

Asasantin® Retard  
200 mg / 25 mg  
Modified Release  
Hard Capsules



Boehringer  
Ingelheim

dipyridamole and acetylsalicylic acid

Read all of this leaflet carefully before you start taking 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 troublesome or serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

In this leaflet:

1. What ASASANTIN Retard is and what it is used for
2. Before you take ASASANTIN Retard
3. How to take ASASANTIN Retard
4. Possible side effects
5. How to store ASASANTIN Retard
6. Further information

1. WHAT ASASANTIN RETARD IS AND WHAT IT IS USED FOR

What ASASANTIN Retard is

The name of your medicine is ASASANTIN Retard 200 mg / 25 mg Modified Release Hard Capsules (called ASASANTIN Retard in this leaflet).

Each capsule of ASASANTIN Retard contains two different medicines called:

- Dipyridamole
- Aspirin (acetylsalicylic acid)

These belong to a group of medicines called ‘anti-thrombotic agents’. Aspirin is also a type of medicine called a ‘Non-Steroidal Anti-inflammatory Drug’ (NSAID).

What ASASANTIN Retard is used for

ASASANTIN Retard is used when you have had a:

- Stroke or
- Transient Ischaemic Attack (TIA, also known as ‘mini-stroke’)

which was caused by a blood clot in your brain. ASASANTIN Retard prevents the blood clots reforming and so reduces the risk of either of these happening again.

2. BEFORE YOU TAKE ASASANTIN RETARD

Do not take ASASANTIN Retard if you are allergic (hypersensitive) to:

- Dipyridamole
- Aspirin or any other medicines containing aspirin (also called ‘salicylates’)
- Any of the other ingredients of ASASANTIN Retard (which are listed in Section 6 of this leaflet)

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

Do not take ASASANTIN Retard if:

- You have any bleeding problems
- You have or have ever had an ulcer in your stomach or gut (duodenum)
- You are in the last three months of pregnancy or if you are breast-feeding
- You have been told by your doctor that you cannot tolerate or digest some sugars (such as lactose or sucrose)
- You are a child under 16. This is because there is a possible association between aspirin and Reye’s syndrome when given to children. Reye’s syndrome is a very rare disease, which affects the brain and liver and can be fatal. For this reason aspirin should not be given to children aged under 16 years, unless on the advice of a doctor

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

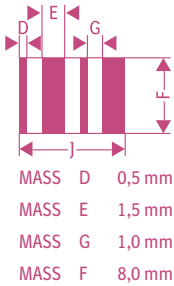
Take special care with ASASANTIN Retard

Check with your doctor or pharmacist before taking your medicine if:

- You have an increased risk of bleeding. You may need to have regular check ups with your doctor
- You have angina or other heart problems (including heart valve or circulation problems) or have had a recent heart attack
- You have a rare muscle problem called ‘myasthenia gravis’
- You have gallstones
- You have asthma
- You have swelling and irritation inside your nose caused by an allergy called ‘allergic rhinitis’
- You have a type of growth in your nose called ‘nasal polyps’
- You have long term or recurring stomach or gut (duodenal) pain
- You have kidney or liver problems
- You have a problem with your red blood cells that can cause anaemia, called ‘glucose-6-phosphate dehydrogenase deficiency’
- You are allergic (hypersensitive) to Non-Steroidal Anti-inflammatory Drugs (NSAIDs) such as ibuprofen
- You are in the first six months of pregnancy or are likely to become pregnant

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking ASASANTIN Retard.

File information					Mandatory in	
					TD	Printfile
Issue date of TD:	01. 09. 2010				Yes	Yes
PPM SKU:	P015107				No	Yes
PPM SKU version:	006				No	Yes
Issue date of artwork:	22.11.2012				No	Yes
Print colors:	PAN Black				No	Yes
Mat. No. Pack. Site:	72918-06				No	Yes
Number of pages:	4					
Legend case version:	V3.0 01/JUN/2010 (please do not change or remove it)					



MASS D 0,5 mm  
MASS E 1,5 mm  
MASS G 1,0 mm  
MASS F 8,0 mm

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c = Manufacturing date		d = Price/Sample/Clinic	
Technical colors			
BI-Diecut-Legendcase	Free area	Gluepoints	

Additional Requirements of Packaging site	
Template name: TD_PI_160x315_doppel	Version: 03/2010

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### Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription and herbal medicines. This is because ASASANTIN Retard can affect the way some other medicines work. Also some other medicines can affect the way ASASANTIN Retard works.

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

- Aspirin or any medicines that contain aspirin (or you are planning to use aspirin for any reason)
- Any other ‘Non-Steroidal Anti-inflammatory Drugs’ (NSAIDs) such as ibuprofen
- Medicines for high blood pressure such as water tablets (diuretics) or ACE-inhibitors
- Medicines for gout such as probenecid or sulphapyrazone
- Medicines for thinning the blood or preventing clots such as warfarin, coumarin derivatives, heparin, clopidogrel and ticlopidine. If you attend an anticoagulant clinic, tell them at your next visit that you are now taking ASASANTIN Retard
- Medicines for depression such as ‘selective serotonin reuptake inhibitors’ (SSRIs)
- Corticosteroids such as prednisolone
- Medicines for lowering blood sugar
- Methotrexate - for joint problems (rheumatoid arthritis) or cancer
- Adenosine - for heart problems or tests on the heart
- Spironolactone - for congestive heart failure
- Valproic acid - for the over excited or ‘high’ feeling (manic episode) that people with bipolar disorder get or for epilepsy (fits)
- Phenytoin - for epilepsy (fits)

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking ASASANTIN Retard.

### Tests

- Heart tests - One of the active ingredients of ASASANTIN Retard is dipyridamole. Dipyridamole is sometimes given as an injection during tests to see if the heart is working properly (also called ‘myocardial imaging’). This means that the test and your medicine may contain the same substance. If you are going to be given an injection of dipyridamole, tell the doctor that you are taking ASASANTIN Retard
- Blood or liver tests - If you are going to have either a blood test or liver function test, tell the person giving the test that you are taking this medicine. This is because ASASANTIN Retard can affect the results of the test

### Taking ASASANTIN Retard with food and alcohol

- It is best to take your capsules with food
- Do not regularly drink alcohol while you are taking ASASANTIN Retard. This is because you are more likely to have stomach and gut related side effects if you regularly drink alcohol. If you want to drink alcohol, your doctor or pharmacist can give you advice on what is an appropriate amount for you while taking this medicine.

### Pregnancy and breast-feeding

- Do not take this medicine if you are in the last three months of pregnancy or if you are breast-feeding
- Talk to your doctor before taking this medicine if you are in the first six months of pregnancy or are likely to become pregnant

### Driving and using machines

You may feel dizzy or confused while taking ASASANTIN Retard. If this happens do not drive or use any tools or machines.

### Important information about some of the other ingredients of ASASANTIN Retard

Do not take this medicine if you have been told by your doctor that you cannot tolerate or digest some sugars. ASASANTIN Retard contains two types of sugar called lactose and sucrose.

### 3. HOW TO TAKE ASASANTIN RETARD

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

#### How much to take

- Take one capsule twice a day
- Usually one in the morning and one in the evening
- It is best to take them with food
- Swallow the capsule whole with a glass of water
- Do not chew the capsule

#### If you take more ASASANTIN Retard than you should

If you take more of this medicine than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you, even if there are no capsules left.

#### If you forget to take ASASANTIN Retard

- If you forget a dose, take it as soon as you remember it
- However, if it is nearly time for your next dose, skip the missed dose
- Do not take a double dose to make up for the 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 ASASANTIN Retard can cause side effects, although not everybody gets them. The following side effects may happen with this medicine.

Allergic reactions

If you have an allergic reaction stop taking your medicine and see a doctor straight away. The signs may include difficulty breathing, rash (including nettle rash) which may be severe, or swelling of the face, lips, tongue or throat.

See a doctor straight away if you notice any of the following side effects

- Having difficulty speaking, moving or thinking as normal. This could be a sign of bleeding in your brain
- Blood in your stools or vomit. This could be a sign of bleeding or ulcers in your stomach or gut
- Faster heart beat (tachycardia)
- Worsening of the symptoms of coronary heart disease such as chest pain and shortness of breath
- Bruising or prolonged bleeding from wounds including during or after surgery or other medical procedures
- A blood problem called ‘thrombocytopenia’ which can cause bruising and prolonged bleeding
- Severe migraine-like headaches at the start of your treatment. Your doctor may need to change your dose for a short period of time. Do not take painkillers containing aspirin to treat your headaches

If you notice any of the side effects listed above, see a doctor straight away.

- Other side effects of ASASANTIN Retard**  
Very Common (affects more than 1 in 10 people)
- Headache
  - Feeling dizzy or sick (nausea)
  - Stomach ache, indigestion or diarrhoea

- Common (affects less than 1 in 10 people)
- Migraine-like headache. This is more common at the start of treatment and usually goes away as treatment continues
  - Nosebleeds
  - Being sick (vomiting)
  - Muscle pain
  - Fainting
  - Anaemia

- Uncommon (affects less than 1 in 100 people)
- Lowered blood pressure
  - Hot flushes
  - Bleeding in your eye

- Rare (affects less than 1 in 1000 people)
- Inflammation of the stomach
  - Anaemia caused by internal bleeding into the stomach and intestines

- Unknown (the frequency of the following side effect cannot be estimated from the available data)
- Bruising or swellings under your skin where blood has collected (haematoma)

Other side effects of the two medicines when taken on their own

In addition there are other side effects that are known for the active ingredients dipyridamole and aspirin (acetylsalicylic acid) when taken on their own. These are listed below and also apply for ASASANTIN Retard.

- Dipyridamole
- In people who already have gallstones, the dipyridamole in this medicine can be absorbed into their gallstones

- Aspirin (acetylsalicylic acid)
- Blood clotting and bleeding problems, bleeding gums
  - Severe allergic reactions, especially in patients who have asthma
  - High blood sugar levels
  - Low blood sugar levels, particularly in children
  - Increased uric acid in the blood, which may cause gout, or other changes in the blood
  - Feeling thirsty or becoming dehydrated
  - Feeling confused or restless
  - Feeling less alert, convulsions (fits) or swelling of the brain
  - Deafness or ringing in the ears
  - Irregular heart beats
  - Difficulty breathing or fast or shallow breathing
  - Swelling in the throat or excess fluid in the lungs
  - Stomach or gut ulcers
  - Stomach ulcers may get holes in them (perforated)
  - Blood in stools or vomit
  - Inflammation of the pancreas
  - Inflammation of the liver (hepatitis)
  - Reye’s syndrome – a rare disease which can be fatal especially if aspirin is given to children
  - Rash with blisters
  - Muscle breakdown
  - Kidney failure or other kidney problems
  - Affect on liver test results
  - Prolonged pregnancy or labour, bleeding before or after birth, having a small baby or stillbirth
  - Fever or low body temperature (hypothermia)

If any of the side effects gets troublesome or serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE ASASANTIN RETARD

Keep out of the sight and reach of children.

Store below 30°C.

Keep bottle tightly closed. Store in the original package in order to protect from moisture.

Do not use ASASANTIN Retard after the expiry date which is stated on the top flap of the carton and the bottle label. The expiry date refers to the last day of that month.

Do not open the container until you are ready to start taking the capsules. If you have any capsules left after 60 days, these should not be taken.

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 protect the environment.

6. FURTHER INFORMATION

**What ASASANTIN Retard contains**  
The active ingredients are dipyridamole and acetylsalicylic acid (aspirin). Each capsule contains dipyridamole 200 mg in modified release form and aspirin (acetylsalicylic acid) 25 mg in standard release form.

The capsule also contains the following inactive ingredients: tartaric acid, acacia, povidone (K25), Methacrylic acid-methacrylate copolymer (1:2), hypromellose phthalate, hypromellose, Dimethicone 350, triacetin, talc, stearic acid 50, lactose monohydrate, aluminium stearate, colloidal anhydrous silica, maize starch, microcrystalline cellulose, sucrose and titanium dioxide (E171).

The capsule shells also contain gelatin, titanium dioxide (E171) and red and yellow iron oxides (E172). The ink printed on the capsule shell contains shellac, ethanol, isopropyl alcohol, propylene glycol, n-butyl alcohol, ammonium hydroxide, potassium hydroxide, purified water and red iron oxide (E172).

**What ASASANTIN Retard looks like and contents of the pack**  
The capsules are red and ivory. They have the company logo and ‘01A’ printed on them. ASASANTIN Retard is available in packs of 60 capsules.

**Marketing Authorisation Holder and Manufacturer**  
The Marketing Authorisation for ASASANTIN Retard is held by:

Boehringer Ingelheim Limited  
Ellesfield Avenue, Bracknell, Berkshire,  
RG12 8YS, UK

and the product is manufactured by:

Boehringer Ingelheim Pharma GmbH & Co. KG  
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This leaflet was revised in November 2012.  
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