PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

AGGREVA 0,05 mg/ml, solution for infusion

Tirofiban

AGGREVA 0,05 mg/ml is sugar free

Read all of this leaflet carefully before you are given AGGREVA 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.**

What is in this leaflet:

1. WHAT AGGREVA 0,05 mg/ml IS AND WHAT IT IS USED FOR:

AGGREVA 0,05 mg/ml is used to help assist the blood flow to your heart and to help prevent chest pain and heart attacks. It works by preventing platelets, cells found in the blood, from forming blood clots.

AGGREVA 0,05 mg/ml is intended for use with unfractionated heparin.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE AGGREVA 0,05 mg/ml:

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

- if you are hypersensitive (allergic) to tirofiban or to any other ingredients of AGGREVA 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
- if you have a history of bleeding in the brain, brain tumour or abnormal blood vessels in the brain
- if you have a low blood platelet count (thrombocytopenia) or problems with blood clotting
- if you developed thrombocytopenia if you had received treatment with AGGREVA 0,05 mg/ml or another medicine in the same group of drugs previously
- if you have been seriously injured or had a major operation within the last month
- if you have a history of stroke within the last 30 days or any history of stroke with bleeding
- a history or symptoms of splitting of the aorta (aortic dissection)
- if you have severe uncontrolled high blood pressure (malignant hypertension)
- if you have an inflammation of the lining around your heart (pericarditis)
- if you have had a recent spinal procedure
- if you have kidney failure and receive haemodialysis
- if your blood takes longer to clot (prolonged INR).

Warnings and precautions:

Tell your doctor or healthcare provider before being given the injection:

Special care should be taken with AGGREVA 0,05 mg/ml if:

- you had cardiopulmonary resuscitation (CPR), a biopsy, or a procedure to break up kidney stones within the last 2 weeks
- you have been seriously injured or had a major operation within the last 3 months
- you had an ulcer in the stomach or intestine (duodenum) within the last 3 months
- you had a recent bleeding disorder (within 1 year) such as bleeding in the stomach or intestine, or blood in your urine or stool
- you have uncontrolled high blood pressure (hypertension)
- you have an inflammation of the lining around your heart (pericarditis)
- you have an inflammation of the blood vessels (vasculitis)
- you have a tear in the inner layer of the large blood vessel branching off the heart (aorta).

- you have problems with the blood vessels in the back of your eye (retina)
- you are taking medicines that help to prevent or dissolve blood clots
- you have a special intravenous line inserted under your collar bone within the last 24 hours
- you have heart failure
- you have very low blood pressure due to a failing heart (cardiogenic shock)
- you have a liver disorder
- you have low blood platelet count
- you have low blood count or anaemia
- concurrent administration of ticlopidine, clopidogrel, adenosine, dipyridamole, sulfinpyrazone, and prostacyclin
- elderly, female patients and a low body weight, they have a higher incidence of bleeding and should be carefully monitored
- kidney problems.

Children:

AGGREVA 0,05 mg/ml should not be used in children.

Other medicines and AGGREVA 0,05 mg/ml:

Always tell your healthcare provider if you are taking any other medicine.

(This includes all complementary or traditional medicines.)

It is especially important to tell your doctor if you are taking other medicines that help prevent your blood from clotting such as:

- warfarin
- aspirin
- clopidogrel.

Pregnancy, breastfeeding and fertility:

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 healthcare provider for advice before receiving AGGREVA 0,05 mg/ml.

You should not receive AGGREVA 0,05 mg/ml if you are pregnant or breastfeeding your baby.

Driving and using machines:

Due to your disease state, you will not be able to drive or operate machinery while AGGREVA 0,05 mg/ml is being used.

AGGREVA 0,05 mg/ml contains sodium:

AGGREVA 0,05 mg/ml contains approximately 2 412,50 mg of sodium per 250 ml bag which should be taken into consideration by patients on a controlled sodium diet.

3. HOW TO USE AGGREVA 0,05 mg/ml:

Do not share medicines prescribed for you with any other person.

Your doctor will tell you how long your treatment with AGGREVA 0,05 mg/ml will last. If you have the impression that the effect of AGGREVA 0,05 mg/ml is too strong or too weak, tell your doctor or pharmacist.

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

You have been given, or are about to be given, AGGREVA 0,05 mg/ml into a vein. Your doctor will decide on the appropriate dose, depending on your condition and your weight.

The use of AGGREVA 0,05 mg/ml in children is not recommended.

If you use more AGGREVA 0,05 mg/ml than you should:

Since a healthcare provider will administer AGGREVA 0,05 mg/ml, he/she will control the dosage. However, in the event of over dosage your doctor will manage the over dosage.

The most frequently reported symptom of overdose is bleeding. If you notice bleeding, you should notify your healthcare provider immediately.

If you forget to use AGGREVA 0,05 mg/ml:

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

4. POSSIBLE SIDE EFFECTS:

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

Not all side effects reported for AGGREVA 0,05 mg/ml are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving AGGREVA 0,05 mg/ml, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, tell your doctor immediately as the administration of AGGREVA 0,05 mg/ml should be stopped:

- swelling of the hands, feet, ankles, face, lips, 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 reaction to AGGREVA 0,05 mg/ml. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Frequent side effects:

- signs of internal bleeding such as coughing up blood or blood in your urine or stool.

Frequency unknown:

- signs of bleeding in the skull such as pain in the head, sensory impairments (visual or hearing), difficulties in speech, numbness or problems with movement or balance.

These are serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- headache

- collection of blood outside of a blood vessel
- nose bleeds
- nausea
- bleeding in the gums and mouth, bleeding
- small red bruises on the skin
- fever
- bleeding after surgery
- bleeding from vessel puncture site
- invisible blood in urine or stool
- reduction in red blood cells (reduced haematocrit and haemoglobin)
- decreases in platelet count below 90 000/mm^3.

Less frequent:

- bleeding in the stomach or intestines
- vomiting of blood
- decreased platelet count below 50 000/mm^3.

Unknown frequency:

- acute and/or severe decreases in platelet counts below < 20 000/mm^3
- haematoma in the spinal region
- accumulation of blood around the heart
- bleeding in the lung
- bleeding in the abdomen of the internal organs.

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 via the **6.04 Adverse Drug Reaction Reporting Form**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of AGGREVA 0,05 mg/ml.

5. HOW TO STORE AGGREVA 0,05 mg/ml:

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store at or below 25 °C.

Do not freeze.

Keep container in foil over pouch to protect from light.

Keep in original packaging until required for use.

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

Return all unused medicine to your pharmacist.

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

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.

Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution as sterility may be impaired.

The AGGREVA 0,05 mg/ml solution should be clear and free of visible particles, if not, the solution should be discarded.

6. CONTENTS OF THE PACK AND OTHER INFORMATION:

What AGGREVA 0,05 mg/ml contains:

The active ingredient is tirofiban. Each ml contains 0,05 mg tirofiban base.

The other ingredients are acetic acid, sodium hydroxide, sodium acetate trihydrate, sodium chloride and water for injection.

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

Clear, colourless solution, free from visible particles.

250 ml solution premixed is packed in a multi-layer PVC-free Polyolefin plastic infusion bag with an administration port, and an injection point for the addition of medication. Each bag is enclosed in a pre-printed foil over-pouch.

Units are packed in outer cardboard cartons with a leaflet.

Holder of Certificate of Registration:

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PASIëNTINLIGTINGSBLAD

SKEDULERINGSTATUS: S4

AGGREVA 0,05 mg/ml, oplossing vir infusie

Tirofibaan

AGGREVA 0,05 mg/ml is suikervry

Lees hierdie hele blad noukeurig deur voordat u begin om AGGREVA 0,05 mg/ml te gebruik.

- Hou hierdie blad. Dit mag nodig wees dat u dit weer moet lees.
- As u nog vrae het, moet u asseblief vir u dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer vra.

Wat in hierdie blad is:

1. WAT AGGREVA 0,05 mg/ml IS EN WAARVOOR DIT GEBRUIK WORD:

AGGREVA 0,05 mg/ml word gebruik om die bloedvloei na u hart te help en om borspyn en hartaanvalle te voorkom. Dit werk deur te voorkom dat bloedplaatjies, selle wat in die bloed voorkom, bloedklonte vorm.

AGGREVA 0,05 mg/ml is bedoel vir gebruik saam met ongefraksioneerde heparien.

2. WAT U MOET WEET VOORDAT U AGGREVA 0,05 mg/ml GEBRUIK:

AGGREVA 0,05 mg/ml moet nie aan u gegee word nie:

- as u allergies (hipersensitief) vir tirofibaan of vir enige van die ander bestanddele (gelys in **afdeling 6**) van AGGREVA 0,05 mg/ml is
- as u inwendig bloei of in die afgelope 30 dae inwendige bloeding gehad het
- as u ’n geskiedenis van bloeding op die brein, ’n breingewas of abnormale bloedvate in die brein het
- as u ’n lae bloedplaatjietelling (trombositopenie) het of probleme met bloedstolling
- as u trombositopenie ontwikkel het as u voorheen behandeling met AGGREVA 0,05 mg/ml of ’n ander middel in dieselfde groep medisyne ontvang het as u in die afgelope maand ernstig beseer was of ’n groot operasie ondergaan het
- as u in die afgelope 30 dae ’n beroerte gehad het of ’n geskiedenis van beroerte met bloeding het
- as u ’n geskiedenis of simptome van splyting van die aorta (aorta-disseksie) het
- as u onbeheerde hoë bloeddruk (kwaadaardige hipertensie) het
- as u ’n ontsteking van die voering om u hart het (perikarditis)
- as u onlangs ’n spinale prosedure gehad het
- as u nierversaking het en hemodialise ondergaan
- as u bloed langer neem om te stol (verlengde INR)

Waarskuwings en voorsorgmaatreëls:

Sê voordat u die inspuiting kry vir u dokter of gesondheidsorgverskaffer: Wees besonder versigtig met AGGREVA 0,05 mg/ml as:

- u in die afgelope 2 weke kardiopulmonêre resussitasie (KPR), ’n biopsie of ’n prosedure gehad het om nierstene te breek
- u in die afgelope 3 maande ernstig beseer was of ’n groot operasie ondergaan het
- in die laaste 3 maande ’n operasie aan u maag of dunderm gehad het
- u ’n onlangse bloedingstoornis gehad het (binne 1 jaar), soos bloeding in die maag of ingewande, of bloed in u urien of stoelgang
- u onbeheerde hoë bloeddruk (hipertensie) het
- u ’n ontsteking van die voering om u hart het (perikarditis)
- u inflammasie van die bloedvate (vaskulitis) het

- u ’n skeur het in die binneste laag van die groot bloedvat wat uit die hart vertak (aorta)
- u ’n probleem met die bloedvate agter in u oë het (retinopatie)
- u medisyne gebruik wat help om bloedklonte te voorkom of op te los
- ’n spesiale binneaarse lyn in die afgelope 24 uur onder u sleutelbeen geplaas is
- u hartversaking het
- u as gevolg van ’n hartversaking baie lae bloeddruk het (kardiogeniese skok)
- u ’n lewerversteuring het
- u ’n lae bloedplaatjietelling het
- u ’n lae bloedtelling of bloedarmoede het
- u terselfdertyd tiklopidien, klopidogrel, adenosien, dipiridamol, sulfinpirasoon of prostasiklien kry
- bejaarde vroulike pasiënte met ’n lae liggaamsmassa het ’n hoër voorkoms van bloeding en moet noukeurig gemonitor word
- nierprobleme
- kinders.

AGGREVA 0,05 mg/ml moet nie aan kinders gegee word nie.

Ander medisyne en AGGREVA 0,05 mg/ml:

Sê altyd vir u gesondheidsorgverskaffer as u enige ander medisyne gebruik (waaronder aanvullende of tradisionele medisyne).

Dit is veral belangrik om vir u dokter te sê as u ander medisyne gebruik wat help keer dat u bloed stol, soos:

- warfarien
- aspirien
- klopidogrel.

Swangerskap, borsvoeding en vrugbaarheid:

As u swanger is of borsvoed, dink dat u dalk swanger kan wees of beplan om ’n baba te hê, moet u u dokter, apteker of ander gesondheidsorgverskaffer asseblief om advies raadpleeg voordat u AGGREVA 0,05 mg/ml kry.

U moet nie AGGREVA 0,05 mg/ml kry as u swanger is of u baba borsvoed nie.

Motorbestuur en gebruik van masjinerie:

As gevolg van u siektetoestand, sal u nie kan bestuur of masjinerie kan gebruik terwyl AGGREVA 0,05 mg/ml gebruik word nie.

AGGREVA 0,05 mg/ml bevat natrium:

AGGREVA 0,05 mg/ml bevat ongeveer 2 412,50 mg natrium per 250 ml-sak wat in ag geneem moet word vir pasiënte op ’n gekontroleerde natriumdieet.

3. HOE OM AGGREVA 0,05 mg/ml TE GEBRUIK:

Moenie medisyne wat vir u voorgeskryf is vir enige ander persoon gee nie.

U dokter sal vir u sê hoe lank u behandeling met AGGREVA 0,05 mg/ml sal duur. Praat met u dokter of apteker as u die indruk het dat die effek van AGGREVA 0,05 mg/ml te sterk of te swak is.

Dit word nie van u verwag om AGGREVA 0,05 mg/ml aan uself te gee nie. Dit sal aan u gegee word deur ’n persoon wat bevoeg is om dit te doen.

AGGREVA 0,05 mg/ml is in ’n aar aan u gegee, of gaan binnekort gegee word. U dokter sal afhangende van u toestand en u massa op ’n geskikte dosis besluit.

Gebruik van AGGREVA 0,05 mg/ml vir kinders word aanbeveel nie.

As u meer AGGREVA 0,05 mg/ml gekry het as wat u moes:

Omdat ’n gesondheidspraktisyn AGGREVA 0,05 mg/ml sal toedien, sal hy/sy die dosis beheer. In geval van oordosering, sal u dokter die oordosering egter bestuur.

Die mees algemene simptoom van oordosis is bloeding. As u bloeding sien, moet u u gesondheidsorgverskaffer onmiddellik daarvan in kennis stel.

As u vergeet om AGGREVA 0,05 mg/ml te gebruik:

Aangesien ’n gesondheidspraktisyn AGGREVA 0,05 mg/ml sal toedien, is dit onwaarskynlik dat ’n dosis oorgeslaan sal word.

4. MOONTLIKE NEWE-EFFEKTE:

AGGREVA 0,05 mg/ml kan newe-effekte hê.

Nie al die newe-effekte wat vir AGGREVA 0,05 mg/ml aangemeld is, is in hierdie blad opgeneem nie.

As u algemene gesondheidstoestand vererger of as u enige newe-effekte ervaar terwyl u AGGREVA 0,05 mg/ml kry, moet u u dokter, apteker of ander gesondheidspraktisyn om advies raadpleeg.

Sê onmiddellik vir u dokter as enige van die volgende gebeur, aangesien die toediening van AGGREVA 0,05 mg/ml gestaak moet word:

- swelling van die hande, voete, enkels, gesig, lippe, mond of keel wat probleme met sluk of asemhaling kan veroorsaak
- veluitslag of jeuk.

Hierdie is almal baie ernstige newe-effekte. As u dit het, kan dit wees dat u ’n ernstige allergiese reaksie op AGGREVA 0,05 mg/ml het. Dit mag wees dat u dringende mediese aandag of hospitalisasie nodig het.

Sê dadelik vir u dokter of gaan na die ongevalle-afdeling van u naaste hospitaal as u enige van die volgende opmerk:

Newe-effekte wat dikwels voorkom:

- tekens van inwendige bloeding, soos die ophoes van bloed of bloed in u urien of stoelgang.

Frekwensie onbekend:

- tekens van bloeding in die skedel, soos pyn in die kop, sensoriese gestremdheid (visie of gehoor), spraakprobleme, gevoelloosheid of probleme met beweging of balans.

Dit is ernstige newe-effekte. Dit mag wees dat u dringende mediese aandag nodig het.

Sê vir u dokter as u enige van die volgende opmerk:

Newe-effekte wat dikwels voorkom:

- hoofpyn
- opbou van bloed buite die bloedvate
- neusbloeding
- naarheid

- bloeding in die tandvleis en mond, bloeding
- klein rooi kneusplekke op die vel
- koors
- bloeding na ’n operasie
- bloeding van die vate by die inspuitplek
- onsigbare bloed in urien of stoelgang
- afname in die aantal rooibloedselle (laer hematokrit en hemoglobien)
- daling in plaatjietelling tot onder 90 000/mm^3.

Minder dikwels:

- bloeding in die maag of ingewande
- braking van bloed
- daling in plaatjietelling tot onder 50 000/mm^3.

Onbekende frekwensie:

- akute en/of erge daling in bloedplaatjietellings tot onder <20 000/mm^3
- hematoom in die ruggraat
- opeenhoping van bloed rondom die hart
- bloeding in die longe
- bloeding in die buik en die interne organe.

As u enige newe-effekte opmerk wat nie in hierdie blad genoem word nie, moet u u dokter of apteker asseblief in kennis stel.

Aanmeld van newe-effekte:

Praat met u dokter, apteker of verpleegkundige as u newe-effekte kry. U kan newe-effekte ook by SAHPRA aanmeld met die toepaslike vorm, naamlik **6.04 Adverse Drug Reaction Reporting Form** wat aanlyn by SAHPRA se publikasies gekry kan word: https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van AGGREVA 0,05 mg/ml te gee.

5. HOE OM AGGREVA 0,05 mg/ml TE BÊRE:

HOU ALLE MEDISYNE BUITE BEREIK VAN KINDERS.

Bêre by of onder 25 °C.

Moenie vries nie.

Hou die oorspronklike verpakking in die foeliesak om dit teen lig te beskerm. Bêre in die oorspronklike houer totdat dit vir gebruik benodig word.

Moenie na die vervaldatum op die etiket gebruik nie. Gee alle ongebruikte medisyne terug aan u apteker.

Moenie ongebruikte medisyne in dreinering- of rioolstelsels (bv. toilette) gooi nie.

Uit ’n mikrobiologiese oogpunt moet die produk onmiddellik gebruik word.

As dit nie onmiddellik gebruik word nie is die tyd waartydens en toestande waaronder dit gebêre word die verantwoordelikheid van die gebruiker.

Kyk vir klein lekke deur die binneste sak stewig te druk. Gooi die oplossing weg as lekkasies gesien word omdat steriliteit aangetas kan wees.

Die oplossing AGGREVA 0,05 mg/ml moet helder en vry van sigbare deeltjies wees en, indien nie, moet die oplossing weggegooi word.

6. INHOUD VAN DIE PAK EN ANDER INLIGTING WAT AGGREVA 0,05 mg/ml BEVAT:

Die aktiewe bestanddeel is tirofibaan. Elke ml bevat 0,05 mg tirofibaanbasis.

Die ander bestanddele is asynsuur, natriumhidroksied, natriumasetaattrihidraat, natriumchloried en water vir inspuiting.

Hoe AGGREVA 0,05 mg/ml lyk en die inhoud van die pakkie:

Helder, kleurlose oplossing sonder enige sigbare deeltjies.

Die oplossing van 250 ml, vooraf gemeng, is verpak in ’n plastiese infusiesak van veellaag PVC-vrye poli-olefien met ’n toedieningspoort en ’n inspuitpunt waar medisyne bygevoeg kan word. Elke sak is in ’n voorafgedrukte foeliesak.

Eenhede word met ’n voubiljet in buitekartonne verpak.

Houer van die registrasiesertifikaat:

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Hierdie blad is laas hersien in:

30 November 2021

Registrasienommer:

49/8.2/0091