetes mellitus) and may become apparent.
- Fast, slow or irregular heartbeat, heart failure
- Signs of psychosis: a loss of contact with reality, such as hearing voices or seeing things that are not there.

Medicines in this group may hide the symptoms like fast heartbeat and shaking (these symptoms may appear in the presence of sugar diabetes and overactive thyroid gland).

Tell your doctor if you notice any of the following:

Common side effects (may affect up to 1 in 10 people)

- Headache
- Excessive sleepiness, difficulty in sleeping, bad dreams, nightmares, tremors (uncontrolled shaking)
- Coldness of hands or feet (Raynaud's disease), hypotension
- Nausea (feeling sick) or vomiting (being sick), pain and discomfort in the belly, dry mouth
- Muscle cramps, joint pain, tiredness.
- Hot flushes or excessive sweating
- Depressed mood
- Unusual skin sensations such as pins and needles, numbness, burning or creeping on the skin
- Lack of energy
- Difficulty in getting or maintaining an erection

Uncommon side effects (may affect up to 1 in 100 people)

- Low blood pressure
- Difficulty in sleeping

Rare side effects (may affect up to 1 in 1,000 people)

- Ringing in the ears
- Constipation
- Muscle weakness
- Sexual inability in men, decrease sexual drive.

Very rare side effects (may affect up to 1 in 10,000 people)

- Mood and behaviour changes
- Confusion
- Skin disease with thickened patches of red skin, often with silvery scales (psoriasis) or worsening of previously existing psoriasis.

Not known: frequency cannot be estimated from the available data

- A cramp-like pain in one or both legs that develops on walking and may eventually cause a limp.
- Hallucinations (false or distorted sensory experiences that appear to be real perceptions. These sensory impressions are generated by the mind rather than by any external stimuli, and may be seen, heard, felt, and even smelled or tasted)
- Impaired vision, blurred vision or visual disturbances, dry eyes to be considered if the patient uses contact lenses
- Diarrhoea (loose stools)

There may be changes in the results of certain laboratory tests

- Increase in Antinuclear antibodies (ANA)
- Increase in liver enzymes such as transaminases
- Blood test may also show abnormal levels of glucose in the blood.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Celiprolol Hydrochloride

Keep this medicine out of the sight and reach of children.

Keep container in the outer carton.

Do not store above 25°C.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Celiprolol Hydrochloride contains:

- The active ingredient is 200 mg or 400 mg of celiprolol hydrochloride
- The other ingredient(s) are microcrystalline cellulose, mannitol, croscarmellose sodium, colloidal anhydrous silica and magnesium stearate.

The film-coating itself contains hypromellose and titanium dioxide (E171), with macrogol 400 and quinoline yellow (E104) in the 200 mg tablets or with macrogol 4000 and lactose monohydrate in the 400 mg tablets.

What Celiprolol Hydrochloride looks like and contents of the pack:

- **Celiprolol Hydrochloride 200 mg tablets** are yellow coloured, capsule shaped, biconvex film-coated tablets, debossed with '200' on one side of the breakline and a deep breakline on the other side.
- **Celiprolol Hydrochloride 400 mg tablets** are white coloured, capsule shaped, biconvex film-coated tablets, debossed with '400' on one side of the breakline and a deep breakline on the other side.
- Celiprolol hydrochloride tablets are available in packs of 10, 20, 28, 30, 50, 56 and 100 film-coated tablets in blister strips.

* Not all pack sizes may be marketed

Marketing Authorisation Holder

Ranbaxy (UK) Limited
5th floor, Hyde Park, Hayes 3
11 Millington Road
Hayes, UB3 4AZ
United Kingdom

Manufacturer

Sun Pharmaceutical Industries Europe B.V.
Polarisavenue 87
2132JH, Hoofddorp
The Netherlands

Alkaloida Chemical Company Zrt
Kabay János u. 29
H-4440 Tiszavasvári
Hungary

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