

## PACKAGE LEAFLET: INFORMATION FOR THE USER

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### Cilazil HCT

5 mg + 12.5 mg Film-coated tablets

CILAZAPRIL, HYDROCHLOROTHIAZIDE

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*• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.*

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*• 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 •*

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#### What is in this leaflet?

1. What Cilazil HCT is and what it is used for
2. Before you take Cilazil HCT
3. How to take Cilazil HCT
4. Possible side effects
5. How to store Cilazil HCT
6. Further information

#### 1. WHAT CILAZIL HCT IS AND WHAT IT IS USED FOR

Cilazil HCT tablets contain two active substances, cilazapril and hydrochlorothiazide. Cilazapril belongs to a group of medicines known as ACE inhibitors.

Hydrochlorothiazide belongs to the Group of medicines known as thiaside diuretics.

Cilazapril and hydrochlorothiazide are used to treat high blood pressure. When these two medicines are combined together, they are more effective than when used individually.

Cilazapril inhibits (blocks) chemical compounds that are found in the body and that are responsible for the increase in blood pressure. Such inhibition leads to lowering of blood pressure. When cilazapril is given along with diuretic (medication for urination) it has more effect, i.e. blood pressure is decreased even more.

#### 2. BEFORE YOU TAKE CILAZIL HCT TABLETS

##### **Do not take Cilazil HCT tablets:**

- If you are allergic to cilazapril, hydrochlorothiazide, medicines that belong to the group of ACE inhibitors or any ingredient of this medicine,
- if you are pregnant or lactating,

- if you have angioedema (swelling of the face, lips, mouth, tongue, or throat), which appeared as a result of taking ACE inhibitors,
- If you have difficulty passing urine (anuria),
- If you have diabetes, impaired kidney function and taking the medicine for lowering the blood pressure that contains aliskiren.

If you are not sure if you need to take Cilazil HCT, consult your doctor.

### ***Be careful with Cilazil HCT tablets***

- If you are pregnant or plan to become pregnant (pregnant women should not take this medicine);
- If you are breast-feeding or intend to breast-feed (nursing women should not take this medicine);
- If you are going to the dialysis;
- If you are taking preparations containing potassium;
- If you are planning to have surgery;
- If you have other health problems such as:
  - liver diseases,
  - kidney diseases,
  - heart disease, diseases of the blood vessels,
  - diabetes mellitus (diabetes),
  - gout,
  - a disease called Porphyria (enzymatic disorder).

If any of the above applies to you, or you are not sure, contact your doctor.

### ***Tell your doctor:***

If you are taking any of the medicines listed below, that are used for the treatment of high blood pressure:

- angiotensin II receptor antagonist (ARB) (also called sartans - such as valsartan, telmesartan, irbesartan), especially if you have kidney problems associated with type 2 diabetes - aliskiren.

A doctor can check your kidney function, blood pressure and the amount of electrolytes (e.g. potassium) in the blood at regular intervals.

See also the information under the heading "do not take Cilazil HCT tablets".

### ***Taking other medicines with Cilazil HCT tablets***

Inform your doctor about all the medicines you are taking or that you recently were taking, including the ones you have obtained without prescription, as well as other dietary preparations and food supplements, such as vitamins.

### ***Cilazil HCT tablets interact with the following medicines:***

non-steroidal anti-inflammatory medicines-medicines used for the treatment of pain, temperature, and inflammation (acetylsalicylic acid, ibuprofen, diclophenac),Diuretics-medications that are used for urination,preparations containing potassium,anti-diabetic medicines used in treating diabetes, A doctor may need to change the dose and/or take other precautions:If you are taking any angiotensin II receptor blocker (ARB) or aliskiren (see also Information under the headings "Do not take Cilazil HCT tablets" and Warnings and precautions).

### ***Pregnancy and breastfeeding***

You may not use Cilazil HCT tablets during pregnancy.

If you are planning a pregnancy or if you got pregnant while taking Cilazil HCT tablets, you must immediately inform your doctor.

### ***Driving and using machines***

HCT tablets can cause a reduced ability to drive and use machines.

Cilazil HCT tablets contain lactose. If your doctor told you that you have intolerance to some sugars, before you start taking this medicine consult your doctor.

### ***Use in children***

Safety and efficacy in children have not been established, therefore Cilazil HCT tablets are not recommended for the treatment of children.

### ***3. HOW TO TAKE CILAZIL HCT***

The usual dose for Cilazil HCT tablets is one tablet once a day.

Since taking of food does not affect absorption, Cilazil HCT tablets can be taken before or after meal. Medicine should always be taken at the same time of the day.

Do not stop the treatment with Cilazil HCT tablets until your doctor tells you to.

### ***Elderly patients***

If you are over 65, the treatment should start with half of the normal dose (1/2 tablets).

If you take more Cilazil HCT tablets than you should

If by mistake you take higher dose of Cilazil HCT tablets than you should, tell your doctor or contact the nearest hospital.

### ***If you forget to take Cilazil HCT tablets***

If you forget to take a dose of Cilazil HCT tablets, you can take it later, on the same day. If you remember the missed dose the next day, do not take it. Do not take two doses on the same day.

If you have any further questions on the use of Cilazil HCT tablets, please contact your doctor or your pharmacist.

### ***4. POSSIBLE SIDE EFFECTS***

Like all other medicines, Cilazil HCT tablets can cause side effects.

The frequency of side effects is classified as:

**Very common:** Appear in more than 1 in 10 patients

**Common:** Appear at 1 to 10 patients on 100 patients

**Uncommon:** Appear at 1 to 10 patients on 1000 patients

**Rare:** Appear at 1 to 10 patients on 10000 patients

**Very rare:** Appear at fewer than 1 patient in the 10000 patients

**Unknown frequency:** Not possible to evaluate from available data

Some side effects can be very serious and require immediate medical assistance: please contact a doctor if you experience symptoms such as;

- swelling of face, lips, tongue, throat,
- constant pain in the stomach,
- symptoms of kidney failure such as; inability to urinate or very reduced urination, drowsiness, nausea, vomiting, difficulty breathing,
- pain in the chest, heart palpitations,
- difficulty in breathing or strong cough.

Serious adverse reactions occur rarely.

**Common:**

- headache,
- dizziness,
- cough,
- nausea,
- fatigue.

**Uncommon:**

- heart palpitations,
- disorder in the digestion,
- skin rash
- jaundice (yellowing of the skin),
- higher sensitivity to light,
- the emergence of cramps in muscles,
- sexual dysfunction.

**Tell your doctor if laboratory analyses find:**

- reduced number of white blood cells (leukocytes) and blood platelets (thrombocytes),
- increased value of liver enzymes,
- deviations in the tested parameters (such as urea, creatinine, cholesterol)
- anemia

**Tell your doctor if you have:**

- inflammation of the pancreas,
- inflammation of the lungs and the pulmonary edema (accumulating liquid in the lungs),
- anorexia nervosa (an eating disorder).

**Reporting of side effects**

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

**5. HOW TO STORE CILAZIL HCT**

Keep out of reach and sight of children.

Store at temperatures below 25 ° C.

The shelf life of the medicinal product is 3 years.

Cilazil HCT tablets must not be used after the expiry date specified on the package.

**6. FURTHER INFORMATION****What do Cilazil HCT tablets contain?**

One film coated tablet contains 5 mg of cilazapril in form of cilazapril hydrate and 12.5 mg of hydrochlorothiazide.

**The other ingredients are:** lactose hydrate; starch; crospovidone; TALC; sodium Stearyl fumarate; Poly (vinyl alcohol) partially hydrogenated; macrogol 3350; titanium dioxide (E171); iron oxide yellow (F172); red iron oxide (E172).

**Pharmaceutical form and contents of the pack**

Cilazil HCT tablets come in a pack of 30 (3 x 10) film coated tablets in blister, in a box.

***Regime of dispensing***

The medicine is issued on doctor's prescription

***Manufacturer***

PLIVA Hrvatska d.o.o.  
Prilaz Baruna Filipovića 25  
10 000 Zagreb, Croatia

***Manufacturer of the medicinal product***

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Prilaz Baruna Filipovića 25  
10 000 Zagreb, Croatia