1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

AGGRASTET 0,05 mg/ml, Solution for Infusion

Tirofiban hydrochloride

Sugar free

Read all of this leaflet carefully before you are given AGGRASTET 0,05 mg/ml

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- AGGRASTET 0,05 mg/ml has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What AGGRASTET 0,05 mg/ml is and what it is used for
2. What you need to know before you are given AGGRASTET 0,05 mg/ml
3. How AGGRASTET 0,05 mg/ml will be administered
4. Possible side effects
5. How to store AGGRASTET 0,05 mg/ml
6. Contents of the pack and other information

1. What AGGRASTET 0,05 mg/ml is and what it is used for

AGGRASTET 0,05 mg/ml keeps platelets from sticking together and forming blood clots.

AGGRASTET 0,05 mg/ml is also used in patients who are having balloon procedures to improve the blood flow in their heart vessels. AGGRASTET 0,05 mg/ml is intended for use with acetylsalicylic acid (aspirin) and heparin.

2. What you need to know before you are given AGGRASTET 0,05 mg/ml

AGGRASTET 0,05 mg/ml should not be administered to you:

- If you are hypersensitive (allergic) to tirofiban or any of the other ingredients of AGGRASTET 0,05 mg/ml (listed in section 6).
- If you are bleeding internally or have a history of bleeding internally within the last 30 days (e.g. bleeding in the stomach and intestines).
- If you have a history of bleeding in the brain, brain tumour or abnormal blood vessels in the brain.
- If you have severe uncontrolled high blood pressure.
- If you have low blood platelet count (thrombocytopenia) or problems with blood clotting.
- If you have developed problems with blood clotting (thrombocytopenia) if you previously received treatment with AGGRASTET 0,05 mg/ml or another medicine in the same group of medicines.
- If you have a history of stroke within the last 30 days or any history of stroke with bleeding.
- If you have been seriously injured or had a major operation within the previous 6 weeks.
- If you suffer from severe liver disease or problems.
- If you are receiving chronic haemodialysis (a process of purifying the blood if the kidneys are not working normally).
- If you have been diagnosed with inflammation of the lining of the heart (acute pericarditis).

- If you are receiving other medicines to prevent your blood from clotting (anti platelet medicines).
- If a recent epidural procedure (an injection in your back to stop you feeling pain in part of your body) has been performed on you.
- If your blood clots more slowly than desired (prolonged INR).
- If you have a history, symptoms, or findings suggestive of aortic dissection (a tear in the inner layer of the body's main artery (aorta)). Symptoms include, but are not limited to a sudden, severe chest or upper back pain that radiates to the neck or down the back, loss of consciousness and shortness of breath.

Warnings and precautions

Take special care with AGGRASTET 0,05 mg/ml

Tell your doctor about any medical problems you have or have had, and about any allergies.

Tell your doctor or health care provider before being given the injection:

- if you recently had serious bleeding problems.
- if you have kidney problems.
- if you had a special intravenous line inserted under your collar bone within the last 24 hours.
- if you have heart problems such as heart failure.
- if you have very low blood pressure due to a failing heart (cardiogenic shock).
- if you have a liver disorder.
- if you have a low blood count or anaemia.
- if you are elderly, female or have a low body weight.

Children

AGGRASTET 0,05 mg/ml should not be administered to children under the age of 18 years of age because the safety in this age group has not been established.

Other medicines and AGGRASTET 0,05 mg/ml

Always tell your health care provider if you are taking any other medicine (this includes all complementary or traditional medicines).

Tell your doctor if you are taking or using any of the following medicines:

Heparin, warfarin, abciximab, enoxaparin, eptifibatide (GP IIb/IIIa inhibitors), ticlopidine, clopidrogrel, aspirin and prasugrel: medicines used to treat or prevent blood clots.

Dextran solutions: medicine used to treat decreased volume of circulating blood plasma, that may result from surgery, trauma or injury, severe burns, or other causes of bleeding.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before AGGRASTET 0,05 mg/ml is administered to you.

The safety of AGGRASTET 0,05 mg/ml during pregnancy and whilst breastfeeding has not been established.

Driving and using machines

It is not always possible to predict to what extent AGGRASTET 0,05 mg/ml may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which AGGRASTET 0,05 mg/ml affects you.

AGGRASTET 0,05 mg/ml contains sodium

AGGRASTET 0,05 mg/ml product contains approximately 40,10 mmol (approximately

992,07 mg) of sodium per 250 ml bag which should be taken into consideration by patients on a controlled sodium diet.

3. How AGGRASTET 0,05 mg/ml will be administered

You have been given, or are about to be given, AGGRASTET 0,05 mg/ml intravenously (into the vein) under supervision of a health care provider. Your doctor will decide on the appropriate dose, depending on your condition and your weight.

You will not be expected to give yourself AGGRASTET 0,05 mg/ml. It will be given to you by a person who is qualified to do so.

If you have the impression that the effect of AGGRASTET 0,05 mg/ml is too strong or too weak, tell your doctor or pharmacist.

If you have received more AGGRASTET 0,05 mg/ml than you should

The most frequently reported symptom of overdose is bleeding.

Since a health care provider will administer AGGRASTET 0,05 mg/ml, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you missed a dose of AGGRASTET 0,05 mg/ml

Since a health care provider will administer AGGRASTET 0,05 mg/ml it is unlikely that the dose will be missed.

4. Possible side effects

AGGRASTET 0,05 mg/ml can have side effects.

Not all side effects reported for AGGRASTET 0,05 mg/ml are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving

AGGRASTET 0,05 mg/ml, please consult health care provider for advice.

If any of the following happens, tell your doctor immediately:

- swelling of the hands, feet, ankles, face, lips, tongue, mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to AGGRASTET 0,05 mg/ml. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately if you notice any of the following:

- signs of bleeding in the skull such as pain in the head (intracranial bleeding), sensory impairments (visual or hearing), difficulties in speech, numbness or problems with movement or balance,
- signs of internal bleeding such as coughing up blood (haemoptysis), vomiting blood (haematemesis) or blood in your urine (haematuria) or stool (GI haemorrhage),
- bleeding after a surgery (post-operative haemorrhage), bleeding into a muscle, causing swelling,
- accumulation of blood around the heart (hemopericardium), with symptoms such as difficulty breathing, abnormal rapid breathing, pressure on the chest and tiredness,
- bleeding in the spaces between the organs (retroperitoneal bleeding) with symptoms such as severe back and groin pain, emerging bruising over the abdomen or flank and low blood pressure,
- a build-up of blood in the spine that can cause complications (spinal epidural haematoma).

Tell your doctor if you notice any of the following:

The following side effects have been frequently reported:

- headache,
- feeling sick (nausea),
- bleeding into the skin (ecchymosis),
- nosebleed (epistaxis), bleeding of the mouth or gums (oral haemorrhage or gingival haemorrhage),
- fever,
- decreased levels of red blood cells and platelets causing tiredness, dizziness, shortness of breath and bleeding or bruising (haematoma),
- bleeding under the skin at the site of injection.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to:

SAHPRA: https://www.sahpra.org.za/Publications/Index/8.

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

By reporting side effects, you can help provide more information on the safety of AGGRASTET 0,05 mg/ml.

5. How to store AGGRASTET 0,05 mg/ml

Store all medicines out of reach of children.

Store at or below 25 °C.

Do not freeze.

Protect from light during storage.

Keep in original packaging until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

Do not use AGGRASTET 0,05 mg/ml if there are visible particles or discolouration of the solution before use.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What AGGRASTET 0,05 mg/ml contains

The active substance is tirofiban. Each 1 ml solution of AGGRASTET 0,05 mg/ml contains 0,05 mg tirofiban as tirofiban hydrochloride monohydrate

Other ingredients are citric acid anhydrous (for pH adjustment), hydrochloric acid (for pH adjustment), sodium chloride, sodium citrate dihydrate (for pH adjustment), sodium hydroxide (for pH adjustment), water for injection.

Sugar free

Contains 160,43 mmol/l of sodium.

What AGGRASTET 0,05 mg/ml looks like and contents of the pack

Clear, colourless solution essentially free from visible particles.

250 ml solution is packed in a colourless (non-PVC plastic) container, multilayer polyolefin film with polyolefin injection moulded tubes. The units are packed in a preprinted foil overpouch, in an outer cardboard carton together with a leaflet.

Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912 (South Africa)

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Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

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