# BEVACOMB 5 mg/80 mg FILM-COATED TABLETS
# BEVACOMB 5 mg/160 mg FILM-COATED TABLETS
# BEVACOMB 10 mg/160 mg FILM-COATED TABLETS

**amlodipine/valsartan**

PACKAGE LEAFLET: INFORMATION FOR THE USER

**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 Bevacomb is and what it is used for

Bevacomb tablets contain two substances called amlodipine and valsartan. Both of these substances help to control high blood pressure.
- Amlodipine belongs to a group of substances called "calcium channel blockers". Amlodipine stops calcium from moving into the blood vessel wall which stops the blood vessels from tightening.
- Valsartan belongs to a group of substances called "angiotensin-II receptor antagonists". Angiotensin II is produced by the body and makes the blood vessels tighten, thus increasing the blood pressure. Valsartan works by blocking the effect of angiotensin II.

This means that both of these substances help to stop the blood vessels tightening. As a result, the blood vessels relax and blood pressure is lowered.

Bevacomb is used to treat high blood pressure in adults whose blood pressure is not controlled enough with either amlodipine or valsartan on its own.

## 2 What you need to know before you take Bevacomb

**Do not take Bevacomb**
- if you are allergic to amlodipine or to any other calcium channel blockers. This may involve itching, reddening of the skin or difficulty in breathing.
- if you are allergic to valsartan or any of the other ingredients of this medicine (listed in section 6). If you think you may be allergic, talk to your doctor before taking Bevacomb.
- if you have severe liver problems or bile problems such as biliary cirrhosis or cholestasis.
- if you are more than 3 months pregnant. (It is also better to avoid Bevacomb in early pregnancy, see Pregnancy section).
- if you have severe low blood pressure (hypotension).
- if you have narrowing of the aortic valve (aortic stenosis) or cardiogenic shock (a condition where your heart is unable to supply enough blood to the body).
- if you suffer from heart failure after a heart attack.
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

**If any of the above applies to you, do not take Bevacomb and talk to your doctor.**

**Warnings and precautions**
Talk to your doctor before taking Bevacomb:
- if you have been sick (vomiting or diarrhoea).
- if you have liver or kidney problems.
- if you have had a kidney transplant or if you had been told that you have a narrowing of your kidney arteries.
- if you have a condition affecting the renal glands called "primary hyperaldosteronism".
- if you have had heart failure or have experienced a heart attack. Follow your doctor's instructions for the starting dose carefully. Your doctor may also check your kidney function.
- if your doctor has told you that you have a narrowing of the valves in your heart (called "aortic or mitral stenosis") or that the thickness of your heart muscle is abnormally increased (called "obstructive hypertrophic cardiomyopathy").
- if you have experienced swelling, particularly of the face and throat, while taking other medicines (including angiotensin converting enzyme inhibitors). If you get these symptoms, stop taking Bevacomb and contact your doctor straight away. You should never take Bevacomb again.
- if you are taking any 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.

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 Bevacomb".

**If any of these apply to you, tell your doctor before taking Bevacomb.**

**Children and adolescents**
The use of Bevacomb in children and adolescents is not recommended (aged below 18 years old).

**Other medicines and Bevacomb**
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Your doctor may need to change your dose and/or to take other precautions. In some cases you may have to stop taking one of the medicines. This applies especially to the medicines listed below:
- ACE inhibitors or aliskiren (see also information under the headings "Do not take Bevacomb" and "Warnings and precautions");
- diuretics (a type of medicine also called "water tablets" which increases the amount of urine you produce);
- lithium (a medicine used to treat some types of depression);
- potassium-sparing diuretics, potassium supplements, salt substitutes containing potassium and other substances that may increase potassium levels;
- certain types of painkillers called non-steroidal anti-inflammatory medicines (NSAIDs) or selective cyclooxygenase-2 inhibitors (COX-2 inhibitors). Your doctor may also check your kidney function;
- anticonvulsant agents (e.g. carbamazepine, phenobarbital, phenytoin, fosphenytoin, primidone);
- St. John's wort;
- nitroglycerin and other nitrates, or other substances called "vasodilators";
- medicines used for HIV/AIDS (e.g. ritonavir, indinavir, nelfinavir);
- medicines used to treat fungal infections (e.g. ketoconazole, itraconazole);
- tacrolimus (used to control your body's immune response, enabling your body to accept the transplanted organ).
- medicines used to treat bacterial infections (such as rifampicin, erythromycin, talithromycin);
- clarithromycin (for infections caused by bacteria);
- verapamil, diltiazem (heart medicines);
- simvastatin (a medicine used to control high cholesterol levels);
- dantrolene (infusion for severe body temperature abnormalities);
- medicines used to protect against transplant rejection (ciclosporin).

**Bevacomb with food and drink**
Grapefruit and grapefruit juice should not be consumed by people who are taking Bevacomb. This is because grapefruit and grapefruit juice can lead to an increase in the blood levels of the active substance amlodipine, which can cause an unpredictable increase in the blood pressure lowering effect of Bevacomb.

**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 Bevacomb before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Bevacomb. Bevacomb is not recommended in early pregnancy (first 3 months), 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**. Bevacomb 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.

Ask your doctor or pharmacist for advice before taking any medicine.

**Driving and using machines**
This medicine may make you feel dizzy. This can affect how well you can concentrate. So, if you are not sure how this medicine will affect you, do not drive, use machinery, or do other activities that you need to concentrate on.

## 3 How to take Bevacomb

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure. This will help you get the best results and lower the risk of side effects.

The usual dose of Bevacomb is one tablet per day.
- It is preferable to take your medicine at the same time each day.

- Swallow the tablets with a glass of water.
- You can take Bevacomb with or without food. Do not take Bevacomb with grapefruit or grapefruit juice.

Depending on how you respond to the treatment, your doctor may suggest a higher or lower dose. Do not exceed the prescribed dose.

**Bevacomb and older people (age 65 years or over)**
Your doctor should exercise caution when increasing your dose.

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

**If you take more Bevacomb than you should**
If you have taken too many tablets of Bevacomb, or if someone else has taken your tablets, consult a doctor immediately.

**If you forget to take Bevacomb**
If you forget to take this medicine, take it as soon as you remember. Then take your next dose at its usual time. However, if it is almost time for your next dose, skip the dose you missed. Do not take a double dose to make up for a forgotten tablet.

**If you stop taking Bevacomb**
Stopping your treatment with Bevacomb may cause your disease to get worse. Do not stop taking your medicine unless your doctor tells you to.

## 4 Possible side effects

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

**Some side effects can be serious and need immediate medical attention:**
A few patients have experienced these serious side effects *(may affect up to 1 in 1,000 people)*. **If any of the following happen, tell your doctor straight away:**
Allergic reaction with symptoms such as rash, itching, swelling of face or lips or tongue, difficulty breathing, low blood pressure (feeling of faintness, light-headedness).

**Other possible side effects of Bevacomb:**
*Common (may affect up to 1 in 10 people):* Influenza (flu); blocked nose, sore throat and discomfort when swallowing; headache; swelling of arms, hands, legs, ankles or feet; tiredness; asthenia (weakness); redness and warm feeling of the face and/or neck.
*Uncommon (may affect up to 1 in 100 people):* Dizziness; nausea and abdominal pain; dry mouth; drowsiness, tingling or numbness of the hands or feet; vertigo; fast heart beat including palpitations; dizziness on standing up; cough; diarrhoea; constipation; skin rash, redness of the skin; joint swelling, back pain; pain in joints.
*Rare (may affect up to 1 in 1,000 people):* Feeling anxious; ringing in the ears (tinnitus); fainting; passing more urine than normal or feeling more of an urge to pass urine; inability to get or maintain an erection; sensation of heaviness; low blood pressure with symptoms such as dizziness, light- headedness; excessive sweating; skin rash all over your body; itching; muscle spasm.
**If any of these affect you severely, tell your doctor.**

**Side effects reported with amlodipine or valsartan alone and either not observed with Bevacomb or observed with a higher frequency than with Bevacomb:**

***Amlodipine***

**Consult a doctor immediately if you experience any of the following very rare, severe side effects after taking this medicine:**
- Sudden wheeziness, chest pain, shortness of breath or difficulty in breathing.
- Swelling of eyelids, face or lips.
- Swelling of the tongue and throat which causes great difficulty breathing.
- Severe skin reactions including intense skin rash, hives, reddening of the skin over your whole body, severe itching, blistering, peeling and swelling of the skin, inflammation of the mucous membranes (Stevens-Johnson Syndrome) or other allergic reactions.
- Heart attack, abnormal heart beat.
- Inflamed pancreas, which may cause severe abdominal and back pain accompanied with feeling of being very unwell.

The following side effects have been reported. If any of these cause you problems or if they last for more than one week, you should contact your doctor.

*Common (may affect up to 1 in 10 people):* Dizziness, sleepiness; palpitations (awareness of your heart beat); flushing, ankle swelling (oedema); abdominal pain, feeling sick (nausea).
*Uncommon (may affect up to 1 in 100 people):* Mood changes, anxiety, depression, sleeplessness, trembling, taste abnormalities, fainting, loss of pain sensation; visual disturbances, visual impairment, ringing in the ears; low blood pressure; sneezing/runny nose caused by inflammation of the lining of the nose (rhinitis); indigestion, vomiting (being sick); hair loss, increased sweating, itchy skin, skin discolouration; disorder in passing urine, increased need to urinate at night, increased number of times of passing urine; inability to obtain an erection, discomfort or enlargement of the breasts in men, pain, feeling unwell, muscle pain, muscle cramps; weight increase or decrease.
*Rare (may affect up to 1 in 1,000 people):* Confusion.
*Very rare (may affect up to 1 in 10,000 people):* Decreased number of white blood cells, decrease in blood platelets which may result in unusual bruising or easy bleeding (red blood cell damage); excess sugar in blood (hyperglycaemia); swelling of the gums, abdominal bloating (gastritis); abnormal liver function, inflammation of the liver (hepatitis), yellowing of the skin (jaundice), liver enzyme increase which may have an effect on some medical tests; increased muscle tension; inflammation of blood vessels often with skin rash, sensitivity to light; disorders combining rigidity, tremor and/or movement disorders.
*Not known (frequency cannot be estimated from the available data):* Trembling, rigid posture, mask-like face, slow movements and a shuffling, unbalanced walk.

***Valsartan***

*Not known (frequency cannot be estimated from the available data):* Decrease in red blood cells, fever, sore throat or mouth sores due to infections; spontaneous bleeding or bruising; high level of potassium in the blood; abnormal liver test results; decreased renal functions and severely decreased renal functions; swelling mainly of the face and the throat; muscle pain; rash, purplish-red spots; fever; itching; allergic reaction; blistering skin (sign of a condition called dermatitis bullous).

If you experience any of these, tell your doctor straight away.

**Reporting of side effects**
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.
By reporting side effects you can help provide more information on the safety of this medicine.

## 5 How to store Bevacomb

**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 carton and blister. The expiry date refers to the last day of that month.

Do not store above 30°C.

Do not use this medicine if you notice that the pack is damaged or shows signs of tampering.

## 6 Contents of the pack and other information

**What Bevacomb contains**
- The active substances of Bevacomb 5 mg/80 mg tablets are amlodipine (as amlodipine besilate) and valsartan. Each tablet contains 5 mg amlodipine and 80 mg valsartan.
- The active substances of Bevacomb 5 mg/160 mg tablets are amlodipine (as amlodipine besilate) and valsartan. Each tablet contains 5 mg amlodipine and 160 mg valsartan.
- The active substances of Bevacomb 10 mg/160 mg tablets are amlodipine (as amlodipine besilate) and valsartan. Each tablet contains 10 mg amlodipine and 160 mg valsartan.
- The other ingredients are cellulose microcrystalline, povidone, croscarmellose sodium, talc, magnesium stearate, hypromellose, macrogol, titanium dioxide (E171); [*5mg/80mg and 5mg/160mg tablets*]: iron oxide, yellow (E172).

**What Bevacomb looks like and contents of the pack**
Bevacomb 5 mg/80 mg tablets are 8mm, round, biconvex and yellow with “I” on one side and “LD” on the other side.

Bevacomb 5 mg/160 mg tablets are 13.5mm long and 7 mm wide, oval, biconvex and yellow with “2” on one side and “LD” on the other side.

Bevacomb 10 mg/160 mg tablets are 13.5mm long and 7 mm wide, oval, biconvex and white with “3” on one side and “LD” on the other side.
Pack sizes: 7, 14, 28, 30, 56, 60, 90, 98 or 280 film-coated tablets

Not all pack sizes may be available in your country.

**Marketing Authorisation Holder**
Teva B.V.
Swensweg 5
2031GA Haarlem
Netherlands

**Manufacturer**
Balkanpharma Dupnitza AD
3 Samokovsko Shosse Str.
Dupnitza 2600,
Bulgaria

**This leaflet was last revised in April 2017.**

**Other sources of information**
Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu

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