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PACKAGE LEAFLET : INFORMATION FOR THE USER

Vascace[®] 0.5 mg Film-coated Tablets

Vascace[®] 1 mg Film-coated Tablets

Vascace[®] 2.5 mg Film-coated Tablets

Vascace[®] 5 mg Film-coated Tablets

Cilazapril

Roche

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. 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**
- What Vascace is and what it is used for
 - What you need to know before you take Vascace
 - How to take Vascace
 - Possible side effects
 - How to store Vascace
 - Contents of the pack and other information

1. What Vascace is and what it is used for

Vascace contains the active substance cilazapril.

Vascace is used to treat the following:

- High blood pressure (hypertension)
- Chronic (long-term) heart failure.

Cilazapril belongs to a group of medicines called ‘ACE inhibitors’ (Angiotensin Converting Enzyme Inhibitors). It works by making your blood vessels relax and widen. This helps to lower your blood pressure. It also makes it easier for your heart to pump blood around your body if you have chronic heart failure.

Your doctor may give you other medicines as well as Vascace to help treat your condition.

2. What you need to know before you take Vascace

- Do not take Vascace**
- if you are allergic (hypersensitive) to cilazapril or any of the other ingredients of this medicine (listed in section 6).
 - if you are allergic (hypersensitive) to other ACE inhibitor medicines. These include captopril, enalapril, lisinopril and ramipril.
 - if you have had a serious side effect called angioedema after taking other ACE inhibitor medicines, hereditary angioedema or angioedema of unknown cause. The signs include swelling of the face, lips, mouth or tongue. There is an increased risk of angioedema if you are taking some oral medicines to treat diabetes or medicines to suppress the immune system.
 - if you are more than 3 months pregnant. (It is also better to avoid Vascace in early pregnancy - see the sections on ‘Pregnancy’ and ‘Breast-feeding’.)
 - if you have diabetes mellitus or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

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

- Warnings and precautions**
- Talk to your doctor or pharmacist before taking Vascace
- if you have a heart problem. Vascace is not suitable for people with certain types of heart problem.
 - if you have had a stroke or have problems with the blood supply to your brain.
 - if you are taking any of the following medicines used to treat high blood pressure:
 - an “angiotensin II -receptor blocker” (ARBs) (also known as sartans – for example valsartan, telmisartan, irbesartan), 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 Vascace”.
- if you are taking medicines to suppress the immune system.
 - if you have severe liver problems or if you develop jaundice.
 - if you have kidney problems or have a problem with the blood supply to your kidneys called renal artery stenosis.
 - if you are on kidney dialysis.
 - if you have recently been vomiting or have had diarrhoea.
 - if you are on a diet to control how much salt (sodium) you take in.
 - if you are planning to have treatment to reduce your allergy to bee or wasp stings (desensitization).
 - if you are planning to have an operation (including dental surgery). This is because some anaesthetics can lower your blood pressure and it may become too low.
 - if you have a build up of fluid in your abdomen (ascites).
 - if you have diabetes and are taking medicines to treat diabetes.
 - if you have a collagen vascular disease.
 - if you undergo LDL apheresis with dextrane sulphate.

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

You must tell your doctor if you think you are (or might become) pregnant. Vascace 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 the sections on ‘Pregnancy’ and ‘Breast-feeding’).

Children and adolescents

Vascace is not recommended for use in children.

Other medicines and Vascace

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

- Your doctor may need to change your dose and/or to take other precautions: If you are taking an angiotensin II receptor blocker (ARB) or aliskiren (see also information under the headings “Do not take Vascace” and “Warnings and precautions”).
- In particular, talk to your doctor or pharmacist if you are taking, have recently taken or might take any of the following medicines:
- Diuretics (‘water tablets’) – see ‘High blood pressure (hypertension)’ in section 3 on ‘How to take Vascace’.
 - Any medicines used to treat high blood pressure.
 - Medicines called ‘non-steroidal anti-inflammatory drugs’ (NSAIDs). These include aspirin, indometacin and ibuprofen.
 - Insulin or other medicines used to treat diabetes.
 - Lithium (used to treat depression).
 - Steroid medicines (such as hydrocortisone, prednisolone and dexamethasone) or other medication which suppress the immune system.
 - Potassium supplements (including salt substitutes) or potassium-sparing diuretics.
 - Aldosterone antagonists.
 - Sympathomimetics.
 - Anaesthetics, narcotics.
 - Tricyclic antidepressants, antipsychotics.
 - Gold compounds (used to treat rheumatoid arthritis).

Vascace with food and drink

Tell your doctor or pharmacist if you are taking food supplements that contain potassium.

Pregnancy

If you are pregnant, think you are pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. Your doctor will normally advise you to stop taking Vascace before you become pregnant, or as soon as you know you are pregnant, and will advise you to take another medicine instead of Vascace. Vascace 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

If you are breast-feeding or about to start breast-feeding ask your doctor for advice before taking the medicine. Vascace 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

You may feel dizzy while taking Vascace. This is more likely to happen when you first start treatment. If you feel dizzy, do not drive or use any tools or machines.

Vascace contains lactose

Vascace contains lactose, which is a type of sugar. If you cannot tolerate or digest some sugars (e.g. if you have a galactose intolerance, a Lapp lactase deficiency or have problems with glucose-galactose absorption), talk to your doctor before taking this medicine.

3. How to take Vascace

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

- High blood pressure (hypertension)**
- The usual **starting** dose for adults is 1 mg per day.
 - Your doctor will then increase your dose until your blood pressure is under control - the usual maintenance dose is between 2.5 mg and 5 mg per day.
 - If you have problems with your kidneys, or if you are elderly, your doctor may give you a lower dose.
 - If you are already taking a diuretic (‘water tablets’), your doctor may tell you to stop taking it about 3 days before you start taking Vascace. The usual starting dose of Vascace is then 0.5 mg per day. Your doctor will then increase your dose until your blood pressure is under control.

Please turn over ➡

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Chronic heart failure

- The usual **starting** dose is 0.5 mg per day.
- Your doctor will then increase the dose - the usual maintenance dose is between 1 mg and 2.5 mg per day.
- If you have problems with your kidneys, or if you are elderly, your doctor may give you a lower dose.
- If you have liver cirrhosis without ascites, your doctor will not give you a dose of more than 0.5 mg per day and will carefully monitor your blood pressure.

Taking this medicine

- Swallow each tablet with a drink of water.
- It does not matter what time of day you take Vascace. However, always take it around the same time.
- Vascace may be taken before or after a meal.
- The tablet can be divided into equal doses.

If you take more Vascace than you should

If you take more Vascace than you should, or if someone else takes your Vascace tablets, talk to a doctor or go to a hospital straight away. Take the medicine pack with you.

The following effects may happen: feeling dizzy or light-headed, shallow breathing, cold clammy skin, being unable to move or speak and a slow heart beat.

If you forget to take Vascace

- If you forget to take a dose, skip the missed dose. Then take the next dose when it is due.
- Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

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

4. Possible side effects

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

Some side effects can be serious and need immediate medical attention:

If you have a severe reaction called angioedema or allergic reaction, stop taking Vascace and see a doctor straight away. The signs may include:

- Sudden swelling of the face, throat, lips or mouth. This can make it difficult to breathe or swallow.

If you get one of the following blood problems talk to a doctor straight away:

- Low numbers of red blood cells (anaemia). The signs include feeling tired, pale skin, fast or uneven heart beat (palpitations) and feeling short of breath.
- Low numbers of all types of white blood cells (neutropenia, agranulocytosis). The signs include increased number of infections, for example in your mouth, gums, throat and lungs.
- Low numbers of platelets in your blood (thrombocytopenia). The signs include bruising easily and nose bleeds.

Other possible side effects

Common (affects less than 1 in 10 people)

- Feeling dizzy
- Coughing
- Nausea
- Feeling tired
- Headache

Uncommon

(affects less than 1 in 100 people)

- Low blood pressure. This may make you feel weak, dizzy or light-headed and may lead to blurred vision and fainting. Excessive lowering of blood pressure may increase the chance of heart attack or stroke in certain patients
- Increased heart rate
- Feeling weak
- Pains in the chest
- Breathing problems, including shortness of breath and tightness in the chest
- A runny or blocked nose and sneezing (rhinitis)
- Dry or swollen mouth
- Lack of appetite
- Change in the way things taste
- Loose stools and vomiting
- Skin rash (which may be severe)
- Muscle cramps or pain in your muscles or joints
- Impotence
- Sweating more than usual
- Flushing
- Sleeping problems

Rare

(affects less than 1 in 1,000 people)

- Blood tests showing a decrease in the number of red blood cells, white blood cells or platelets (anaemia, neutropenia, agranulocytosis and thrombocytopenia)
- A type of severe allergic reaction (anaphylaxis)
- Cerebral ischaemia, transient ischaemic attack, ischaemic stroke (may occur if blood pressure becomes too low)
- Myocardial infarction (may occur if blood pressure becomes too low)
- Irregular heartbeat
- Interstitial lung disease
- A disorder resembling systemic lupus erythematosus
- Pins and needles or numbness in the hands or feet
- Wheezing
- A feeling of fullness or a throbbing pain behind the nose, cheeks and eyes (sinusitis).
- Soreness of your tongue
- Pancreatitis (inflammation of the pancreas). The signs include severe pain in the stomach which spreads to your back
- Changes in the way your liver or kidneys work (shown in blood and urine tests)
- Liver problems such as hepatitis (inflammation of the liver) or liver damage
- Severe skin reactions including blistering or peeling of skin
- Increased sensitivity to light
- Hair loss (which may be temporary)
- Loosening or separation of a nail from its bed
- Breast enlargement in men

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 to:

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 the medicine.

5. How to store Vascace

Keep this medicine out of the sight and reach of children.

0.5 mg: “Do not store above 25 °C”
1 mg: “Do not store above 25 °C”
2.5 mg: “Do not store above 25 °C”
5 mg: This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the pack and blister after EXP.

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 to protect the environment.

6. Contents of the pack and other information

What Vascace contains

- The active substance in Vascace is cilazapril.
Each film-coated tablet contains:
Vascace 0.5 mg: 0.522 mg cilazapril equivalent to 0.5 mg cilazapril anhydrous
Vascace 1 mg: 1.044 mg cilazapril equivalent to 1 mg cilazapril anhydrous
Vascace 2,5 mg: 2.61 mg cilazapril equivalent to 2.5 mg cilazapril anhydrous
Vascace 5 mg: 5.22 mg cilazapril equivalent to 5 mg cilazapril anhydrous
- The other ingredients are lactose monohydrate, maize starch, hypromellose 3 cP, talc, sodium stearyl fumarate, hypromellose 6 cP, titanium dioxide (E171).
Vascace 1 mg: in addition iron oxide yellow (E 172)
Vascace 2.5 mg: in addition iron oxide yellow (E 172) and iron oxide red (E 172)
Vascace 5 mg: in addition iron oxide red (E 172)
(See section 2: Vascace contains lactose monohydrate)

What Vascace looks like and contents of the pack

Film-coated tablet:
White, oval, biconvex film-coated tablets with a score on one side and imprinted “CIL 0.5” on the other side

Light yellow, oval, biconvex film-coated tablets with a score on one side and imprinted “CIL 1” on the other side

Dull red, oval, biconvex film-coated tablets with a score on one side and imprinted “CIL 2.5” on the other side

Reddish-brown, oval, biconvex film-coated tablets with a score on one side and imprinted “CIL 5” on the other side

Vascace is supplied in blister packs containing 14, 20, 28, 30, 50, 56, 60,98 film-coated tablets or glass bottles containing 28, 100 film-coated tablets.

Not all packs sizes may be marketed.

Marketing Authorisation Holder

Roche Products Limited
6 Falcon Way
Shire Park
Welwyn Garden City
AL7 1TW
United Kingdom

Manufacturer

Roche Pharma AG
Emil-Barell-Str. 1
D-79639 Grenzach-Wyhlen
Germany

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

Austria: Inhibace “Roche”
Belgium, Bulgaria, Czech Republic, Hungary, Luxembourg, Poland, Inhibace
Germany: Dynorm
Greece, Ireland: Vascace
Italy, Portugal: Inibace

This leaflet was last revised in September 2014

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