

## PACKAGE LEAFLET: INFORMATION FOR THE USER

Ascal Brisper Cardio-Neuro 100mg effervescent tablets  
Carbasalate Calcium

**Read all of this leaflet carefully before you start using this medicine.**

- 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 symptoms are the same as yours.
- 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.

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1. What Ascal Brisper Cardio-Neuro 100mg is and what it is used for
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### **1. WHAT ASCAL BRISPER CARDIO-NEURO 100MG IS AND WHAT IT IS USED FOR**

Acetylsalicylic acid reduces platelet stickiness. This impedes the formation of clots ("small lumps of platelets") resulting in less blocking of blood vessels by these clots.

Your doctor may prescribe you Ascal Brisper Cardio-Neuro 100mg if you:

- have had a heart infarct. Ascal Brisper Cardio-Neuro 100mg is then applied to prevent another infarct;
- have unstable angina pectoris (chest pain);
- have stable angina pectoris;
- have undergone a bypass operation;
- have had a brain infarction or a stroke, or a TIA (mini-stroke), but not a brain haemorrhage.

In all these conditions, the formation of platelet clots must be prevented. Ascal Brisper Cardio-Neuro 100mg is a medicine with a preventive action. This means that patients with the above conditions have a reduced risk of a second blood flow impairment, if they use a medicine like Ascal Brisper Cardio-Neuro 100mg in accordance with the prescription.

#### ***Elaborate description of condition in which Ascal Brisper Cardio-Neuro 100mg is used***

The blood contains small cells, the platelets. The platelets play an important role in blood coagulation. They clot when a small wound develops and form a small plug around the wound, which stops the bleeding from the wound (haemostasis).

In several conditions the platelets tend to clot faster than normal, even when there is no wound (for example in blood vessel disorders). This can cause occlusion of a blood vessel. It is also possible that small parts of such a clot become detached. These parts are then carried along by the blood flow and may block a blood vessel further on. If this occurs in blood vessels of the brain for example, it may lead to a brain infarction or stroke. The formation of these clots is undesirable and must be prevented.

## **2. BEFORE YOU TAKE Ascal Brisper Cardio-Neuro 100mg**

### **Do not take Ascal Brisper Cardio-Neuro 100mg**

- if you have a stomach ulcer or an ulcer in the duodenum or gullet;
- if you have bleeds in the stomach or intestines;
- if you are a gastric patient or experienced stomach ache during earlier use;
- if you have had a brain haemorrhage;
- if you are hypersensitive to salicylic acid compounds or similar painkillers or any of the other ingredients of Ascal Brisper Cardio-Neuro 100mg; (for example some asthma patients may experience an asthma attack or a fainting spell)
- if you have a severe kidney or liver dysfunction;
- if you have a bleeding tendency or coagulation disorder.
- if you use more than 15 mg methotrexate on a weekly basis
- if you take more than 1 Ascal Brisper Cardio-Neuro 100mg tablet daily and have been pregnant for more than 6 months.

### **Take special care with Ascal Brisper Cardio-Neuro 100mg**

- if you are receiving anticoagulant therapy. The bleeding time must then be regularly checked, you must be attentive to signs of bleeding, particular in the abdomen (gastric/intestinal bleeds).
- if you have symptoms of inflammation of the mucous membrane of the nose due to a hypersensitivity reaction characterised by a stuffed-up nose, with sneezing, urticaria and watery discharge, and itching and watery eyes (allergic rhinitis)
- if you suffer from recurring, short-term breathlessness (wheezing caused by cramping of bronchial muscles) and swelling of mucous membrane of the airways, often accompanied with coughing and slime production ((bronchial) asthma)
- if you have had a stomach ulcer in the past or a duodenal ulcer or an ulcer in the gullet.
- if you undergo a procedure involving an increased risk of bleeds, or if you have very profuse menstrual bleeds. For example teeth extraction or an operation, because you may then experience a longer duration of the bleeding. Your doctor can advise you as to whether you should stop taking Ascal Brisper Cardio-Neuro 100mg and for how long.
- if you are under 16, unless there are special reasons for the use (see dosage prescription)
- if you have a diminished renal or liver function. If your liver function is slightly or moderately impaired your doctor may wish to perform liver function tests regularly.
- if you have high blood pressure.
- if you are using products that stimulate the excretion of uric acid (uricosuric agents).

Consult your doctor if one of the above warnings is applicable in your case, or has been applicable in the past.

### **Taking other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

N.B.: The following remarks may also be applicable to the use of medicines in the near past or near future.

Effect of the treatment may be influenced if Ascal Brisper Cardio-Neuro 100mg is concomitantly taken with some other medicines for:

- Blood clot (e.g. coumarin derivatives, heparin)
- High blood pressure (e.g. diuretics)
- Pain and inflammation (e.g. steroids or anti-inflammatory medicines)
- Gout (benzbromazone, probenecid and sulphinpyrazone)
- Cancer or rheumatoid arthritis (methotrexate) (see 'Do not take Ascal Brisper Cardio-Neuro 100mg')
- Excess acid in the stomach (antacids)

Before using Ascal Brisper Cardio-Neuro 100mg inform your doctor about the medicines you are taking. If you are using Ascal Brisper Cardio-Neuro 100mg regularly seek advice of your doctor before taking any other medicine (including OTC medicines).

### **Using Ascal Brisper Cardio-Neuro 100mg with food and drink**

If you take Ascal Brisper Cardio-Neuro 100mg along with alcohol, you have an increased risk of developing gastric complaints. In addition, a bleed may take longer to stop.

### **Pregnancy and breast-feeding**

#### *Pregnancy*

If you are trying to become pregnant or if you are in the first 6 months of pregnancy, only use Ascal Brisper Cardio-Neuro 100mg if its use is absolutely essential, and even then in the lowest possible dose.

During the last 3 months of your pregnancy, you may not use more than 1 Ascal Brisper Cardio-Neuro 100mg tablet daily if absolutely essential.

#### *Breast-feeding*

Only meagre quantities of acetylsalicylic acid pass into breast milk. Breast-feeding may continue if no more than 1 effervescent tablet is used daily. In case of chronic use breast-feeding should be stopped.

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

### **Driving and using machines**

As a rule, no influence on the ability to drive and use machines is expected. If you experience symptoms of dizziness, do not drive and/or do not use machines that require alertness.

### **Important information about some of the ingredients of Ascal Brisper Cardio-Neuro 100mg**

Ascal Brisper Cardio-Neuro 100mg contains, among others, 150 mg lactose (milk sugar) per effervescent tablet.

If your doctor has told you that you do not tolerate certain sugars, please contact your doctor before taking this medicine.

## **3. HOW TO TAKE Ascal Brisper Cardio-Neuro 100mg**

Take Ascal Brisper Cardio-Neuro 100mg exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The usual dose is:

#### *In order to prevent a heart infarct:*

In acute cases, start with a dosage of 2 effervescent tablets daily on day 1, followed by 1 to 2 effervescent tablets daily.

In acute cases, the first dose must be taken as soon as possible after the diagnosis has been made.

#### *In order to prevent stable and unstable angina pectoris (tight, painful feeling in the chest):*

In acute cases, start with a dosage of 2 effervescent tablets daily on day 1, followed by 1 to 2 effervescent tablets daily. In acute cases, the first dose must be taken as soon as possible after the diagnosis has been made.

#### *As a preventive measure after a brain infarction/stroke (or a TIA), on condition that brain haemorrhages have been excluded.*

In acute cases, start with a dosage of 2 effervescent tablets daily on day 1, followed by 1 effervescent tablet daily. In acute cases, the first dose must be taken as soon as possible after the diagnosis has been made.

*In order to prevent a blood flow impairment after a bypass operation.*

In acute cases, start with a dosage of 2 effervescent tablets daily on day 1, followed by 1 to 2 effervescent tablets daily. In acute cases, the first dose must be taken as soon as possible after the diagnosis has been made.

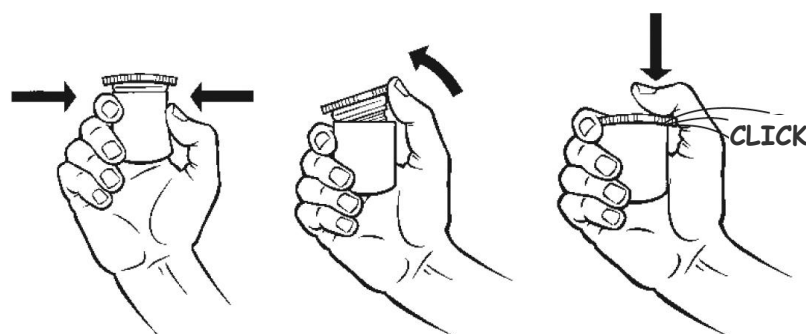
#### *How and when to take Ascal Brisper Cardio-Neuro 100mg*

Ascal Brisper Cardio-Neuro 100mg must be taken after rehydration. Ascal Brisper Cardio-Neuro 100mg is entirely soluble in water. This reduces the chance of side effects in the stomach. This is important, especially as most patients have to use Ascal Brisper Cardio-Neuro 100mg all their lives. Dissolve the effervescent tablet in a glass of water until the solution has nearly become clear; then drink the entire contents of the glass.

Not to be taken by children and adolescents under 16 (see section 2)

The best effect is achieved if you take your tablets at the same time each day. Moreover, this will help you to remember when to take the tablets.

1. Squeeze just under the cap of the jar with thumb and index finger, so that the cap is lifted up.
2. Then push the cap off with your thumb and take out the correct amount of tablets.
3. Close the jar well after use: push the cap down until you hear a click.



(Figure 1)

(Figure 2)

(Figure 3)

#### **If you take more Ascal Brisper Cardio-Neuro 100mg than you should**

If you have taken more Ascal Brisper Cardio-Neuro 100mg than you should, contact your doctor or pharmacist immediately.

Symptoms of moderate poisoning: dizziness, headache, ringing in the ears, mental confusion, nausea, vomiting and stomach ache. An attempt can be made to make the patient vomit; if that is not successful, gastric lavage must be carried out by a healthcare professional.

Symptoms of severe poisoning: fever, excessive perspiration resulting in dehydration, restlessness, convulsion, hallucinations, coma and respiratory arrest.

#### **If you forget to take Ascal Brisper Cardio-Neuro 100mg**

If you realise on the same day that you have forgotten a dose, you should yet take the prescribed effervescent tablet or tablets for that day. If you do not realise it until the next day, only take the normal prescribed dose for that day. Do not take a double dose to make up for a forgotten dose.

#### **If you stop taking Ascal Brisper Cardio-Neuro 100mg**

Always discuss the matter with your doctor if you are planning to stop using Ascal Brisper Cardio-Neuro 100mg. If you stop, you will not notice any unfamiliar effect. However, the clotting of platelets will no

longer be reduced, which means that the risk of a (second) blood flow impairment will no longer be lowered.

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

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

Like all medicines, Ascal Brisper Cardio-Neuro 100mg can cause side effects, although not everybody gets them.

##### *Description of the frequency of side effects:*

very common: affects more than 1 user in 10

common: affects 1 to 10 users in 100

uncommon: affects 1 to 10 users in 1,000

rare: affects 1 to 10 users in 10,000

very rare: affects less than 1 user in 10,000

not known: frequency cannot be estimated from the available data

##### *Gastrointestinal disorders:*

- Very common: stomach complaints for example heartburn and nausea
- Common: vomiting; inflammation of the stomach (gastritis); diarrhoea, mild to moderate blood loss in the alimentary canal (gastrointestinal tract); with long-term or frequent use this blood loss may result in anaemia
- Uncommon: stomach bleeding; stomach ulcer
- Very rare: hole in the wall of the alimentary canal (perforation of the stomach or intestine)

##### *Nervous system disorders:*

- Rare: dizziness; headache; ringing in the ears. These are usually the first signs of overdose (see “If you take more Ascal Brisper 100 mg than you should”)

##### *Blood disorders:*

- Common: prolonged bleeding time. This effect may persist for a few days after stopping the use of Ascal Brisper and may cause an increased risk of bleeds in the case of an operation or teeth extraction. It may also result in more profuse menstrual bleeds.
- Uncommon: bleed in the skull (intracranial bleed); blood in the urine
- Rare: bloody nose, bleeding of the gums, vomiting of blood and bloody or dark stools (haemorrhagic syndrome)

##### *Immune system disorders:*

- Uncommon: urticaria; skin rash; sudden fluid accumulation in the skin and mucous membranes for example throat or tongue (angioedema); inflammation of the mucous membrane of the nose characterised by a stuffed-up nose, sneezing, watery discharge and itching and watery eyes (rhinitis); breathlessness due to cramping of the muscles of the airways (bronchial spasm)
- Very rare: shock, characterised by a marked decrease of the blood pressure, paleness, restlessness, weak and rapid pulse, clammy skin, decreased consciousness (anaphylactic shock); worsening of the allergic symptoms of food allergy.

##### *Skin and subcutaneous tissue disorders:*

- Very rare: severe skin reaction

##### *Metabolism and nutrition disorders:*

- Very rare: low blood glucose level, among others accompanied with a hunger feeling, sweating, dizziness and palpitations (hypoglycaemia). Low-dose acetylsalicylic acid may reduce the excretion of uric acid, which increases the chance of the development of gout.

#### *Hepatobiliary disorders / Renal and urinary disorders*

- Very rare: liver damage and acute renal failure, in particular in kidney patients, cardiac disorder, nephrotic syndrome (Epstein's syndrome), additional use of uricosuric agents

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 Ascal Brisper Cardio-Neuro 100mg**

Keep out of the reach and sight of children.

Do not use Ascal Brisper Cardio-Neuro 100mg after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Storage after first opening of jar containing 30 effervescent tablets is 1 month

Storage after first opening of jar containing 90 effervescent tablets is 3 months

Storage after first opening of jar containing 100 effervescent tablets is 100 days

Do not refrigerate or freeze.

Store in the original package in order to protect from moisture.

Keep the container tightly closed. You will hear a click when the jar is properly closed. Only then will the effervescent tablets be protected from moisture by the drying agent in the cap.

Store below 30°C.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

### **6. FURTHER INFORMATION**

#### **What Ascal Brisper Cardio-Neuro 100mg contains**

- The active substance is Ascal Brisper Cardio-Neuro 100mg, a complex of calcium acetylsalicylic acid and urea.
- Each tablet contains 100 mg carbasalate calcium,, corresponding to 78 mg acetyl salicylic acid.
- The other ingredients (additives) are lactose monohydrate, adipic acid (E 355), sodium hydrogen carbonate (E 500a), magnesium stearate (E 470b), crospovidone (E 1202) and povidone K90 (E 1201).

#### **What Ascal Brisper Cardio-Neuro 100mg looks like and contents of the pack**

1 plastic container with Ascal Brisper contains 30, 90 or 100 effervescent tablets. The effervescent tablets are white to cream-coloured, round, flat tablets with a bevelled edge.

Not all pack sizes are marketed.

#### **Marketing Authorisation Holder and Manufacturer**

Meda Health Sales Ireland Limited,  
Unit 34/35, Block A,  
Dunboyne Business Park,  
Dunboyne, Co. Meath,  
Ireland

*Manufacturer*

Vemedia Manufacturing B.V.  
Verrijn Stuartweg 60  
1112 AX Diemen  
The Netherlands

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

*Austria*

Vascal 100 mg-lösliche Tabletten

*Germany*

Carbasalat Calcium VIATRIS 100 mg Brausetabletten

*Ireland*

Ascal Brisper Cardio-Neuro 100mg effervescent tablets

*The Netherlands*

Ascal Brisper Cardio-Neuro 100mg/100 mg

*Portugal*

Ascal 100

**This leaflet was last approved in: March 2013**