AFSTYLA®

Lonoctocog alfa (250IU, 500IU, 1000IU, 2000IU, 3000IU)

What is in this leaflet

1. What AFSTYLA is used for
2. How AFSTYLA works
3. Before you use AFSTYLA
4. How to use AFSTYLA
5. While you are using AFSTYLA
6. Side effects
7. Storage and Disposal of AFSTYLA
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision
11. Serial number

What AFSTYLA is used for

AFSTYLA is an injectable clotting (coagulation) factor VIII product that is produced by recombinant DNA technology. The active substance AFSTYLA is lonoctocog alfa.

AFSTYLA is used to treat, prevent, or reduce the frequency of bleeding episodes in patients with haemophilia A (inborn factor VIII deficiency) and can be used for all age groups. It can be used during surgeries too.

How AFSTYLA works

Factor VIII is involved in blood clotting. Lack of this factor means that blood does not clot as quickly as it should so there is an increased tendency to bleed. AFSTYLA works by replacing factor VIII in haemophilia A patients to enable their blood to clot

Before you use AFSTYLA

- *When you must not use it:*

Do not use AFSTYLA if you have had a life-threatening allergic reaction to AFSTYLA, any of its components or excipients (listed in section "Product Description"), or hamster proteins.

- *Before you start to use it*

Talk to your doctor, pharmacist or nurse before using AFSTYLA.

- Allergic (hypersensitivity) reactions are possible. The product contains traces of hamster proteins (see also When you must not use it"). If symptoms of hypersensitivity occur, you should stop using the medicine immediately and contact your doctor. Your doctor should inform you of the early signs of hypersensitivity reactions. These include hives, generalised skin rash, tightness of the chest, wheezing, fall in blood pressure and anaphylaxis (a serious allergic reaction that causes severe difficulty in breathing, or dizziness).
- Because of the risk of allergic reactions with factor VIII, your initial administration of AFSTYLA should be performed under medical observation where proper medical care for allergic reactions can be provided.
- The formation of inhibitors (neutralising antibodies) is a known complication that can occur during treatment, which stops the treatment working properly. If your bleeding is not being controlled with AFSTYLA, tell your doctor immediately. You should be monitored carefully for the development of inhibitors.

Record of use

It is strongly recommended that every time AFSTYLA is given, you record the date of administration, the batch number and the injected volume in your treatment diary.

Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Pregnancy and breast-feeding

- If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
- During pregnancy and breast-feeding, AFSTYLA should be given only if it is clearly indicated.

How to use AFSTYLA

Your treatment should be started and monitored by a doctor who is experienced in the treatment of blood clotting disorders.

In case your doctor thinks you could take AFSTYLA on your own, appropriate instructions will be provided to you by your doctor. Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

- *How much to use*

Your doctor will calculate the dose of AFSTYLA you need. The amount of AFSTYLA you need to take and the duration of treatment depend on:

- the severity of your disease
- the site and intensity of the bleeding
- your clinical condition and response
- your body weight

Follow the directions given to you by your doctor.

- *When to use it*

Use as directed by your doctor or pharmacist.

- *How long to use it*

- Continue taking AFSTYLA for as long as your doctor recommends.
- Do not stop using AFSTYLA without consulting your doctor.

AFSTYLA®

Lonoctocog alfa (250IU, 500IU, 1000IU, 2000IU, 3000IU)

- *If you forget to use it*
  - Consult your doctor or pharmacist on what you should do if you forget to use it.
  - Do not take a double dose to make up for the missed dose

- *If you use too much (overdose)*

Please contact your doctor immediately if you inject more AFSTYLA than your doctor recommends.

While you are using it

- *Things you must do*
  - Take your medicine exactly as your doctor has told you.
  - Tell all the doctors, dentists and pharmacists treating you that you are taking AFSTYLA.
  - Tell your doctor immediately if you become pregnant while taking this medication.

Reconstitution and application

General Instructions

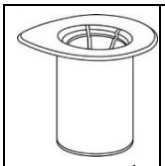
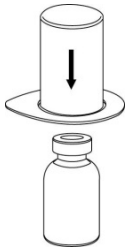
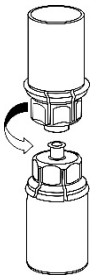
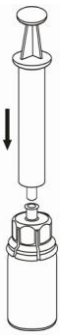
- The powder must be mixed with the solvent (liquid) and withdrawn from the vial under aseptic conditions.
- AFSTYLA must not be mixed with other medicines, diluents or solvents except those mentioned in section "Product description"
- The solution should be clear or slightly opalescent, yellow to colourless, i.e. it might be sparkling when held up to the light but must not contain any obvious particles. After filtering or withdrawal (see below) the solution should be checked by eye, before it is used. Do not use the solution if it is visibly cloudy or if it contains flakes or particles.
- Any unused product or waste material should be disposed of in accordance with local requirements and as instructed by your doctor.

Reconstitution

Without opening the vials, warm the AFSTYLA powder and the liquid to room or body temperature. This can be done either by leaving the vials at room temperature for about an hour, or by holding them in your hands for a few minutes.

DO NOT expose the vials to direct heat. The vials must not be heated above body temperature (37 °C).

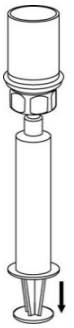
Carefully remove the protective caps from the vials, and clean the exposed rubber stoppers with an alcohol swab. Allow the vials to dry before opening the Mix2Vial package (which contains the filter transfer device), then follow the instructions given below.

 1	Open the Mix2Vial package by peeling off the lid. Do **not** remove the Mix2Vial from the blister package!
 2	2. Place the **solvent vial** on an even, clean surface and hold the vial tight. Take the Mix2Vial together with the blister package and push the spike of the **blue** adapter end **straight down** through the solvent vial stopper.
 3	3. Carefully remove the blister package from the Mix2Vial set by holding at the rim, and pulling **vertically** upwards. Make sure that you only pull away the blister package and not the Mix2Vial set.
 4	4. Place the **AFSTYLA vial** on an even and firm surface. Invert the solvent vial with the Mix2Vial set attached and push the spike of the **transparent** adapter end **straight down** through the AFSTYLA vial stopper. The solvent will automatically flow into the AFYSTLA vial.
 5	5. With one hand grasp the AFSTYLA - side of the Mix2Vial set and with the other hand grasp the solvent-side and unscrew the set carefully counterclockwise into two pieces. Discard the solvent vial with the blue Mix2Vial adapter attached.
 6	6. Gently swirl the AFSTYLA vial with the transparent adapter attached until the substance is fully dissolved. Do not shake.
 7	7. Draw air into an empty, sterile syringe. While the AFSTYLA vial is upright, connect the syringe to the Mix2Vial's Luer Lock fitting by screwing clockwise. Inject air into the AFSTYLA vial.

AFSTYLA®

Lonoctocog alfa (250IU, 500IU, 1000IU, 2000IU, 3000IU)

Withdrawal and Application

 8	8. While keeping the syringe plunger pressed, turn the system upside down and draw the solution into the syringe by pulling the plunger back slowly.
 9	9. Now that the solution has been transferred into the syringe, firmly hold on to the barrel of the syringe (keeping the syringe plunger facing down) and disconnect the transparent Mix2Vial adapter from the syringe by unscrewing counterclockwise.

Use the venipuncture kit supplied with the product, insert the needle into a vein. Let blood flow back to the end of the tube. Attach the syringe to the threaded, locking end of the venipuncture kit. **Inject the reconstituted solution slowly (as comfortable for you, up to a maximum of 10ml/min) into the vein** following the instructions given to you by your doctor. Take care not to get any blood in the syringe containing the product.

Check yourself for any side effects that might happen straight away. If you have any side effects that might be related to the administration of AFSTYLA the injection should be stopped (see also section "Before you use AFSTYLA).

Use in children and adolescents
AFSTYLA can be used in children of all ages. In children (below the age of 12) higher doses or more frequent injections may be needed.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

- *Things you must not do*
  - Do not stop taking the medicine unless advised by your doctor.
  - Do not take any new medicines without consulting your doctor.
  - Do not give AFSTYLA to anyone else, even if they have the same symptoms or condition as you.

- *Things to be careful of*
  - Driving and using machines AFSTYLA does not effect your ability to drive and use machines.
  - AFSTYLA contains sodium AFSTYLA contains up to 7.0 mg (0.30 mmol) sodium per ml after reconstitution.

Side effects

Like all medicines, AFSTYLA can cause side effects, although not everybody gets them.

Please contact your doctor immediately in case of emergency:
- if you notice symptoms of allergic reactions (see below).
- if you notice that the medicine stops working properly

Common side effects (may affect up to 1 in 10 users)
- allergic reaction
- dizziness
- tingling or numbness (paraesthesia)
- rash
- fever

Uncommon side effects (may affect up to 1 in 100 users)
- itching
- redness of the skin
- pain at the injection site
- chills
- feeling hot

The following side effects have generally been observed with factor VIII products, including AFSTYLA:
- Allergic type hypersensitivity reactions are possible and may include the following symptoms: hives, generalised urticaria, tightness of the chest, wheezing, hypotension and anaphylaxis. If this happens, you should stop using the medicine immediately and contact your doctor. Allergic reactions have been observed in clinical trials with AFSTYLA.
- Inhibitors: the medicine stops working properly (continuous bleeding). You may develop an inhibitor (neutralising antibody) to factor VIII, including AFSTYLA, in which case factor VIII will not work properly any more. If this happens, you should stop using the medicine immediately and contact your doctor. No such reactions have been observed in completed clinical trials in previously treated patients with AFSTYLA. Inhibitor development has been observed in previously untreated patients and these patients are at the greatest risk for inhibitor development .

Side effects in children and adolescents
Side effects in children are expected to be the same as in adults.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more

information on the safety of this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumer → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of AFSTYLA

- Storage

- Do not use this medicine after the expiry date, which is stated on the label and carton.
- Store at 2-8°C.
- Before the AFSTYLA powder is reconstituted it may be kept at room temperature (below 25 °C) for a single period not exceeding 3 months, within the expiration date printed on the cartons and the vials. Please record the date from when you start to store AFSTYLA at room temperature on the product carton. Do not freeze.
- Keep the vial in the outer carton in order to protect from light.
- The reconstituted product should preferably be used immediately.
- If the reconstituted product is not administered immediately, storage times and conditions prior to use should not exceed 4 hours at room temperature (below 25 °C).

-Disposal

- Do not throw away any medicines via waste water or household waste.
- Ask your doctor or healthcare professional how to throw away medicines you no longer use. These measures will help protect the environment.

Product Description

- What it loks like

AFSTYLA is presented as white or slightly yellow powder or friable mass and clear, colourless solvent for solution for injection.
The reconstituted solution should be clear to slightly opalescent, yellow to colourless i.e. it might sparkle when held up to the light but must not contain any obvious particles.

Presentations

Box with 250, 500 or 1000 IU containing:
1 vial with powder
1 vial with 2.5 ml water for injections
1 filter transfer device 20/20
Administration set (inner box):
1 disposable 5 ml syringe
1 venipuncture set
2 alcohol swabs

Box with 2000 or 3000 IU containing:
1 vial with powder
1 vial with 5 ml water for injections
1 filter transfer device 20/20
Administration set (inner box):
1 disposable 10 ml syringe
1 venipuncture set
2 alcohol swabs

Not all pack sizes may be marketed.

- Ingredients

Active ingredients:
250 IU per vial; after reconstitution with 2.5 ml of water for injections the solution contains 100 IU/ml of lonoctocog alfa.
500 IU per vial; after reconstitution with 2.5 ml of water for injections the solution contains 200 IU/ml of lonoctocog alfa.
1000 IU per vial; after reconstitution with 2.5 ml of water for injections the solution contains 400 IU/ml of lonoctocog alfa.
2000 IU per vial; after reconstitution with 5 ml of water for injections the solution contains 400 IU/ml of lonoctocog alfa.
3000 IU per vial; after reconstitution with 5 ml of water for injections the solution contains 600 IU/ml of lonoctocog alfa.

Inactive ingredients:
L-Histidine, polysorbate 80, calcium chloride di-hydrate, sodium chloride, sucrose.
Solvent: Water for injections.

- MAL number:

AFSTYLA 250IU powder and solvent for solution for injection
MAL20046087ARZ

AFSTYLA 500IU powder and solvent for solution for injection
MAL20046088ARZ

AFSTYLA 1000IU powder and solvent for solution for injection
MAL20046089ARZ

AFSTYLA 2000IU powder and solvent for solution for injection
MAL20046090ARZ

AFSTYLA 3000IU powder and solvent for solution for injection
MAL20046091ARZ

Manufacturer
CSL Behring GmbH
Emil von Behring Straße 76
35041 Marburg
Germany

Product Registration Holder
DKSH Malaysia Sdn Bhd
B-11-01, The Ascent Paradigm, No.1, Jalan SS7/26A Kelana Jaya 47301 Petaling Jaya Selangor.

Date of revision
08 Dec 2025

Serial Number
NPRA(R3)18/008