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 or pharmacist.
- 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 or pharmacist. 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

The name of your medicine is Celiprolol Hydrochloride 200 mg and 400 mg Tablets (referred to as Celiprolol Hydrochloride throughout this leaflet).

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

Your medicine comes as a film-coated tablet. The active ingredient is celiprolol hydrochloride. The other ingredients are listed in section 6. Celiprolol Hydrochloride belongs to a family of medicines known as beta-blockers.

Celiprolol Hydrochloride is used:
- to treat high blood pressure (hypertension)
- to prevent and control angina.

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

Do not take Celiprolol Hydrochloride:
- if you are allergic to celiprolol or any of the other 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
- if you have suffered an allergic reaction to a beta-blocker in the past
- if you have too much acid in your blood (known as metabolic acidosis), which may cause an increased rate of breathing
- if you suffer from a very slow heart beat (known as bradycardia)
- if you have low blood pressure (hypotension)
- if you have a tumour of the adrenal gland (phaeochromocytoma) and your high blood pressure has not yet been treated with a type of medicine known as an alpha blocker, such as doxazosin or terazosin
- if you have severe kidney problems
- if you suffer from uncontrolled heart failure, missed heart beats (heart block) or you suffer from hardened arteries
• if you have or have had asthma or wheezing
• if you are using theophylline for the treatment of asthma
• if you are taking or have taken verapamil (used for angina or severe allergies). If you stop treatment with verapamil, you must wait until at least 48 hours before you start treatment with Celiprolol Hydrochloride. After stopping treatment with a Celiprolol Hydrochloride, you must wait at least 48 hours before you can start treatment with verapamil (by injection or infusion).

Warnings and precautions
Talk to your doctor or pharmacist before taking Celiprolol Hydrochloride:
• if you have liver problems
• if you have mild to moderate kidney problems
• if you have any heart problems
• if you have Printzmetal’s angina (chest pain while resting)
• if you have poor blood circulation eg. Raynaud’s disease. Symptoms include fingers and toes changing colour when cold and tingling or pain on warming up
• if you have diabetes
• if you have ever had psoriasis
• if you have a history of severe allergies, including anaphylactic reactions
• if you have an overactive thyroid gland, as celiprolol can hide some of the symptoms associated with this condition
• if you have breathing problems due to long term lung problems (called bronchitis or emphysema)
• if you have a tumour of the adrenal gland (phaeochromocytoma) and your high blood pressure is medicine known as an alpha blocker, such as doxazosin or terazosin
• if you need to have surgery and will be given an anaesthetic; tell your doctor, dentist or hospital staff.

Children and adolescents
Celiprolol Hydrochloride should not be given to children.

Other medicines and Celiprolol Hydrochloride
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Do not take Celiprolol Hydrochloride if you are already taking any of the following:
* theophylline (for the treatment of asthma)
* medicines for chest pain (angina) such as verapamil (also used for severe allergies), nifedipine and diltiazem or medicines used for heart problems such as digitalis
* disopyramide, quinidine or amiodarone given by injection to treat abnormal heart rhythm
* medicines used to lower blood pressure such as clonidine or diuretics (‘water’ tablets) e.g. chlorthalidone and hydrochlorothiazide
* medicines to treat depression called MAOIs (Monoamine Oxidase Inhibitors) such as moclobemide, phenelzine or tranylcypromine, or if you have taken them in the last 2 weeks.

Tell your doctor if you are already taking any of the following as they may interact with your medicine:
* medicines used to treat heart problems such as lidocaine (also used as local anaesthetic), disopyramide, nifedipine, quinidine, amiodarone, sotalol, hydroquinidine, ibutilide, dofetilide and propafenone
* medicine used for the prevention of malaria such as mefloquine
* other medicines to treat heart conditions or high blood pressure e.g. reserpine, alpha-methylldopa, guanfacine, moxonidine, rilmenidine
* medicines which cause a heart rhythm condition known as torsades de pointes (except sulitropride), including the following:
— some medicines for mental illness (antipsychotic medicine) including chlorpromazine, cyamemazine, levomepromazine, thioridazine, trifluoperazine, amisulpiride, sulpiride, tiapride, droperidol, haloperidol, pimozide
— bepridil, cisapride, diphemanil, spiramycin or erythromycin (by injection), halofantrine, antibacterial medicines such as moxifloxacin or pentamidine and vincamycin (by injection), astemizole, terfenadine, mizolastine

* medicine to treat urinary retention such as alfuzosin, doxazosin, prazosin, tamsulosin and terazosin
* insulin or tablets to treat diabetes; your blood sugar may need to be monitored closely
* antidepressants or other medicines to treat mental illness (antipsychotic medicines) such as barbiturates or other phenothiazines
* anti-inflammatory painkillers (NSAIDs such as ibuprofen etoricoxib, aspirin (in high doses) and indometacin
* cough and cold remedies containing, ephedrine, pseudoephedrine or adrenaline bought over the counter (including nose and eye drops).

**Celiprolol Hydrochloride with food, drink and alcohol**

If you take this medicine with food it may not work as well: Celiprolol Hydrochloride should be taken 30 minutes before food or two hours after it. Drinking alcohol can increase the effect of this medicine and you may feel dizzy.

**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 advice before taking this medicine.

If your doctor cannot find a safer alternative you may be given Celiprolol Hydrochloride. If you take Celiprolol Hydrochloride during pregnancy, particularly in the last 3 months, you should tell to 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 your baby if you are taking Celiprolol Hydrochloride as small amounts of Celiprolol Hydrochloride may pass into your breast milk.

**Driving and using machines**

You may feel dizzy or tired, have problems seeing, shaking or headaches whilst taking this medicine. If this happens, do not drive or use tools or machines.

**Celiprolol Hydrochloride 200 mg contains lactose**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

### 3. How to take Celiprolol Hydrochloride

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

**Adults including the elderly**

The recommended starting dose is 200 mg of Celiprolol Hydrochloride once a day. If needed, your doctor will increase the dose to 400 mg once a day.

**Patients with kidney problems**

If you have kidney problems, your doctor will give you a lower dose than stated above.

**Use in children and adolescents**

Celiprolol Hydrochloride must not be given to children.
Method of administration
- Swallow the tablets whole with a drink of water.
- Take the tablets preferably first thing in the morning, 30 minutes before food, or 2 hours after a meal.
- Take your medicine at the same time each day.

If you take more Celiprolol Hydrochloride than you should
If you take more Celiprolol Hydrochloride than you should, contact your doctor or go to the nearest hospital casualty department immediately. Take the container and any remaining tablets with you. The following effects may happen: feeling dizzy or weak, difficulty breathing or wheezing.

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

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.

Stop taking Celiprolol Hydrochloride and contact your doctor or go to your nearest hospital emergency department immediately if you think you may have any of the following side effects.

Rare (may affect up to 1 in 1,000 people):
- swelling of the hands, feet, ankles, face, lips or throat which may cause difficulty in swallowing or breathing. You could also notice itchy, lumps rash (hives) or nettle rash (urticaria). This may mean you are having an allergic reaction to Celiprolol Hydrochloride
- pain in your chest and feeling weak or dizzy with breathlessness and swollen ankles. These could be signs of heart problems.

Very rare (may affect up to 1 in 10,000 people)
- 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).

Not known (frequency cannot be estimated from the available data):
- 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 Erythematous (SLE). These symptoms will usually go away after Celiprolol Hydrochloride has been stopped.

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

Common (may affect up to 1 in 10 people):
- headache
- dizziness
• sleep problems
• nightmares
• tremor
• cold fingers and toes
• slowing of the heart beat
• an irregular heart rhythm or missed beats (palpitations)
• low blood pressure causing dizziness or light-headedness, including when standing up
• feeling or being sick
• stomach pain or discomfort
• muscle cramps
• feeling tired.

Rare (may affect up to 1 in 1,000 people):
• feeling depressed
• ringing in the ears
• tingling or numbness in the arms and legs
• diarrhoea or constipation
• muscle weakness
• difficulty in getting or maintaining an erection or in ejaculating (impotence)
• painful cold fingers and toes and worsening of patients with circulation problems e.g. Raynaud’s disease
• wheezing, coughing, difficulty in breathing or worsening of existing asthma, sometimes with fever, chills, dry cough and a tight feeling in your chest (pneumonitis).

Very rare (may affect up to 1 in 10,000 people):
• seeing or hearing things that are not there (hallucinations), confusion
• problems with eyesight such as blurred vision
• dryness or redness of the eye
• psoriasis or worsening of psoriasis.

Not known (frequency cannot be estimated from the available data):
• nervousness
• hot flushes
• low blood sugar level (hypoglycaemia). You may feel a sense of nervousness, shaky or sweaty
• lack of interest in sexual activities (libido)
• unusual weakness.

Blood Tests:
• the result of some blood tests may show higher level of liver enzymes than normal
• blood tests may also show abnormal levels of glucose in the blood
• blood tests may also show abnormal levels of antinuclear antibodies (ANA) in the blood.

Celiprolol hydrochloride may worsen diabetes. Patients with diabetes or an overactive thyroid gland should be aware that the symptoms of low blood sugar (hypoglycaemia) or an overactive thyroid gland (thyrotoxicosis) may be hidden by beta-blocker medicines.

If you feel more thirsty than usual, feel unusually tired or pass more urine than usual, tell your doctor as celiprolol hydrochloride may be affecting the amount of glucose (sugar) in your blood, which can lead to diabetes.

Taking Celiprolol Hydrochloride may lead to an increase in the risk of heart rhythm disorders. Your doctor may want to monitor you.

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.

Do not use this medicine after the expiry date which is stated on the label, blister or carton after ‘EXP’. The expiry date refers to the last day of that month.

There are no special storage requirements for this medicine.

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 tablets contains
Each film-coated tablet contains either 200 mg or 400 mg of the active ingredient celiprolol hydrochloride.

The other ingredients are cellulose, microcrystalline; mannitol (E421); croscarmellose sodium; magnesium stearate; hypromellose (E464) and macrogol. The 200 mg tablet coating also contains lactose monohydrate; titanium dioxide (E171); iron oxide yellow (E172); quinoline yellow lake (E104) and glycerol triacetate.

What Celiprolol Hydrochloride tablets look like and contents of the pack
The 200 mg film-coated tablets are yellow and marked ‘CL/200’ and the 400 mg film-coated tablets are white and marked ‘CL 400’, on one side. All tablets are round with a ‘G’ on the other side.

Celiprolol Hydrochloride is available in blister packs of 5, 7, 10, 14, 15, 20, 21, 28, 30, 50, 56, 60, 84, 90 & 100 film-coated tablets and polypropylene bottle with polyethylene caps in packs of 30 & 100 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Mylan, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom.

Manufacturers
Gerard Laboratories, 35/36 Baldoyle, Industrial Estate, Grange Road, Dublin 13, Ireland.
Generics [UK] Limited, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom.
Mylan Hungary Kft, H-2900 Komárom, Mylan utca 1, Hungary.

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