

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 AGGRENEX was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about AGGRENEX. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

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

A 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.

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

AGGRENEX 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:

AGGRENEX capsules belong to a group of medicines called antiplatelet drugs. Platelets are very small structures in blood, which clump together during blood clotting. AGGRENEX works by preventing the early formation of blood clots (a process called thrombosis).

When it should not be used:

AGGRENEX should not be used:

- if you are sensitive or allergic to any component of the drug (see "What the non-medicinal ingredients are");
- if you have allergy to non-steroidal anti-inflammatory drugs (NSAIDs);
- if you have asthma, rhinitis or nasal polyps; or
- if you have fructose and/or galactose intolerance.

What the medicinal ingredient is:

AGGRENEX is a combination of dipyridamole and acetylsalicylic acid (ASA). AGGRENEX 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 AGGRENEX 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;
- if you are breast feeding. Both dipyridamole and ASA are excreted in human breast milk. You and your doctor will discuss this issue;
- if you are consuming alcoholic beverages;
- if you have any other health problems, including anaemia, liver disease, renal (kidney) disorders, asthma, allergic rhinitis, nasal polyps, 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.
- if you 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); non-steroidal anti-inflammatory drugs used to treat painful and/or inflammatory muscle and joint conditions; or anti-diabetic medicines. (See "Interactions with this medication");
- if you are allergic (experience skin rash or asthma) to any of the components of this drug, including ASA (Aspirin®).
- if you will be having surgery. Your doctor may ask you to stop AGGRENEX for 10 days before your surgery.
- if you have a history of hemorrhagic stroke (stroke due to bleeding).

INTERACTIONS WITH THIS MEDICATION

DO NOT take any other medication unless your doctor tells you to. Be sure to tell any other doctor, dentist, or pharmacist that you speak to that you are using AGGRENOX.

AGGRENOX contains ASA (Aspirin®). You should not take AGGRENOX at the same time as the following medications without the advice of your doctor:

- any other medications containing ASA;
- other blood thinners (e.g. warfarin or heparin);
- antiplatelet agents (e.g. clopidogrel, ticlopidine);
- selective serotonin reuptake inhibitors (SSRIs);
- non-steroidal anti-inflammatory drugs (NSAIDs, including ibuprofen);
- methotrexate;
- drugs affecting gout;
- adenosine;
- cholinesterase inhibitors;
- acetazolamide;
- angiotensin converting enzyme (ACE) inhibitors;
- phenytoin or valproic acid;
- beta-blockers;
- corticosteroids;
- diuretics;
- oral hypoglycaemics.

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:

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 overdose, 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.

Common side effects that can occur include: headache, dizziness, indigestion, and diarrhoea.

Uncommon side effects include: hot flashes, and myalgia (muscle pain).

If the above symptoms 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	Internal Bleeding with symptoms such as easy bruising, bleeding nose and gums, bloody urine, dark stools, persistent abdominal pain and vomiting.		✓	✓
	Gastrointestinal problems such as ulcers, or gastritis (stomach inflammation) with symptoms such as		✓	✓

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

	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

To monitor drug safety, Health Canada collects information on serious and unexpected effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Health Canada by:

Toll-free telephone: 866-234-2345
 Toll-free fax: 866-678-6789
 By email: cadmp@hc-sc.gc.ca

By regular mail:
 National AR Centre
 Marketed Health Products Safety and Effectiveness
 Information Division
 Marketed Health Products Directorate
 Tunney's Pasture, AL 0701C
 Ottawa ON K1A 0K9

NOTE: Before contacting Health Canada, you should contact your physician or pharmacist.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at: <http://www.boehringer-ingenelheim.ca> or by contacting the sponsor, Boehringer Ingelheim (Canada) Ltd., at: 1-800-263-5103, ext. 4633 (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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