

PACKAGE LEAFLET
Package leaflet: Information for the user

Asacard® 162.5 mg prolonged release hard capsules
aspirin

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

. Always take this medicine exactly as described in this leaflet or as your pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor before you start taking this medicine.
- If you get any of side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet

1. What Asacard® is and what it is used for
2. What you need to know before you take Asacard®
3. How to take Asacard®
4. Possible side effects
5. How to store Asacard®
6. Contents of the pack and other further information

1. What Asacard® is and what it is used for

The name of your medicine is Asacard® 162.5 mg prolonged release hard capsules (called Asacard® in this leaflet). Asacard® contains the active substance aspirin (acetylsalicylic acid).

Asacard® is used in patients who have already suffered a heart attack, a stroke or have had coronary artery bypass surgery. It is used to prevent further:

- Heart attacks
- Strokes including mini strokes
- Stable and unstable angina (chest pain due to reduced oxygen supply to the heart).
- Problems following coronary angioplasty (procedure used to treat narrowed (diseased) coronary arteries to improve the blood flow to the heart muscle).

Asacard® affects ‘platelets’, which are tiny cells in your blood that make your blood clot. Asacard® works by helping to stop the platelets in your blood from sticking together and making a clot.

Do not take Asacard® for headaches or other pains. This is because the amount of aspirin in Asacard® is too low for pain-relief.

There is a special coating around the small particles in Asacard®. This helps to stop the aspirin in Asacard® from irritating your stomach, but means that the capsule should not be used if an immediate effect is required such as during a heart or angina attack.

2. What you need to know before you take Asacard®

Do not take Asacard®

- You are allergic (hypersensitive) to aspirin or any of the other ingredients of Asacard® (listed in section 6). An allergic reaction may include a rash or a runny or blocked nose. Asthma patients may experience an asthma attack or faint.

- You are allergic (hypersensitive) to medicines like aspirin –called “Non-steroidal anti-inflammatory drugs” or NSAIDs. These include amongst others ibuprofen and naproxen.
- You have a stomach ulcer or bleeding in the stomach (gastrointestinal hemorrhages).
- You suffer from stomach problems or have suffered stomach pain when taking this medicine before.
- You are taking methotrexate, used in the treatment of cancer and rheumatoid arthritis at does higher than 15 mg per week.
- You have had a stroke with bleeding in your head.
- You have a severe problem with your kidneys or your liver.
- You have a blood problem that makes you bleed or bruise easily or if you bleed easily for any other reason.
- You are in the last three months of pregnancy or breast feeding (see ‘Pregnancy and breastfeeding’ below).

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

Warnings and Precautions

Talk to your doctor or pharmacist before taking Asacard® if:

- You have gout
- You have asthma
- You have high blood pressure
- You have kidney or liver problems
- You have any bleeding problems
- You have heavy monthly periods
- You have been told that your blood does not have enough of something called ‘glucose-6-phosphate dehydrogenase’ enzyme
- You have a rash or a runny nose
- You have a history of peptic ulcer disease

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

Children and adolescents

Flamasacard® should not be given to children under 16 years of age, unless on the advice of a doctor..

Other medicines and Flamasacard®

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

In particular tell your doctor or pharmacist if you are taking any of the following medicines, before taking Asacard®

- Medicines to treat cancer, certain skin diseases or rheumatoid arthritis – such as methotrexate. Patients taking methotrexate at doses higher than 15 mg per week cannot use Asacard® capsules. Those on lower doses of methotrexate can use Asacard® but will need regular (weekly) monitoring of their blood.
- Medicines for high blood pressure – such as diuretics or ACE-inhibitors.
- Medicines for rejection of organ after transplantation – such as ciclosporin, tacrolimus.
- Medicines for pain and inflammation – such as steroids or anti-inflammatory medicines.
- Medicines for epilepsy – such as phenytoin or valproic acid and sodium valproate.
- Medicines for gout –such as benzbromarone, probenecid or suphinpyrazone.
- Medicines for blood clot –such as warfarin, ticlopidin, clopidogrel, tirofiban, eptifibatide or heparin, hirudine, fondaparinux.

- Medicines for diabetes – such as sulphonylureas and insulin (your blood sugar might become too low).
- Medicines for too much acid in your stomach –called antacids. They may make Asacard® work less well.
- Non-steroidal anti-inflammatory medicines or NSAIDs – like ibuprofen or naproxen.

Operations or tests

Tell your doctor that you are taking Asacard® if you have to have an operation, including dental procedures such as having a tooth removed. You may need to stop taking the medicine prior to your operation to reduce the risk of bleeding problems.

Taking Asacard® with food and drink

Take the capsules in the morning, 15 minutes before breakfast.

If you drink alcohol while taking Asacard® this may make stomach irritation worse. Alcohol can also affect how your blood clots. Talk to your doctor or pharmacist if you are not sure.

Pregnancy, breast-feeding and fertility

Do not take Asacard® in the last three months of pregnancy. The capsules should only be taken in the first six months of pregnancy if the doctor decides it is necessary.

Do not breast-feed if you are taking Asacard®.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Asacard® is not likely to affect you being able to drive or use any tools or machines.

3. How to take Asacard®

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

Take one capsule every morning, 15 minutes before breakfast.

- Swallow the capsule whole with a drink of water.
- Do not crush or chew the capsules or their contents.

This could affect the way the medicine is absorbed into your body.

- Take this medicine as long as your doctor tells you to do so.

Use in children and adolescents

There is a possible association between the aspirin in Asacard® and ‘Reye’s syndrome’ when it is given to children.

- Reye’s syndrome is a very rare disease, which can be fatal.
- For this reason, Asacard® should not be given to children under 16 years unless on the advice of a doctor.

If you take more Asacard® than you should

If you take more Asacard® than you should, talk to a doctor or go to a hospital straight away. The following effects may happen: headache, feeling dizzy, feeling drowsy, having buzzing in the ears, feeling sick (nausea), being sick/vomiting, stomach ache, difficulty breathing, feeling hot, sweating, convulsions.

If you forget to take Asacard®

- If you forget a dose, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose.
- Do not take a double dose (2 capsules at once) to make up for a forgotten dose.

If you stop taking Asacard®

- Ask your doctor for advice before you stop taking this medicine.
- If you have any further questions on the use of this medicine, ask your doctor or your pharmacist.

4. Possible side effects

Like all medicines, Asacard® can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Allergic reactions

If you have any signs of an allergic reaction, stop taking Asacard® and see a doctor straight away.

The signs may include

- Severe rash, itching or hives on the skin
- Swelling of the face, lips, tongue or other parts of the body (oedema).
- Shortness of breath, wheezing or difficult breathing.

These side effects are uncommon (affects less than 1 in 100 users) or even very rare (affects less than 1 in 1,000 users).

Tell your doctor straight away if you notice any of the following serious side effects:

- Confusion, a headache that won't go away or feeling of being sick. These could be signs of bleeding inside your head (intracranial bleeding) which is uncommon (affects less than 1 in 100 users).
- Abdominal pain, fever or chills. These could be signs of a hole in your stomach, small intestine or bowel (gastrointestinal perforation) which is very rare (affects less than 1 in 10,000 users).
- Being sick with blood or having blood in your stools (they will look black). This is rare (affects less than 1 in 1,000 users). However, these could be signs of bleeding in your stomach (gastric bleeding) which is uncommon (affects less than 1 in 100 users).

Other possible side effects:

- **Very common** (affects more than 1 in 10 users)
 - Stomach problems such as heartburn or feeling sick (nausea).
- **Common** (affects less than 1 in 10 users)
 - Being sick (vomiting),
 - Inflamed stomach (gastritis). This may cause pain, feeling or being sick, or being sick with blood, or having blood in your stools (they will look black),
 - Mild to moderate blood loss in your digestive tract,
 - Diarrhoea,
 - Your blood taking longer to clot.
- **Uncommon** (affects less than 1 in 100 users):
 - Stomach ulcers
 - Blood in your urine
- **Rare** (affects less than 1 in 1,000 users):
 - Feeling dizzy
 - Headache
 - Ringing in your ears (tinnitus),
 - Bleeding (hemorrhages) such as bleeding in your nose or gums, or increase menstrual bleeding.
- **Very rare** (affects less than 1 in 10,000) users including isolated reports
 - Fainting
 - Worsening of food allergy signs
 - Lowering of blood sugar levels (hypoglycaemia)
 - Liver or kidney problems, or too much uric acid in your blood (this can cause gout in pre-disposed patients): this is shown in blood tests.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet. You can also report side effects directly via the 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 Asacard®

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

Do not store above 25°C. Store in the original packaging.

Do not use Asacard® 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 use Asacard® if you notice that the colour of the capsules has changed.

Do not throw any medicines away 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 Asacard® 162.5 mg Capsules contain

- The active substance is aspirin (acetylsalicylic acid) Each prolonged release hard capsule contains 162.5 mg of aspirin.
- The other ingredients are: ethylcellulose, povidone, castor oil, magnesium stearate, colloidal anhydrous silica, tartaric acid and talc. The capsule shell contains gelatin and colours called titanium dioxide (E171) , erythrosine (E127) and indigotine (E132).

What Asacard® 162.5 mg capsules look like and contents of the pack

- The capsules have a white body and a red cap and are sealed into a blister.
- The packs contain blister strips of 4, 10, 28, 30 or 100 capsules in a carton.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

New Haven Pharma (UK) Limited
1 Park Row
Leeds
LS1 AB
UK

Manufacturer

FLAMEL TECHNOLOGIES S.A
Flamel Technologies
Parc Industriel Bersol 1
11, Avenue Gustave Eiffel
F 33608 Pessac Cedex
France
Tel: 33(0)5 57 25 07 70
Fax: 33 (0)5 56 36 58 91

Email: info@flamel.com

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

Denmark: Asacard® 162,5 mg dopotkapsler, harde

Ireland: Asacard® 162.5 mg prolonged release hard capsules

Netherlands: Asacard® 162,5 mg harde capsules met verlengde afgigte

United Kingdom: Flamasacard® 162.5 mg prolonged release hard capsules

This leaflet was last approved in 2016