

1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

PROPRIETARY NAME AND DOSAGE FORM

AGGRASTET 0,05 mg/ml

Solution for Infusion

Read all of this leaflet carefully before you start 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 or your pharmacist.
- 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 AGGRASTET 0,05 mg/ml CONTAINS

Each 1 ml solution of AGGRASTET 0,05 mg/ml contains 0,05 mg tirofiban as tirofiban hydrochloride monohydrate

Other ingredients:

Sodium chloride, water for injection.

Sugar free

WHAT AGGRASTET 0,05 mg/ml 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 and heparin.

BEFORE YOU ARE GIVEN AGGRASTET 0,05 mg/ml

You should not be given AGGRASTET 0,05 mg/ml:

- If you are hypersensitive (allergic) to tirofiban or any of the other ingredients.
- If you are bleeding internally or have a history of bleeding internally within the last 30 days.
- 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 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 last month.

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 if you have or have had:

- a recent bleeding disorder (within 1 year) such as gastrointestinal bleeding, or blood in your urine or stool
- treatment with medications that help to prevent or dissolve blood clots

Pregnancy and breastfeeding

Always tell your healthcare provider if you are taking any other medicine. If you are pregnant or breastfeeding your baby, please consult your healthcare provider for advice before receiving AGGRASTET 0,05 mg/ml.

Safe use of AGGRASTET 0,05 mg/ml in pregnancy and breastfeeding has not been established.

Driving and using machinery

No data are available on whether AGGRASTET 0,05 mg/ml impairs the ability to drive or operate machinery.

Important information about some of the ingredients of AGGRASTET 0,05 mg/ml

AGGRASTET 0,05 mg/ml product contains approximately 917 mg of sodium per 250 ml bag which should be taken into consideration by patients on a controlled sodium diet.

Taking other medicines with AGGRASTET 0,05 mg/ml

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of AGGRASTET 0,05 mg/ml with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare provider, for advice.

In general, AGGRASTET 0,05 mg/ml can be used with other medicines. However, it is important to tell your doctor about other medicines that you are taking, including those obtained without a prescription, as some medicines may affect each other's action. It is especially important to tell your doctor if you are taking other medicines that help prevent your blood from clotting such as warfarin.

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) by a healthcare provider. Your doctor will decide on the appropriate dose,

depending on your condition and your weight.

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

The most frequently reported symptom of overdose is bleeding.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

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 missed a dose of AGGRASTET 0,05 mg/ml

Receive your missed dose as soon as you remember, if within a few hours after missing a dose. Do not receive a double dose to make up for forgotten individual doses.

If you have not received your AGGRASTET 0,05 mg/ml, your doctor will decide when to administer the dose.

POSSIBLE SIDE EFFECTS

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

Not all side effects reported for AGGRASTET 0,05 mg/ml are included in this leaflet. Should your general health worsen while receiving AGGRASTET 0,05 mg/ml, please consult your healthcare provider for advice.

If any of the following happens, stop taking AGGRASTET 0,05 mg/ml and tell your doctor immediately or go to the casualty department at your nearest hospital:

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

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

The most common side effect reported during treatment with AGGRASTET 0,05 mg/ml was bleeding.

Tell your doctor straight away if you notice any of the following serious side effects - you may need urgent medical treatment:

- Bleeding

- You have blood in the urine and faeces
- You experience a fever and chills

Tell your doctor if any of the following side effects get serious or lasts longer than a few days:

- Feeling sick (nausea)
- Headache

STORING AND DISPOSING OF AGGRASTET 0,05 mg/ml

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.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

PRESENTATION OF AGGRASTET 0,05 mg/ml

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.

IDENTIFICATION OF AGGRASTET 0,05 mg/ml

Clear, colourless solution essentially free from visible particles.

REGISTRATION NUMBER

34/8.2/0481

NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912

DATE OF PUBLICATION

Date of registration: 07 August 2002



Date of the most recent amendment to the patient information leaflet as approved by the

Authority: 20 April 2012

ZA_AGGRSOL0,05_1204_02