

PACKAGE LEAFLET: INFORMATION FOR THE USER
CELECTOL 200 AND 400 TABLETS
Celiprolol Hydrochloride

Is this leaflet hard to see or read? Phone 0845 372 7101 for help

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 further questions, ask your doctor or your pharmacist.
- This medicine has been prescribed for you only. Do not pass it onto 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. WHAT CELECTOL IS AND WHAT IT IS USED FOR

What Celectol is

The name of your medicine is Celectol 200 or 400 Tablets (called Celectol throughout this leaflet). Celectol contains a medicine called celiprolol hydrochloride. This belongs to a group of medicines called beta-blockers.

How Celectol works

It works by slowing your heart rate or lowering your blood pressure.

What Celectol is used for

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

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CELECTOL

Do not take Celectol if:

- X You are allergic (hypersensitive) to celiprolol or any of the other ingredients in Celectol (listed in section 6).
Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- X You have or have had asthma or wheezing.
- X You have a very slow heart beat (bradycardia).
- X You have heart problems – where you have difficulty breathing and swollen ankles.
- X You have kidney problems.
- X You have a tumour of the adrenal gland (phaeochromocytoma) and your blood pressure has not yet been treated with a type of medicine known as an alpha blocker, such as doxazosin or terazosin.
- X You have low blood pressure (hypotension).
- X You have abnormal levels of acid in your blood (metabolic acidosis).

- X You have been diagnosed by your doctor with late stages of a peripheral arterial disease (such as Raynaud's disease). Symptoms include persistent cramping pain in legs even at rest, and development of non-healing ulcers over fingers or toes.

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 Celectol.

Warnings and precautions

Talk to your doctor or pharmacist before taking Celectol if:

- You have any heart problems.
- You have breathing problems due to long term lung problems (called bronchitis or emphysema).
- You have diabetes.
- You have liver problems.
- You have a tumour of the adrenal gland (phaeochromocytoma) and your blood pressure is not yet controlled by a type of medicine known as an alpha blocker, such as doxazosin or terazosin.
- You have an overactive thyroid gland, as celiprolol can hide some of the symptoms associated with this condition.
- You have a history of severe allergies, including anaphylactic reactions.
- You have ever suffered from psoriasis.
- You suffer from a type of chest pain called Prinzmetal's angina.
- You suffer from poor circulation (such as Raynaud's disease). Symptoms include fingers and toes changing colour when cold and tingling or painful on warming up. Your doctor may closely monitor you while taking this medicine.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Celectol.

Operations or anaesthetics

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

Other medicines and Celectol

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

In particular tell your doctor if you are taking any of the following:

- Insulin or tablets to treat diabetes.
- Medicines, including some cough and cold medicines, containing ephedrine, pseudoephedrine or adrenaline.
- Medicines to treat depression called MAOIs (monoamine oxidase inhibitors) or have taken them in the last 2 weeks. MAOIs are medicines such as meclobemide, phenelzine or tranylcypromine.
- Medicines used for mental problems (antipsychotic medicines) – such as chlorpromazine or other phenothiazines.
- Medicines used for asthma (such as theophylline).
- Medicines for chest pain (angina) – such as verapamil, nifedipine and diltiazem.
- Medicines used for heart problems – such as lidocaine (also used as a local anaesthetic) amiodarone, digitalis, diltiazem, disopyramide, nifedipine, quinidine and verapamil (also used for severe allergies).
- Diltiazem as it may lead to increased risk of depression.
- Non-Steroidal Anti-inflammatory Drugs (NSAIDs) – used to relieve pain such as ibuprofen and indometacin.
- Medicines used to lower blood pressure – such as chlorthalidone, hydrochlorothiazide and clonidine.
- Medicines used for the prevention of malaria such as mefloquine.

- Some antibiotics or antifungal medicines e.g. rifampicin, erythromycin, clarithromycin, ketoconazole, itraconazole.
- Medicines used to alter the way your immune system works e.g. fingolimod, ciclosporin.
- Medicines obtained without a prescription e.g. St John's Wort.

If you are not sure, talk to your doctor or pharmacist before taking Celectol.

Celectol with food and drink

- Celectol should be taken preferably first thing in the morning, 30 minutes before food or two hours after a meal.
- Citrus fruit juices should be avoided when taking this medicine as they can decrease the absorption of celiprolol.

Pregnancy and breast-feeding

Talk to your doctor before taking this medicine if you are pregnant, think you may be pregnant or are planning to have a baby.

If your doctor cannot find a safer alternative you may be given Celectol. If you take Celectol during pregnancy, particularly in the last 3 months, you should tell your midwife. This is because your baby may be affected when it is born. Any effects usually begin on the first day after birth and can include lower than normal levels of glucose in the blood (hypoglycaemia), slow heart beat, heart failure or having trouble breathing. If your baby has any of these side effects when it is born and you are worried, tell your doctor or midwife.

You should not breast-feed if you are taking Celectol. This is because small amounts may pass into the mother's milk. If you are breast-feeding or planning to breast-feed, talk to your doctor or pharmacist before taking this medicine.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

Driving and using machines

You may feel tired or dizzy whilst taking Celectol. If this happens, do not drive or use any tools or machines.

Drug tests in sport

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

3. HOW TO TAKE CELECTOL

Always take Celectol exactly as your doctor has told you. The dose of Celectol will depend on your needs and the illness being treated. Check with your doctor or pharmacist before taking Celectol.

Taking this medicine

- Swallow the tablets whole with a drink of water.
- Take your medicine at the same time each day, preferably first thing in the morning, 30 minutes before food, or 2 hours after a meal.

How much to take

Adults

- The usual starting dose is 200mg once daily.
- The maximum dose is 400mg once daily.

Children

Celectol should not be given to children.

Elderly patients and patients with kidney problems

Your doctor may decide to lower your dose of Celectol if necessary.

If you take more Celectol than you should

Tell your doctor or go to the nearest hospital casualty department straight away. Remember to take with you any tablets that are left and the pack. This is so the doctor knows what you have taken. The following effects may happen: feeling dizzy or weak, difficulty breathing or wheezing.

If you forget to take Celectol

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 Celectol

Keep taking your medicine until your doctor tells you to stop. Do not stop taking Celectol just because you feel better. If you stop taking Celectol, your illness may get worse. When your doctor says that you can stop taking Celectol, you need to do this gradually. Your doctor will help you do this.

If you have any further questions about this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

Stop taking Celectol and see a doctor or go to a hospital straight away if:

- You get swelling of the hands, feet, ankles, face, lips or throat which may cause difficulty in swallowing or breathing. You could also notice an itchy, lumpy rash (hives) or nettle rash (urticaria). This may mean you are having an **allergic reaction** to Celectol.
- 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 usually go away after Celectol has been stopped.

Tell your doctor as soon as possible if you have any of the following side effects:

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

- Feeling shaky (tremor), tired, drowsy or weak
- Stomach pain
- Depression
- Hot flushes
- Skin rashes

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

- Slow heart rate or very fast, uneven or forceful heartbeat (palpitations).
- Feeling dizzy or weak. These could be signs of low blood pressure.
- Difficulty breathing or shortness of breath
- Difficulty sleeping (insomnia).

Not known (frequency cannot be estimated from available data)

- Pain in your chest and feeling weak or dizzy. These could be signs of a heart problem.
- Slow or irregular heart rate
- Changes in behaviour and feeling that you are losing touch with reality, or are unable to think or judge things clearly. You may also feel more aggressive than usual. These could be signs of a serious mental health problem (psychoses).
- Seeing or hearing things that are not there (hallucinations), confusion, nightmares.
- Problems with your eyesight such as blurred vision.

- Dryness or redness of the eye.
- Diarrhoea
- Appearance of scaly skin rash (psoriasis-like rash) or worsening of existing psoriasis
- Low blood sugar levels (hypoglycaemia). You may feel a sense of nervousness, shaky or sweaty.
- High blood sugar levels (hyperglycaemia). You may be passing large amounts of urine, have excessive thirst and a dry mouth or skin. You may also get frequent infections such as thrush.

Tell your doctor or pharmacist if any of the following side effects gets serious or last longer than a few days:

Common side effects (may affect 1 in 10 people)

- Feeling sick (nausea) or being sick (vomiting), dry mouth
- Feeling dizzy or light-headed, headache
- Sweating more than usual
- Worsening of existing circulation disorders of the extremities. Symptoms may include a cold or numb feeling in your fingers or toes (Raynaud’s disease or syndrome), or cramping pain in the legs (claudication).
- Unusual skin sensations such as numbness, tingling, pricking, burning or creeping on the skin
- Difficulty in getting or maintaining an erection, or in ejaculating (impotence)

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

- Muscle spasms

Not known (frequency cannot be estimated from available data)

- Fainting
- Breathing problems such as asthma or productive cough
- Lack of interest in sexual activities (libido)
- Pain in your joints (arthralgia)

Blood tests

- The results of some blood tests may show higher levels of liver enzymes than normal.
- Blood tests may show abnormal levels of glucose in the blood.
- Blood tests may show abnormal levels of autoimmune factors.

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 or search for MHRA Yellow Card on the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE CELECTOL

- Keep out of the sight and reach of children.
- Do not take this medicine after the expiry date, which you will find on the pack after “EXP”.
- Store below 25°C.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer require. This will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Celectol contains

Each tablet contains 200mg or 400mg of celiprolol hydrochloride as the active substance.

Each tablet also contains mannitol, microcrystalline cellulose, croscarmellose sodium and magnesium stearate.

Film-coating:

200mg tablet: Opadry Y-1-7000 (white) which contains E464, E171 and polyethylene glycol

400mg tablet: Opadry YS-1-7006 (clear) which contains E464 and polyethylene glycol

What Celectol looks like and the contents of the pack

Celectol 200 Tablets are white, biconvex, heart shaped and engraved with the logo on one side, and 200 and a breakline on the other.

Celectol 400 Tablets are white, biconvex, heart shaped and engraved with the logo on one side, and 400 on the other.

Celectol tablets are supplied in blister packs of 28 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Neon Healthcare Ltd., Mill Studio Business Centre, Crane Mead, Ware, Hertfordshire, SG12 9PY, UK

Manufacturer

Sanofi Winthrop Industrie, 56 route de Choisy au Bac 60205 Compiègne, France.

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