PACKAGE LEAFLET: INFORMATION FOR THE USER

Blopress Plus 8 mg/12.5 mg tablets
Blopress Plus 16 mg/12.5 mg tablets
Blopress Plus 32 mg/12.5 mg tablets
Blopress Plus 32 mg/25 mg tablets

candesartan cilexetil/hydrochlorothiazide

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. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. WHAT BLOPRESS PLUS IS AND WHAT IT IS USED FOR

The name of your medicine is Blopress Plus. It is used for treating high blood pressure (hypertension) in adult patients. It contains two active ingredients: candesartan cilexetil and hydrochlorothiazide. These work together to lower your blood pressure.

- Candesartan cilexetil belongs to a group of medicines called angiotensin II receptor antagonists. It makes your blood vessels relax and widen. This helps to lower your blood pressure.
- Hydrochlorothiazide belongs to a group of medicines called diuretics (water tablets). It helps your body to get rid of water and salts like sodium in your urine. This helps to lower your blood pressure.

Your doctor may prescribe Blopress Plus if your blood pressure has not been properly controlled by candesartan cilexetil or hydrochlorothiazide alone.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE BLOPRESS PLUS

Do not take Blopress Plus:
- if you are allergic to candesartan cilexetil or hydrochlorothiazide or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic to sulphonamide medicines. If you are not sure if this applies to you, please ask your doctor.
- if you are more than 3 months pregnant (it is also better to avoid Blopress Plus in early pregnancy – see pregnancy section).
- if you have severe kidney problems.

- if you have severe liver disease or biliary obstruction (a problem with the drainage of the bile from the gall bladder).
- if you have persistently low levels of potassium in your blood.
- if you have persistently high levels of calcium in your blood.
- if you have ever had gout.
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

If you are not sure if any of these apply to you, talk to your doctor or pharmacist before taking Blopress Plus.

Warnings and precautions
Talk to your doctor before taking Blopress Plus:
- if you have diabetes.
- if you have heart, liver or kidney problems.
- if you have recently had a kidney transplant.
- if you are vomiting, have recently had severe vomiting, or have diarrhoea.
- if you have a disease of the adrenal gland called Conn's syndrome (also called primary hyperaldosteronism).
- if you have ever had a disease called systemic lupus erythaematosus (SLE).
- if you have low blood pressure.
- if you have ever had a stroke.
- if you have ever had allergy or asthma.
- you must tell your doctor if you think you are (or might become) pregnant. Blopress Plus is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see pregnancy section).
- if you are taking any of of the following medicines used to treat high blood pressure:
  - an "ACE inhibitor" (for example enalapril, lisinopril, ramipril), in particular if you have diabetes-related kidney problems
  - aliskiren.
- if you have had skin cancer or if you develop an unexpected skin lesion during the treatment. Treatment with hydrochlorothiazide, particularly long term use with high doses, may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer). Protect your skin from sun exposure and UV rays while taking Blopress Plus.
- if you experience a decrease in vision or eye pain. These could be symptoms of fluid accumulation in the vascular layer of the eye (choroidal effusion) or an increase of pressure in your eye and can happen within hours to weeks of taking Blopress Comp. This can lead to permanent vision loss, if not treated. If you earlier have had a penicillin or sulfonamide allergy, you can be at higher risk of developing this.
- If you experienced breathing or lung problems (including inflammation or fluid in the lungs) following hydrochlorothiazide intake in the past. If you develop any severe shortness of breath or difficulty breathing after taking Blopress Plus, seek medical attention immediately.

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

See also information under the heading "Do not take Blopress Plus".

Your doctor may want to see you more often and do some tests if you have any of these conditions.

If you are going to have an operation, tell your doctor or dentist that you are taking Blopress Plus. This is because Blopress Plus, when combined with some anaesthetics, may cause a drop in blood pressure.

Blopress Plus may cause increased sensitivity of the skin to sun.

Use in children
There is no experience with the use of Blopress Plus in children (below the age of 18 years). Therefore Blopress Plus should not be given to children.

Other medicines and Blopress Plus
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. Blopress Plus can affect the way some other medicines work and some medicines can have an effect on Blopress Plus. If you are using certain medicines, your doctor may need to do blood tests from time to time.

In particular, tell your doctor if you are using any of the following medicines as your doctor may need to change your dose and/or take other precautions:
- Other medicines to help lower your blood pressure, including beta-blockers, diazoxide and Angiotensin Converting Enzyme (ACE) inhibitors such as enalapril, captopril, lisinopril or ramipril.
- Non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen, naproxen, diclofenac, celecoxib or etoricoxib (medicines to relieve pain and inflammation).
- Acetylsalicylic acid (if you are taking more than 3g each day) (medicine to relieve pain and inflammation).
- Potassium supplements or salt substitutes containing potassium (medicines that increase the amount of potassium in your blood).
- Calcium or Vitamin D supplements.
- Medicines to lower your cholesterol, such as colestipol or cholestyramine.
- Medicines for diabetes (tablets or insulin).
- Medicines to control your heart beat (antiarrhythmic agents) such as digoxin and beta-blockers.
- Medicines that can be affected by potassium blood levels such as some antipsychotic medicines.
- Heparin (a medicine for thinning the blood).
- Water tablets (diuretics).
- Laxatives.
- Penicillin (an antibiotic).
- Amphotericin (for the treatment of fungal infections).
- Lithium (a medicine for mental health problems).
- Steroids such as prednisolone.
- Pituitary hormone (ACTH)
- Medicines to treat cancer.
- Amantadine (for the treatment of Parkinson's disease or for serious infections caused by viruses).
- Barbiturates (a type of sedative, also used to treat epilepsy).
- Carbenoxolone (for treatment of oesophageal disease, or oral ulcers).
- Anticholinergic agents such as atropine and biperiden.
- Cyclosporine, a medicine used for organ transplant to avoid organ rejection.
- Other medicines that may lead to enhancement of the antihypertensive effect such as baclofen (a medicine for relief of spasticity), amifostin (used in cancer treatment) and some antipsychotic medicines.
- If you are taking an ACE inhibitor or aliskiren (see also information under the heading "Do not take Blopress Plus:" and "Warnings and precautions").

Blopress Plus with food, drink and alcohol
- You can take Blopress Plus with or without food.
- When you are prescribed Blopress Plus, discuss with your doctor before drinking alcohol. Alcohol may make you feel faint or dizzy.

Pregnancy and breast-feeding

Pregnancy

You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking Blopress Plus before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Blopress Plus. Blopress Plus is not recommended in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

Breast-feeding

Tell your doctor if you are breast-feeding or about to start breast-feeding. Blopress Plus is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is newborn, or was born prematurely.

Driving and using machines

Some people may feel tired or dizzy when taking Blopress Plus. If this happens to you, do not drive or use any tools or machines.

Blopress Plus contains lactose. Lactose is a type of sugar. 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 BLOPRESS PLUS

Always take Blopress Plus exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. It is important to keep taking Blopress Plus every day.
The recommended dose of Blopress Plus is one tablet once a day.
Swallow the tablet with a drink of water.
Try to take the tablet at the same time each day. This will help you to remember to take it.

Blopress Plus 8/12.5mg and 16/12.5mg tablets: The tablet can be divided into equal doses.
Blopress Plus 32/12.5mg and 32/25mg tablets: The score line is only there to help you break the tablet if you have difficulty swallowing it whole.

If you take more Blopress Plus than you should

If you take more Blopress Plus than prescribed by your doctor, contact a doctor or pharmacist immediately for advice.

If you forget to take Blopress Plus

Do not take a double dose to make up for a forgotten tablet. Just take the next dose as normal.

If you stop taking Blopress Plus

If you stop taking Blopress Plus, your blood pressure may increase again. Therefore do not stop taking Blopress Plus without first talking to your doctor.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Blopress Plus can cause side effects, although not everybody gets them. It is important that you are aware of what these side effects may be. Some of the side effects of Blopress Plus are caused by candesartan cilexetil and some are caused by hydrochlorothiazide.

Stop taking Blopress Plus and seek medical help immediately if you have any of the following allergic reactions:

- difficulties in breathing, with or without swelling of the face, lips, tongue and/or throat

- swelling of the face, lips, tongue and/or throat, which may cause difficulties in swallowing
- severe itching of the skin (with raised lumps)

Blopress Plus may cause a reduction in number of white blood cells. Your resistance to infection may be decreased and you may notice tiredness, an infection or a fever. If this happens contact your doctor. Your doctor may occasionally do blood tests to check whether Blopress Plus has had any effect on your blood (agranulocytosis).

Other possible side effects include:

Common (affects 1 to 10 users in 100)
- Changes in blood test results:
    - A reduced amount of sodium in your blood. If this is severe then you may notice weakness, lack of energy, or muscle cramps.
    - An increased or reduced amount of potassium in your blood, especially if you already have kidney problems or heart failure. If this is severe, you may notice tiredness, weakness, irregular heartbeat or pins and needles.
    - An increased amount of cholesterol, sugar, or uric acid in your blood.
- Sugar in your urine.
- Feeling dizzy/spinning sensation or weak.
- Headache.
- Respiratory infection.

Uncommon (affects less than 1 user in 100)
- Low blood pressure. This may make you feel faint or dizzy.
- Loss of appetite, diarrhoea, constipation, stomach irritation.
- Skin rash, lumpy rash (hives), rash caused by sensitivity to sunlight.

Rare (affects less than 1 user in 1,000)
- Jaundice (yellowing of the skin or the whites of your eyes). If this happens to you, contact your doctor immediately.
- Effects on how your kidneys work, especially if you have kidney problems or heart failure.
- Difficulty in sleeping, depression, being restless.
- Tingling or prickling in your arms or legs.
- Blurred vision for a short time.
- Abnormal heart beat.
- Breathing difficulties (including lung inflammation and fluid in the lungs).
- High temperature (fever).
- Inflammation of the pancreas. This causes moderate to severe pain in the stomach.
- Muscle cramps.
- Damage to blood vessels causing red or purple dots in the skin.
- A reduction in your red or white blood cells or platelets. You may notice tiredness, an infection, fever or easy bruising.
- A severe rash that develops quickly, with blistering or peeling of the skin and possibly blistering in the mouth.
- Worsening of existing lupus erythaematosus-like reactions or appearance of unusual skin reactions.

Very rare (affects less than 1 user in 10,000)
- Swelling of the face, lips, tongue and/or throat.
- Acute respiratory distress (signs include severe shortness of breath, fever, weakness, and confusion).
- Itching.

- Back pain, pain in joints and muscles.
- Changes in how your liver is working, including inflammation of the liver (hepatitis). You may notice tiredness, yellowing of your skin and the whites of your eyes and flu like symptoms.
- Cough.
- Nausea.

Not known (frequency cannot be estimated from the available data)
- Sudden shortsightedness
- Decrease in vision or pain in your eyes due to high pressure (possible signs of fluid accumulation in the vascular layer of the eye (choroidal effusion) or acute angle-closure glaucoma)
- Skin and lip cancer (Non-melanoma skin cancer)

Reporting of side effects
If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE BLOPRESS PLUS

- Keep out of the sight and reach of children.
- This medicinal product does not require any special storage conditions.
- Do not use Blopress Plus after the expiry date which is stated on the carton label and blister foil after (EXP). The expiry date refers to the last day of that month.

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

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Blopress Plus contains

- The active substances of Blopress Plus tablets are candesartan cilexetil and hydrochlorothiazide.
  Blopress 8 mg/12.5 mg tablets contain 8 mg of candesartan cilexetil and 12.5 mg of hydrochlorothiazide.
  Blopress Plus 16 mg/12.5 mg tablets contain 16 mg of candesartan cilexetil and 12.5 mg of hydrochlorothiazide.
  Blopress Plus 32 mg/12.5 mg tablets contain 32 mg of candesartan cilexetil and 12.5 mg of hydrochlorothiazide.
  Blopress Plus 32 mg/25 mg tablets contain 32 mg candesartan cilexetil and 25 mg of hydrochlorothiazide.

- The other ingredients are carmellose calcium, hydroxypropylcellulose, lactose monohydrate, magnesium stearate, maize starch, macrogol, yellow iron oxide E172 (32 mg/12.5 mg tablet) and red iron oxide E172 (16 mg/12.5 mg and 32 mg/25 mg tablet).

What Blopress Plus looks like and contents of the pack

- Blopress Plus 8 mg/12.5 mg tablets are white to off-white, oval flat tablets approximately 8.5 mm by 5.1 mm with a score and debossing 8/C on both sides.
- Blopress Plus 16 mg/12.5 mg tablets are light pink, oval, flat tablets approximately 8.5 mm by 5.1 mm with a score and debossing 16/C on both sides.

- Blopress Plus 32 mg/12.5mg tablets are light yellow, oval, flat tablets approximately 11 mm by 6.5 mm with debossing 32 | C1 on both sides.
- Blopress Plus 32 mg/25mg tablets are light pink, oval, flat tablets approximately 11 mm by 6.5 mm with debossing 32 | C2 on both sides.

Blopress Plus tablets come in blister packs containing 7, 14, 20, 28, 50, 56, 98, 98 x 1 (single dose unit, only applicable to Blopress 8 mg/12.5 mg), 100 or 300 tablets and calendar packs of 7, 14, 28, 56 and 98 tablets.

Not all pack sizes may be marketed in every country.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

CHEPLAPHARM Arzneimittel GmbH
Ziegelhof 24
17489 Greifswald
Germany

Manufacturer

Delpharm Novara S.r.l, Via Crosa 86, 28065 Cerano (No), Italy or by
Takeda Ireland Ltd., Bray Business Park, Kilruddery, Co. Wicklow, Ireland (only applicable to Blopress Plus 8 mg/12,5 mg and Blopress Plus 16/12,5 mg).

This medicinal product is authorised in the Member States of the EEA under the following names:

Name	Member State
Blopress Comp 8 mg/12.5 mg Blopress Comp 16 mg/12.5 mg Blopress Comp 32mg/12.5mg Blopress Comp 32mg/25mg	Sweden
Blopress Plus 8 mg/12,5 mg Blopress Plus 16 mg/12,5 mg Blopress Plus 32mg/12,5 mg Blopress Plus 32mg/25 mg	Austria
Blopress 8 mg Plus 12,5 mg Blopress 16 mg Plus 12,5 mg Blopress 32 mg Plus 12,5 mg Blopress forte 32 mg Plus 25 mg	Germany
Blopress Plus 8 mg/12.5 mg Blopress Plus 16 mg/12.5 mg Blopress Plus 32mg/12.5 mg Blopress Plus 32mg/25 mg	Ireland
Blopresid 8 mg/12,5mg Blopresid 16 mg/12,5mg Blopresid 32 mg/12,5mg Blopresid 32 mg/25mg	Italy
Blopress Plus 16/12,5 mg Blopress Plus 32/12,5 mg Blopress Forte 32/25 mg	Spain

Blopress 8 mg + 12,5mg Blopress 16 mg + 12,5 mg Blopress 32 mg + 12,5 mg Blopress 32 mg + 25 mg	Portugal
CoKenzen 8 mg/12,5 mg CoKenzen 16 mg/12,5 mg	France

This leaflet was last revised in December 2021.

Other sources of information

Detailed information on this medicine is available on the website of the HPRA.