

PART III: CONSUMER INFORMATION

Pr Aggrenox®

Dipyridamole/Acetylsalicylic Acid Capsules
Extended Release Dipyridamole/Immediate Release
Acetylsalicylic Acid (ASA)

This leaflet is part III of a three-part "Product Monograph" published when AGGRENOX was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about AGGRENOX. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

AGGRENOX capsules are prescribed to help prevent a stroke in people who have had a prior stroke or a transient ischemic attack (TIA).

Stroke is caused by the interruption of the blood supply to the brain and often results in brain damage. A stroke can affect people in different ways. The damage caused by a stroke can affect your senses, your ability to move, your speech, your ability to understand speech, how you behave, how you think, and your memory.

Transient Ischemic Attack is a temporary interference with blood supply to the brain. The symptoms of TIA include dizziness, light-headedness, numbness, and difficulty swallowing. They may last for only a few minutes or several hours.

AGGRENOX has been prescribed to you. DO NOT give it to anyone else, even if you think they have the same condition as you.

What it does:

AGGRENOX capsules belong to a group of medicines called antiplatelet drugs. Platelets are very small structures in blood, which clump together during blood clotting.

AGGRENOX works by preventing the early formation of blood clots (a process called thrombosis).

When it should not be used:

AGGRENOX should not be used if you:

- are sensitive or allergic to any component of the drug, including ASA (Aspirin®) (see "What the non-medical ingredients are");
- have allergy to non-steroidal anti-inflammatory drugs (NSAIDs);
- have active stomach or duodenal ulcers or bleeding

disorders;

- have asthma, rhinitis or nasal polyps;
- have fructose and/or galactose intolerance;
- are in the third trimester of pregnancy.

What the medicinal ingredients are:

AGGRENOX is a combination of dipyridamole and acetylsalicylic acid (ASA). AGGRENOX is not interchangeable with the individual components of ASA and dipyridamole tablets.

What the non-medicinal ingredients are (in alphabetical order):

Acacia, aluminium stearate, colloidal silicon dioxide, corn starch, dimethicone, hydroxypropyl methylcellulose, hydroxypropyl methylcellulose phthalate, lactose monohydrate, methacrylic acid copolymer, microcrystalline cellulose, povidone, stearic acid, sucrose, talc, tartaric acid, titanium dioxide, and triacetin.

The capsule shell contains gelatine, red iron oxide and yellow iron oxide, titanium dioxide and water.

What dosage forms it comes in:

Capsules - each capsule contains yellow extended release pellets of dipyridamole (200 mg) and a round, white tablet of ASA (25 mg).

WARNINGS AND PRECAUTIONS

BEFORE you use AGGRENOX talk to your doctor or pharmacist if you:

- are pregnant or intend to become pregnant. Your doctor will advise you that this medication should not be taken during the third trimester of pregnancy and will discuss with you whether it should be taken in the first and second trimester;
- are breast feeding. Both dipyridamole and ASA are excreted in human breast milk. You and your doctor will discuss this issue;
- are consuming alcoholic beverages;
- have any other health problems, including anaemia, liver disease, renal (kidney) disorders, history of stomach or duodenal ulcers, bleeding disorders (such as haemophilia), heart disease (including angina and recent heart attack), gout, and abnormal menstruation or vaginal bleeding;
- are taking any other medication, including any other medication you can buy without a prescription; medication such as acetylsalicylic acid; drugs used to reduce blood clotting such as warfarin and heparin; antiplatelet agents (e.g. clopidogrel, ticlopidine), NSAIDs used to treat painful and/or inflammatory muscle and joint

conditions; or anti-diabetic medicines. (See “Interactions with this medication”);

- will be having surgery. Your doctor may ask you to stop AGGRENOX for 10 days before your surgery;
- have a history of hemorrhagic stroke (stroke due to bleeding).

Long term daily use of ibuprofen can interfere with the preventative benefits of AGGRENOX. (See “Interactions with this medication”).

INTERACTIONS WITH THIS MEDICATION

DO NOT take any other medication unless your doctor tells you to. Please tell your doctor, nurse, or pharmacist about all the medicines you take, including drugs prescribed by other doctors, vitamins, minerals, natural supplements or alternative medicines.

AGGRENOX contains ASA (Aspirin®*). You should not take AGGRENOX with the following medications without the advice of your doctor:

- other medications containing ASA;
- other blood thinners (e.g. warfarin or heparin);
- antiplatelet agents (e.g. clopidogrel, ticlopidine);
- selective serotonin reuptake inhibitors (SSRIs: e.g. sertraline, fluoxetine);
- non-steroidal anti-inflammatory drugs (NSAIDs, including ibuprofen);
- methotrexate;
- drugs affecting gout;
- anagrelide (platelet-reducing agent);
- adenosine;
- cholinesterase inhibitors (e.g. some medications used for Myasthenia Gravis Syndrome);
- acetazolamide;
- angiotensin converting enzyme (ACE) inhibitors (e.g. enalapril, captopril);
- phenytoin or valproic acid;
- beta-blockers (e.g. atenolol, propranolol);
- corticosteroids (e.g. prednisone);
- diuretics (e.g. hydrochlorothiazide, furosemide);
- oral hypoglycaemics for diabetes.

If you experience symptoms such as dizziness or confusion you should avoid potentially hazardous tasks such as driving or operating machinery.

PROPER USE OF THIS MEDICATION

Usual dose:

Adults (including the elderly):

The recommended dosage is one capsule twice daily, once in the morning and once in the evening, with or without food. The capsules should be swallowed whole without chewing.

Alternative regimen in case of intolerable headaches:

In the event of intolerable headaches soon after starting treatment with AGGRENOX, talk to your doctor about an alternative dosing regimen. This regimen is comprised of one capsule of AGGRENOX at bedtime and a low dose of ASA in the morning. Headaches should become less of a problem as treatment continues, usually within one week. After a week or so without headache, your doctor will generally recommend that you return to the usual twice-daily dosing regimen of AGGRENOX.

Children and adolescents:

AGGRENOX is not recommended for children or adolescents below 18 years of age.

Missed dose:

If you forget to take a dose, take it as soon as you remember, but if it is almost time for the next dose, wait and take your next dose. Do not take a double dose.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Do not exceed the recommended dosage of AGGRENOX. If you accidentally take too many capsules, you should get medical help immediately, either by calling your doctor or by going to the nearest hospital. Always take the labelled medicine container with you whether or not there are any AGGRENOX capsules remaining. Symptoms of overdosage, especially in the elderly patients, are: ear buzzing, sensation of decreased hearing acuity, and headaches.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

You should be aware that AGGRENOX as a prescription medicine may cause side effects. In most cases these side effects are mild and may disappear with continued treatment. Discuss with your doctor the risks of taking AGGRENOX against the expected benefits. If you do experience any unusual or unwanted effects while you are using AGGRENOX, you should contact your doctor.

Some patients starting on AGGRENOX may develop a severe headache due to the dilation of the vessels in the brain related to the dipyridamole component of the drug. This headache tends to decrease and go away as the body gets used to the medicine. If you develop a severe headache call your doctor.

AGGRENOX is a blood thinner and you may experience bleeding from the nose, bleeding around the gums when eating or brushing teeth, blood in the urine or in the stools, or bruising more easily. If you notice abnormal or excessive bleeding tell your doctor.

Very common side effects include: headache, dizziness, dyspepsia, diarrhoea, nausea, abdominal pain.

Common side effects include: anaemia, hypersensitivity reaction (such as rash, urticaria, bronchospasm, edema), migraine like headache, vomiting, fainting, muscle pain, bleeding inside the brain.

Uncommon side effects include: low blood pressure, stomach ulcer, rapid heart beat, bleeding inside the eye, hot flashes.

Rare side effects include: iron deficiency anemia, reduction in platelet count and erosions in the stomach lining.

The following side effects have also been reported: purple-colored spots and patches on the skin, prolonged bleeding time, bleeding after surgery or other procedures.

If you experience any of the above symptoms that become bothersome, consult your doctor.

Consult your doctor immediately if you experience any of the following:

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Common	Allergic reaction (symptoms like itching, swelling of the face, lips, tongue and throat, difficulty in breathing etc.)			✓
	Internal bleeding with symptoms such as easy bruising, bleeding nose and gums, bloody urine, dark stools, persistent abdominal pain and vomiting.			✓

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and call your
	Gastrointestinal problems such as ulcers, or gastritis (stomach inflammation) with symptoms such as abdominal pain, bloody urine or dark stools.		
Anaemia (reduction in red blood cells) with symptoms such as fatigue, breathlessness, loss of stamina, fast heartbeat.		✓	
Uncommon Worsening of heart problems such as angina (symptoms such as weakness, pain, breathlessness)		✓	

Do not be alarmed by this list of possible side effects. You may not experience any of them.

This is not a complete list of side effects. For any unexpected effects while taking AGGRENOX, contact your doctor or pharmacist.

HOW TO STORE IT

- AGGRENOX capsules must be kept out of the reach of children.
- AGGRENOX should be stored at room temperature (15-30°C). Keep AGGRENOX in the sealed container provided by your doctor or pharmacist, and protect from excessive moisture.
- The expiry date of this medicine is printed on the label. Do not use the medicine after this date has passed.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701D
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at: www.boehringer-ingelheim.ca or by contacting the sponsor, Boehringer Ingelheim (Canada) Ltd., at: 1-800-263-5103, ext. 84633 (Medical Information).

Please check our website to see if more up-to-date information has been posted.

This leaflet was prepared by Boehringer Ingelheim (Canada) Ltd.

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