Package leaflet: Information for the patient

Dipyridamol/Acetylsalicylzuur Sandoz® 200/25 mg, capsules met gereguleerde afgifte, hard

dipyridamole and acetylsalicylic acid

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 [Nationally completed name] is and what it is used for

The name of your medicine is [Nationally completed name]. It contains two different medicines called dipyridamole and acetylsalicylic acid*. Both belong to a group of medicines called 'anti-thrombotic medicines'. Acetylsalicylic acid* is also a type of medicine called a 'Non-Steroidal Anti-inflammatory Drug' (NSAID).

[Nationally completed name] belongs to a group of medicines called 'anti-thrombotic agents'. They are used to stop blood clots forming. [Nationally completed name] is used for people who have had a
- Stroke
- Transient Ischaemic Attack (TIA)

which are caused by a clot in the brain. This medicine reduces the risk of them happening again.

2. What you need to know before you take [Nationally completed name]

Do not take [Nationally completed name] if you:
- are **allergic** to **dipyridamole, acetylsalicylic acid*** or any other medicines containing substances similar to acetylsalicylic acid* (also called 'salicylates') or to any of the other ingredients of this medicine (listed in section 6)
- are **allergic** to **peanut or soya**
- have any **bleeding problems**
- have ever had an **ulcer in your stomach or gut** (duodenum)
- have **severe kidney or liver problems**
- are taking **methotrexate** at doses higher than 15 mg/week
- have ever had **abnormal bleeding** in the **brain**
- have had **stomach pain** when previously taking this medicine

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 [Nationally completed name].

Warnings and precautions
Talk to your doctor or pharmacist before taking [Nationally completed name] if you:
- have an **increased risk of bleeding** as you might require careful follow up by your doctor
- have **angina or other heart problems** (including a recent heart attack, heart failure, heart valve or circulation problems), as this medicine can cause widening of your blood vessels
- have **myasthenia gravis** (a rare muscle problem). The dose of medicine you take for myasthenia gravis may need to be adjusted, especially when the dose of [Nationally completed name] is changed
- have **asthma, hayfever or nasal polyps** (a type of growth in the nose)
- have **kidney or liver** problems. If these are **severe**, do not take this medicine
- are **allergic to Non-Steroidal Anti-Inflammatory Drugs** (NSAIDs) such as ibuprofen
- are taking **medicines that increase the risk of bleeding** such as anti-platelet medicines (e.g. clopidogrel) or some antidepressants (SSRIs e,g, paroxetine, sertraline, fluoxetine)
- have long-term or recurring **stomach or intestine problems**, causing your stools to be darker in colour
- are about to have **surgery** such as having a tooth removed. Your doctor may want you to stop taking this medicine up to 7 days before.

If you get a severe migraine-like headache at the start of your treatment tell your doctor. **DO NOT** take painkillers containing acetylsalicylic acid* to treat your headache.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking [Nationally completed name].

Children and adolescents
[Nationally completed name] should not be given to children and adolescents.

Other medicines and [Nationally completed name]
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes herbal medicines. This is because [Nationally completed name] can affect the way some other medicines work. Also some other medicines can affect the way [Nationally completed name] works.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:
- **acetylsalicylic acid*** or medicines containing acetylsalicylic acid* (or planning to for any condition)
- medicines for **high blood pressure**. The blood pressure lowing effects of these medicines could be increased
- medicines to **thin the blood** such as warfarin, heparin, coumarins, clopidogrel and ticlopidine. The effect of these medicines could be increased, increasing the risk of bleeding. If you attend an anticoagulant clinic tell them at your next visit
- medicines for depression called '**selective serotonin reuptake inhibitors**' such as fluoxetine, paroxetine or sertraline. The risk of bleeding could be increased
- other **Non-Steroidal Anti-inflammatory Drugs** (such as **ibuprofen**) for another condition, or **steroids** (such as prednisolone). The risk of side effects of your stomach and intestines could be increased
- **metamizole** (substance to decrease pain and fever) may reduce the effect of acetylsalicylic acid on platelet aggregation (blood cells sticking together and forming a blood clot), when taken concomitantly. Therefore, this combination should be used with caution in patients taking low dose acetylsalicylic acid for cardioprotection.

- **methotrexate** - used for joint problems or cancer. The risk of side effects may be increased. Your doctor may want to do some blood tests. **Do not take** this medicine if your dose of methotrexate is higher than 15 mg/week
- medicines to **lower your blood sugar**. The effect of these medicines may be increased
- **adenosine** - used for heart problems or tests on the heart. Your doctor may want to change the amount of adenosine you are taking
- **spironolactone** - a water tablet. The effect of this medicine may be reduced
- **uricosuric medicines** used to treat gout, such as probenecid or sulphinpyrazone. The effect of these medicines may be reduced
- **valproic acid** - used for treating epilepsy or during the manic episodes in people with bipolar disorder. The risk of side effects could be increased
- **phenytoin** - used to treat epilepsy (seizures). The risk of side effects could be increased
- **cholinesterase inhibitors**. The effect of these medicines could be reduced leading to a worsening of myasthenia gravis.

If you are having heart tests
[Nationally completed name] contains dipyridamole. Dipyridamole is also 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 have an injection of dipyridamole, tell the doctor that you are taking [Nationally completed name].

[Nationally completed name] with alcohol
Do not take [Nationally completed name] capsules at the same time as an alcoholic drink. Avoid drinking excessive amount of alcohol because the risk of side effects to your stomach and intestines could be increased.

Pregnancy and breast-feeding
[Nationally completed name] is not recommended during pregnancy and breast-feeding. 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
You may feel dizzy or confused while taking [Nationally completed name]. If this happens, do not drive or use any tools or machines.

[Nationally completed name] contains lactose, parahydroxybenzoates, azo colouring agents, soya lecithin and sodium
If you have been told by your doctor that you have an intolerance to some sugars contact your doctor before taking this medicine.

This medicine contains methyl parahydroxybenzoate (E 218) and propyl parahydroxybenzoate (E 216), which may cause allergic reactions (possibly delayed).

This medicine contains the azo colouring agents ponceau 4R (E 124) and sunset yellow (E 110), which may cause allergic reactions.

This medicine contains soya lecithin. If you are allergic to peanut or soya, do not use this medicine.

This medicine contains less than 1mmol (23 mg) sodium per modified-release hard capsule, that is to say essentially 'sodium-free'.

3. How to take [Nationally completed name]

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

For Belgium only:
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.

The recommended dose is
- One capsule twice a day, usually one in the morning and one in the evening.
- Swallow the capsule whole with a glass of water.
- **Do not** crush or chew it.

If you get a severe migraine-like headache at the start of your treatment tell your doctor as they may need to change your dose for a short period of time. **DO NOT** take painkillers containing acetylsalicylic acid* to treat your headache.

Use in children and adolescents
This medicine should not be given to children and adolescents (see also section 2 “Warnings and precautions”).

If you take more [Nationally completed name] than you should
If you take more of this medicine than you should, talk to a doctor or go to a hospital straight away. You may experience symptoms of dizziness, tinnitus (ringing in your ears), breathing too fast, feeling sick, being sick, loss of hearing, warm feeling, flushing of the face, sweating, restlessness, a drop in blood pressure, weakness or heart problems. Take the medicine pack with you, even if there are no capsules left.

If you forget to take [Nationally completed name]
If you forget a dose, take it as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose. Do not take a double dose to make up for the forgotten dose.

If you stop taking [Nationally completed name]
Do not stop treatment without talking to your doctor first.

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

4. Possible side effects

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

Bleeding
Bleeding at different sites within the body can occur which in some cases may be serious. **In such cases stop taking your medicine and seek urgent medical advice.**

The following side effects have been seen with the combination of acetylsalicylic acid and dipyridamole:

Very Common, affects more than 1 in 10 people
- headache. If this occurs, tell your doctor. DO NOT take painkillers containing acetylsalicylic acid* to treat your headache
- feeling dizzy
- feeling sick (nausea)

- stomach ache
- indigestion or diarrhoea

Common, affects less than 1 in 10 people but more than 1 in 100 people
- allergic reactions. The signs may include difficulty breathing, rash of the skin which may be severe with itching, or swelling of the throat or face.
- bleeding in the brain
- bleeding in the stomach or gut
- nosebleeds
- reduction in red blood cells which can make the skin pale and cause weakness or breathlessness (anaemia)
- worsening of the symptoms of heart disease
- migraine. This is more common at the start of treatment.
- being sick (vomiting)
- muscle pain
- fainting

Uncommon, affects less than 1 in 100 people but more than 1 in 1,000 people
- bleeding in the eye
- faster heart beat
- lowering of blood pressure
- hot flushes
- stomach ulcers. Signs may be continuous heartburn, black tarry stools, abdominal discomfort.

Rare, affects less than 1 in 1,000 people but more than 1 in 10,000 people
- reduction in blood platelets, which increases risk of bleeding or bruising (thrombocytopenia)
- anaemia due to internal bleeding into the stomach
- inflammation of the stomach

Frequency not known, frequency cannot be estimated from the available data
- prolonged bleeding from wounds including during or after surgery or other medical procedures, skin bleeding
- bruising or swellings where blood has collected (haematoma)
- blood in the stools or vomiting blood
- inflammation of the pancreas, which causes severe pain in the abdomen and back
- inflammation of the liver (hepatitis)
- abnormal muscle breakdown which can lead to kidney problems (rhabdomyolysis)
- kidney failure and other kidney problems
- convulsions (fits) or swelling of the brain
- deafness or ringing in the ears
- Reye's syndrome, a rare disease which affects major organs and can be fatal. It especially occurs if acetylsalicylic acid* is given to children.
- swelling in the throat
- blood clotting problems and bleeding gums
- severe allergic reactions especially in patients who have asthma
- high or low blood sugar levels
- increased uric acid in the blood, which may cause gout, or other changes in the composition of the blood
- feeling thirsty or becoming dehydrated
- feeling confused or restless
- feeling less alert
- irregular heart beats

- difficulty breathing or fast or shallow breathing
- excess fluid in the lungs
- perforated ulcers in the stomach and gut
- rash with blisters
- possible effect on liver test results
- prolonged pregnancy or labour, bleeding before or after birth, small baby or stillbirth
- fever or low body temperature (hypothermia)
- In people who have gallstones, dipyridamole can be absorbed into the gallstones.

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 via {the national reporting system listed in Appendix V of the QRD template; to be completed nationally}. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [Nationally completed name]

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 the bottle after "EXP". The expiry date refers to the last day of that month.

Store in the original package in order to protect from moisture.
Keep the bottle tightly closed.
This medicine does not require any special temperature storage conditions.

Do not open the bottle until you are ready to start taking the capsules. If you have any capsules left in the bottle after 30 days, **these should not be taken.**

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 protect the environment.

6. Contents of the pack and other information

What [Nationally completed name] contains
- The active substances are dipyridamole and acetylsalicylic acid.
  Each capsule contains 200 mg dipyridamole in modified release form and 25 mg acetylsalicylic acid in standard release form.
- The other ingredients are: ***Dipyridamole pellets*** – tartaric acid; hypromellose; acacia; talc; povidone; methacrylic acid-methyl methacrylate copolymer (1:2); hypromellose phthalate; dimethicone 350; triacetin, stearic acid; ***Acetylsalicylic acid tablet*** - cellulose, microcrystalline; lactose anhydrous; maize starch pregelatinised; silica, colloidal anhydrous; stearic acid; polyvinyl alcohol – part hydrolysed; titanium dioxide (E 171); talc; quinoline yellow aluminium lake (E 104); lecithin, soya (E 322); xanthan gum (E 415); ***Capsule shells*** - gelatin; purified water; methyl parahydroxybenzoate (E 218); propyl parahydroxybenzoate (E 216); ponceau 4R (E 124) (contains sodium); patent blue V (E 131) (contains sodium); quinoline yellow (E 104) (contains sodium); sunset yellow (E 110) (contains sodium); titanium dioxide (E 171).

What [Nationally completed name] looks like and contents of the pack

The capsules have an orange cap and a white to off-white body.

White, HDPE bottles with child resistant closure, containing a desiccant made from molecular sieves.

Pack sizes:
30, 30 (sample), 50, 60 (2x30), 100 (2x50).

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant

Houder van de vergunning voor het in de handel brengen
Sandoz B.V., Hospitaaldreef 29, 1315 RC Almere, Nederland

Fabrikant

Salutas Pharma GmbH
Otto-von-Guericke-Allee 1
39179 Barleben
Duitsland

In het register ingeschreven onder:
RVG 109873

Dit geneesmiddel is geregistreerd in lidstaten van de EEA onder de volgende namen:

Duitsland:	ASS HEXAL plus Dipyridamol 25 mg/200 mg
Nederland:	Dipyridamol/Acetylsalicylzuur Sandoz 200/25 mg, capsules met gereguleerde afgifte, hard
Verenigd Koninkrijk:	Svelux 200 mg/25 mg modified-release capsules, hard

Deze bijsluiter is voor het laatst goedgekeurd in februari 2024.