Patient Leaflet According to the Pharmacists' Regulations (Preparations) - 1986

This medicine is sold with a doctor's prescription only

Aggrenox®

Controlled Release Capsules

Active ingredients:
Each capsule contains: Acetylsalicylic acid 25 mg and Dipyridamole 200 mg.
For a list of inactive ingredients, please see section 6. Also see 'Important information about some of the medicine's ingredients' in section 2.

Read this entire leaflet carefully before using this medicine.
This leaflet contains concise information about the medicine. If you have any further questions, please refer to your doctor or pharmacist.
This medicine has been prescribed for the treatment of your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

1. What is the medicine intended for?

The medicine is intended for prevention of an additional cerebrovascular event (ischemic stroke or transient ischemic attack).

Therapeutic group:
Coagulation inhibitors - platelet aggregation inhibitors (Antiaggregants).

2. Before you take the medicine

Do not use this medicine if:

- Do not use if you are sensitive (allergic) to the active ingredients, to salicylates or to any of the other ingredients of this medicine (for a list of inactive ingredients, please see section 6).
- Do not use if you suffer from gastric or duodenal ulcer.
- Do not use if you suffer from any bleeding problem.
- Do not use if you suffer from severe liver/kidney insufficiency.
- Do not use during the third trimester of pregnancy.

Special warnings regarding the use of this medicine:

- As with other anticoagulants, caution is required in patients with a high risk of bleeding and in patients taking medicines that increase the risk of bleeding (see below). Be aware for signs of bleeding (including occult blood which can be manifested by black stool) and refer to your doctor immediatly, if you notice this.
- In rare cases severe life-threatening bleeding may occur, especially in patients that are taking anticoagulants and/or suffer from uncontrolled high blood pressure.
- Inform your attending doctor about taking this medicine before any urgent treatment or surgery (including dental).
- If you are about to undergo a cardiac test that includes injecting dipyridamole– inform the doctor about taking this medicine.
- If headaches appear (which may occur especially at the beginning of the treatment), do not use aspirin as a pain reliever.
- If you suffer from migraine-like headaches at the beginning of the treatment- refer to your doctor, as a change in the dosage may be needed for a short period.
- If you are sensitive to any kind of food or medicine, inform your doctor before taking this medicine.

Before the treatment with Aggrenox tell your doctor:

- If you suffer from G6PD deficiency or if you are sensitive (allergic) to: pain relievers, non-steroidal anti-inflammatory drugs (NSAIDs), other anti inflammatory medicines, or other allergenic substances.
- If you suffer or have suffered in the past from impaired function of the: heart/blood system, kidneys, liver, gallbladder, respiratory system and/or the digestive system (such as gastric or duodenum problems).
- If you suffer or have suffered in the past from myasthenia gravis, asthma, allergic rhinitis or any other allergy, hay fever, nasal polyps.

If you are taking or have recently taken any other medicines, including non-prescription medicines and nutrition supplements, please tell your doctor or pharmacist. Especially inform your doctor or pharmacist if you are taking the following medicines (it should be noted that the following list mentions the active ingredients of the medicines. If you are unsure whether you are using one of these medicines, please consult with your doctor or pharmacist):

- Anticoagulants (e.g. coumarin derivatives, warfarin, heparin), medicines that increase the risk of bleeding (e.g. clopidogrel, ticlopidine, aspirin, antidepressants of the SSRIs group).
- Corticosteroids, non-steroidal anti-inflammatory drugs - NSAIDs (e.g. ibuprofen).
- Medicines for the treatment of high blood pressure (including ACE enzyme inhibitors), loop diuretics (e.g. furosemide), aldosterone blockers (spironolactone and canrenoate).
- Orally administered medicines for lowering blood sugar levels (e.g. sulphonylurea), medicines for the treatment of gout (e.g. probenecid, sulphinpyrazone).
- Adenosine, cholinesterase inhibitors, digoxin, methotrexate, valproic acid and phenytoin (for the treatment of epilepsy).

Use of this medicine and food: It is recommended to take this medicine after a meal.

Use of this medicine and alcohol consumption:
Do not drink wines or alcoholic beverages, during the treatment period with this medicine. Alcohol increases the risk of bleeding and side effects of the digestive system (including ulcers).

Pregnancy and breastfeeding:

- Do not use the medicine during the third trimester of pregnancy.
- Do not use the medicine without consulting your doctor before starting the treatment if you are planning a pregnancy or within the first six months of a pregnancy.
- Do not use the medicine without consulting your doctor before starting the treatment if you are breastfeeding (Aggrenox is excreted in breast milk in small amounts).

Driving and use of machinery: The medicine may cause dizziness or confusion. If you experience these effects, avoid driving or operating machinery.

Use in children: This medicine is not intended for the use of children and adolescents. Do not use in any case in children and adolescents suffering from a viral disease and/or fever, because of the risk of Reye's syndrome.

Important information about some of the medicine's ingredients:

- This medicine contains lactose. If you are sensitive to lactose, inform your doctor before taking this medicine - see section 6.
- This medicine contains sugar (sucrose) - see section 6.

3. How to use this medicine?

Always use according to the doctor's instructions. Check with your doctor or pharmacist if you are not sure.
The dosage and the manner of treatment will be determined by the doctor only.
Use the medicine at set intervals, as determined by the attending doctor.
The standard dosage is usually: one capsule, twice a day (one in the morning and one in the evening).
Do not exceed the recommended dose.
Swallow the capsule whole with water, preferably after a meal.
Tests and follow up: In patients with increased tendency of bleeding, closer medical monitoring may be needed.
If you have accidentally taken a higher dosage or if a child or has accidentally swallowed the medicine, proceed immediately to a doctor or hospital emergency room and bring the package of the medicine with you. Overdose symptoms may include: feeling of warmth, flushing, sweating, accelerated pulse, restlessness, weakness, dizziness, decrease in blood pressure, angina (pain in the heart), accelerated breathing, ringing in the ears, nausea, vomiting, impaired vision or hearing, headache, vertigo, confusion, drowsiness, decrease of blood sugar levels, rash, digestive system bleeding, stomach pain.
If you forget to take this medicine at the set time, take a dose as soon as you remember, but do not take a double dose to compensate for the forgotten dose!
Continue with the treatment as recommended by your doctor.
If you stop taking the medicine: Even if your state of health improves, do not stop the treatment with this medicine without consulting your doctor.
Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.
If you have any further questions regarding the use of this medicine, consult your doctor or pharmacist.

4. Side effects:

Like any medicine, the use of Aggrenox may cause side effects in some users. If these side effects persist or if they are bothersome or get worse, consult your doctor. Do not be alarmed while reading the list of side effects, you may not suffer from any of them.
Stop the treatment and refer to your doctor immediately if the following appears: an allergic reaction (common), which can be manifested, among other things, as breathing difficulties, rash, itching, urticaria, angioedema, swelling of the face and throat (edema).
Additional side effects:
Very common side effects (appear in more than one user out of ten):

- Headache, dizziness, vertigo (spinning), nausea, diarrhea - these effects usually resolve after adaptation to the medicine.
- Abdominal pain, indigestion.

Common side effects (appear in 1-10 users out of 100):

- Migraine, muscle pain, vomiting - these effects usually resolve after adaptation to the medicine.
- Anemia, digestive system bleeding (which may be severe), nosebleeds, intracranial hemorrhage, worsening of heart disease symptoms (e.g. chest pain and shortness of breath), fainting.

Uncommon side effects (appear in 1-10 users out of 1,000): rapid heartbeat, decrease in blood pressure, hot flashes, digestive system ulcers, bleeding in the eye.
Rare side effects (appear in 1-10 users out of 10,000): thrombocytopenia (reduced number of platelets) which can be manifested by skin bruises or increased bleeding, occult bleeding of the digestive system that may cause anemia, stomach inflammation.
Side effects with an unknown frequency (effects that there frequency has not yet been determined): skin bleeding such as hemorrhage under the skin, prolonged bleeding time, increased bleeding during surgery or after surgery and other procedures.
Side effects which have been observed during the use of medicines that contain only dipyridamole as the active ingredient: absorption of the active ingredient into gallstones.
Side effects which have been observed during the use of medicines that contain only Acetylsalicylic acid as the active ingredient: blood clotting problems, bleeding of the gums, severe allergic reaction and shock (especially in patients with asthma), increase or decrease in blood sugar levels, changes in blood composition (e.g. increase in the level of potassium, changes in acid-base balance, increase in uric acid that may cause gout), thirst, dehydration, confusion, extreme restlessness, lack of motivation, convulsions, brain edema, ringing in the ears, deafness, heart rate disturbances, breathing difficulties, shortness of breath, rapid breathing, swelling (edema) of the throat, lung edema, perforated ulcers in the digestive system, blood in the stool (black stool), bloody vomit, pancreas inflammation, liver inflammation (hepatitis), Reye's syndrome (a rare syndrome that may be life threatening, especially in children), severe skin reaction (which includes redness, rash, blisters), muscle breakdown, urinary system and kidney problems (including kidney failure), increased protein excretion in the urine, changes in liver function tests, pregnancy prolongation, prolonged labor, bleeding before and after giving birth, giving birth to a small or dead infant, changes in body heat (increase or decrease), clotting time (PT) prolongation in tests.
In any case you experience side effects that are not mentioned in this leaflet, or if there is a change in your general feeling, consult your doctor immediately!

5. How to store the medicine?

Avoid poisoning! This medicine, and any other medicine, must be stored in a safe place out of the reach of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.

- Do not use the medicine after the expiry date (exp. date) stated on the package. The expiry date refers to the last day of that month.
- Storage conditions: Store below 25°C in the original package tightly closed.
- The medicine can be used up to one month after first opening the container of the medicine, but not later than the expiry date stated on the package.

6. Additional information

In addition to the active ingredients, the medicine also contains the following inactive ingredients:
Lactose monohydrate, microcrystalline cellulose, maize starch dried, silica colloidal anhydrous, aluminium stearate, sucrose, talc, acacia, tartaric acid, polyvidone K25, methacrylic acid-methyl methacrylate copolymer, hypromellose phthalate, hypromellose, glycerol triacetate, dimethicone 350, stearic acid, gelatin, titanium dioxide (E171), red iron oxide (E172), yellow iron oxide (E172), water.
Each capsule contains approximately 53 mg lactose and approximately 11 mg sucrose.

What does the medicine look like and what does the package contain?
Red and yellowish capsules (half red half yellowish) which contain yellow granules and one small white tablet.
The container of the medicine contain 60 or 20 capsules. Not all package sizes may be marketed.

Marketing authorization holder: Boehringer Ingelheim Israel Ltd., 89 Medinat Ha-Yehudim St.
P.O. Box 4124 Hertzliya-Pituach 4676672

Manufacturer: Boehringer Ingelheim Pharma, Germany.

Medicine registration number in the National Medicine Registry of the Ministry of Health: 140 53 31735

This leaflet was checked and approved by the Ministry of Health in April 2014.

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