

## Patient Information

### **AGGRENOX® (AG-reh-nox) (aspirin/extended-release dipyridamole) Capsules**

Read this Patient Information before you start taking AGGRENOX and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

#### **What is AGGRENOX?**

AGGRENOX is a prescription medicine that contains aspirin and a medicine that is slowly released in your body, called dipyridamole. AGGRENOX is used to lower the risk of stroke in people who have had a “mini-stroke” (transient ischemic attack or TIA) or stroke due to a blood clot.

It is not known if AGGRENOX is safe and effective in children. See “**Who should not take AGGRENOX?**”

#### **Who should not take AGGRENOX?**

**Do not take AGGRENOX** if you:

- are allergic to any of the ingredients in AGGRENOX. See the end of this leaflet for a list of ingredients in AGGRENOX.
- are allergic to non-steroidal anti-inflammatory drugs (NSAIDs)
- have asthma in combination with runny nose and nasal polyps

**Do not give AGGRENOX to a child or teenager with a viral illness. Reye syndrome, a life-threatening condition, can happen when aspirin (an ingredient in AGGRENOX) is used in children and teenagers who have certain viral illnesses.**

#### **What should I tell my doctor before using AGGRENOX?**

**Before taking AGGRENOX, tell your healthcare provider if you:**

- have stomach ulcers
- have a history of bleeding problems
- have heart problems
- have kidney or liver problems
- have low blood pressure
- have myasthenia gravis
- have any other medical conditions
- are pregnant or plan to become pregnant. You should not take AGGRENOX during pregnancy without first talking to your healthcare provider. Tell your healthcare provider right away if you become pregnant while taking AGGRENOX.
- are breast-feeding or plan to breast-feed. AGGRENOX can pass into your milk. Talk to your healthcare provider about the best way to feed your baby if you take AGGRENOX.

Tell your doctor you are taking AGGRENOX if you are scheduled to have a stress test for your heart.

**Tell your doctor about all the medicines you take**, including prescription and non-prescription medicines, vitamins and herbal supplements. AGGRENOX and other medicines may affect each other causing side effects. AGGRENOX may affect the way other medicines work, and other medicines may affect how AGGRENOX works.

Especially tell your healthcare provider if you take:

- **a medicine for high blood pressure, irregular heart beat, or heart failure**
- **acetazolamide [Diamox®]**
- **any blood thinner medicines**
- **warfarin sodium [Coumadin®, Jantoven®]**
- **a heparin medicine**
- **anagrelide [Agrylin®]**
- **a seizure medicine**
- **a medicine for Alzheimer’s disease**
- **a water pill**

- **methotrexate sodium [Trexall®]**
- **aspirin or a non-steroidal anti-inflammatory drug (NSAIDs). You should not take NSAIDs during treatment with AGGRENOX.** Using these medicines with AGGRENOX can increase your risk of bleeding.
- **a medicine for diabetes**
- **probenecid [Probalan®, Col-Probenecid®]**

Ask your healthcare provider or pharmacist if you are not sure if your medicine is one that is listed above.

Know the medicines you take. Keep a list of them and show your healthcare provider and pharmacist when you get a new medicine.

### How should I take AGGRENOX?

- Take AGGRENOX exactly as prescribed. Your healthcare provider will tell you how many AGGRENOX to take and when to take them.
- Headaches are not uncommon when you first start taking AGGRENOX, but often lessen as treatment continues. Tell your healthcare provider if you have a severe headache. Your healthcare provider may change the instructions for taking AGGRENOX.
- Swallow AGGRENOX whole. Do not crush or chew the capsules.
- You can take AGGRENOX with or without food.
- ***If you miss a dose, take your next dose at the usual time. Do not take two doses at one time.***
- If you take more AGGRENOX (overdose) than prescribed, call your healthcare provider or Poison Control Center, or get emergency help right away.

### Symptoms of an overdose of AGGRENOX include:

- a warm feeling or flushing
- sweating
- restlessness
- weakness or dizziness
- a fast heart rate
- ringing in the ears

### What should I avoid while using AGGRENOX?

- **heavy alcohol use.** People who drink three or more alcoholic drinks every day have a higher risk of bleeding during treatment with AGGRENOX, because it contains aspirin.

### What are the possible side effects of AGGRENOX?

#### AGGRENOX may cause serious side effects, including:

- **increased risk of bleeding.** You may bleed more easily during AGGRENOX treatment, and it may take longer than usual for bleeding to stop. This can include:
  - **bleeding into your brain (intracranial hemorrhage).** This can be a medical emergency. Get medical help right away if you have any of these symptoms while taking AGGRENOX:
    - severe headache with drowsiness
    - confusion or memory change
    - pass out (become unconscious)
  - **bleeding in your stomach or intestine.**
    - stomach pain
    - heartburn or nausea
    - vomiting blood or vomit looks like “coffee grounds”
    - red or bloody stools
    - black stools that look like tar
- **new or worsening chest pain in some people with heart disease.** Tell your healthcare provider if you have new chest pain or have any change in your chest pain during treatment with AGGRENOX.
- **liver problems,** including increased liver function tests and liver failure. Tell your healthcare provider if you have any of these symptoms of a liver problem while taking AGGRENOX:
  - loss of appetite
  - pale colored stool
  - stomach area (abdomen) pain

- yellowing of your skin or whites of your eyes
- dark urine
- itching

Call your healthcare provider right away if you have any of the symptoms listed above.

**The most common side effects of AGGRENOX include:**

- headache
- upset stomach
- diarrhea

These are not all the possible side effects of AGGRENOX. Tell your healthcare provider or pharmacist if you have any side effect that bothers you or that does not go away.

Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

**How should I store AGGRENOX?**

- Store AGGRENOX at room temperature 68°F to 77°F (20°C to 25°C).
- Keep AGGRENOX capsules dry.

**Keep AGGRENOX and all medicines out of the reach of children.**

**General information about AGGRENOX**

Medicines are sometimes prescribed for purposes other than those listed in the Patient Information. Do not use AGGRENOX for a condition for which it was not prescribed. Do not give AGGRENOX to other people, even if they have the same symptoms that you have. It may harm them.

This Patient Information summarizes the most important information about AGGRENOX. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about AGGRENOX that is written for health professionals.

For current prescribing information, scan the code below or for additional information, you may also call Boehringer Ingelheim Pharmaceuticals, Inc. at 1-800-542-6257, or 1-800-459-9906 TTY.



**What are the ingredients in AGGRENOX?**

**Active Ingredients:** dipyridamole in an extended-release form and aspirin

**Inactive Ingredients:** acacia, aluminum stearate, colloidal silicon dioxide, corn starch, dimethicone, hypromellose, hypromellose phthalate, lactose monohydrate, methacrylic acid copolymer, microcrystalline cellulose, povidone, stearic acid, sucrose, talc, tartaric acid, titanium dioxide and triacetin. Each capsule shell contains gelatin, red iron oxide and yellow iron oxide, titanium dioxide, and water.

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