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Consumer Medicine Information

AGGRASTAT®

Single dose vial

tirofiban hydrochloride

What is in this leaflet

This leaflet answers some common questions about AGGRASTAT. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using AGGRASTAT against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your doctor or pharmacist.

Keep this leaflet. You may need to read it again.

What AGGRASTAT is used for

AGGRASTAT, in combination with heparin (another medicine used to prevent blood clots), is used to prevent complications that may occur in people who have unstable angina (a type of chest pain) or are having a heart attack.

AGGRASTAT belongs to a group of medicines called platelet aggregation inhibitors.

It works by preventing cells in the blood, called platelets, from sticking together to form blood clots. If blood clots are not treated or prevented, they can block blood vessels. This can lead to complications such as angina or heart attacks.

Before you are given AGGRASTAT

When you must not be given it

Do not use AGGRASTAT if you have an allergy to AGGRASTAT or any of the ingredients listed at the end of this leaflet.

Do not use AGGRASTAT if you have any of the following medical conditions:

- bleeding inside your body
- a history of bleeding in the brain
- a history of brain tumour
- a history of abnormal or deformed arteries or veins
- a history of swelling and weakening of a part of a blood vessel, also called aneurysm
- major surgery or physical trauma, including falls or blows to the body or head, especially within the last



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section, a disease of a large blood vessel

swelling of the lining that surrounds the heart.

Do not use AGGRASTAT if you have received AGGRASTAT before and developed a low platelet count. If you are not sure whether you have received AGGRASTAT before and developed a low platelet count, ask your doctor.

Do not use AGGRASTAT if you have conditions that require treatment with medicines to dissolve blood clots.

Do not use AGGRASTAT if you are breast-feeding or intend to breast-feed. AGGRASTAT is not recommended for use while breast-feeding. It is not known whether it passes into breast milk.

Do not use AGGRASTAT in children. The safety and effectiveness in children have not been established.

If you are not sure whether you should start receiving AGGRASTAT, talk to your doctor.

Before you are given it

Tell your doctor if:

1. you are pregnant
Like most medicines, AGGRASTAT is generally not recommended during pregnancy. However, if there is a need to consider using AGGRASTAT during pregnancy, your doctor will discuss the possible risks and benefits to you and your unborn baby.
2. you have or have had any medical conditions, especially the following:
 - any bleeding problems, including stomach bleeding, or blood in your urine or stools, within the last year
 - blood clotting problems or platelet diseases, including low platelet count
 - disease of the blood vessels of the brain, including stroke, within the last year
 - problems with the blood vessels in the back of your eye/s
 - kidney disease
 - a recent spinal/epidural procedure.
3. if you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.

If you have not told your doctor about any of the above, tell them before you are given AGGRASTAT.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. Some medicines and AGGRASTAT may interfere with each other. This includes medicines used to dissolve or prevent blood clots, including warfarin.

These medicines may be affected by AGGRASTAT, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or to avoid while being given AGGRASTAT.

How AGGRASTAT is given

AGGRASTAT is given as a slow injection into a vein.

AGGRASTAT must only be given by a doctor or nurse.



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g you will receive AGGRASTAT. This depends on your ar factors, such as your weight and kidney function.

Adverse Effects

Tell your doctor, nurse, or pharmacist as soon as possible if you do not feel well while you are being given AGGRASTAT.

AGGRASTAT helps most people, but it may have unwanted adverse effects in a few people. All medicines can have adverse effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or nurse immediately if you notice any unusual bleeding or bruising. This includes bleeding gums, nose bleeds, blood in your urine, bloody or black, tarry stools, coughing up blood, vomiting blood or material that looks like coffee grounds.

These may be serious adverse effects of AGGRASTAT. You may need urgent medical attention.

Tell your doctor or nurse if you notice any of the following and they worry you:

- fever
- nausea
- headache
- rash or allergic reaction.

These are usually mild adverse effects of AGGRASTAT.

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

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

Storage

AGGRASTAT will be stored in the pharmacy or on the ward.
The solution is kept in a cool, dry place where the temperature stays below 30°C and where it is protected from light.

Product Description

What it looks like

AGGRASTAT Concentrate for Infusion comes in a glass vial, containing 50 mL of solution.

Ingredients

Active ingredients:

- AGGRASTAT Concentrate for Infusion - 0.25 mg of tirofiban per mL.

Inactive ingredients:

- citric acid anhydrous
- sodium citrate dihydrate
- sodium chloride
- water for injections

Supplier



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