IDELVION®

Albutrepenonacog alfa (250IU, 500IU, 1000IU, 2000IU)

What is in this leaflet

What IDELVION is used for

IDELVION is used in children and adults with hemophilia B to control and prevent bleeding episodes. Your healthcare provider may give you IDELVION when you have surgery. IDELVION can reduce the number of bleeding episodes when used regularly (prophylaxis).

How IDELVION works

IDELVION is a haemophilia medicine that replaces a natural blood clotting (coagulation) factor IX. The active substance in IDELVION is albutrepenonacog alfa (recombinant fusion protein linking coagulation factor IX with albumin (rIX-FP)).

Factor IX is involved in blood clotting. Patients with haemophilia B have a lack of this factor which means that their blood does not clot as quickly as it should so there is an increased tendency to bleed. IDELVION works by replacing factor IX in haemophilia B patients to enable their blood to clot.

Before you use IDELVION

- *When you must not use it*

If you are allergic to the active ingredient (albutrepenonacog alfa) or any of the other ingredients listedbelow.

- *Before you start use it*

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

• Allergic (hypersensitivity) reactions are possible. The product contains traces of hamster proteins (see also "When you must not use it"). If symptoms of allergic reactions 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, low blood pressure (hypotension), and anaphylaxis (a serious allergic reaction that causes severe difficulty in breathing, ordizziness).

• Because of the risk of allergic reactions with factor IX, your initial administration of IDELVION should be performed under medical observation where proper medical care for allergic reactions can be provided.

• The formation of neutralising antibodies (inhibitors) is a known complication that has been reported during treatment with Idelvion, which stops the treatment from working properly. If your bleeding is not being controlled with IDELVION, tell your doctor immediately. You should be monitored carefully for thedevelopment of inhibitors.

• If you suffer from liver or cardiac disease or if you have recently had major surgery, please inform your doctor, as there is an increased risk for blood clotting (coagulation) complications.

Record of use

It is strongly recommended that every time IDELVION is given, the date of administration, the batch number andthe injected volume is recorded in the treatment diary.

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, IDELVION should be given only if it is clearly indicated.

- *Taking other medicines*

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

How to use IDELVION

- *How much to use*

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

Dose

Your doctor will calculate the dose of IDELVION you need. The amount of IDELVION 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 IDELVION for as long as your doctor recommends.

Do not stop using IDELVION without consulting your doctor.

- *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 IDELVION 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 IDELVION.

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.

• IDELVION must not be mixed with other medicines 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 cloudy or if it contains flakes or particles.

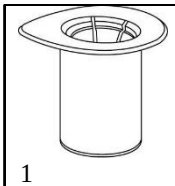
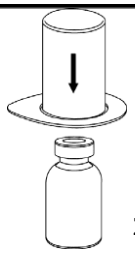
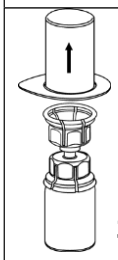
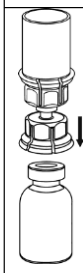
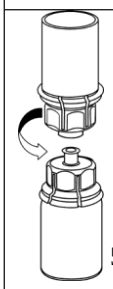
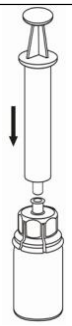
• Any unused product or waste material should be disposed of in accordance with local requirements and as instructed by your doctor.

Reconstitution

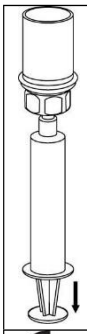
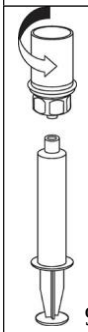
Without opening the vials, warm the IDELVION powder and the liquid to room or body temperature. This can be done either by leaving the vials at room temperature for about an hour, or by holding them in your hands for a few minutes.

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 (device pack), then follow the instructions given below.

 1	1. Open the Mix2Vial 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.
 attached 4	4. Place the **powder vial** on an even and firm surface. Invert the solvent vial with the Mix2Vial set and push the spike of the **transparent** adapter end **straight down** through the product vial stopper. The solvent will automatically flow into the product vial.
 5	5. With one hand grasp the powder-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 product 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 product vial is upright, connect the syringe to the Mix2Vial's Luer Lock fitting by screwing clockwise. Inject air into the product vial.

Withdrawal and Application

 8	8. While keeping the syringe plunger pressed, turn the system upside down and draw the solution into the syringeby pulling the plunger back slowly.
 9	9. Now that the solution has been transferred intothe 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) 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 IDELVION, the injection should be stopped (see also sections Before you use IDELVION and Side effects).

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 IDELVION to anyone else, even if they have the same symptoms or condition as you.

- *Things to be careful of*

Driving and using machines

IDELVION does not affect your ability to drive and use machines.

IDELVION *contains sodium*
Sodium approximately 75 mmol/l (1.7243 g/l).

Side effects

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

Please contact your doctor immediately:
• if you notice symptoms of allergic reactions (see below)
• if you notice that the medicine stops working properly

The following side effects have been observed with factor IX medicines:
• Allergic-type hypersensitivity reactions are possible and may include the following symptoms: hives, skin rashes (generalised urticaria), tightness of the chest, wheezing, low blood pressure (hypotension) and anaphylaxis (a serious reaction that causes severe difficulty in breathing or dizziness). If this happens, you should stop using the medicine immediately and contact your doctor.
• Inhibitors: the medicine stops working properly (continuous bleeding). You may develop a neutralising antibody (inhibitor) to factor IX, in which case factor IX will not work properly any more. If this happens, you should stop using the medicine immediately and contact your doctor.

The following side effects have been observed with IDELVION **commonly** (may affect up to 1 in 10 people):
• Headache
• Injection site reactions
• Dizziness

The following side effects occurred **uncommonly** (may affect up to 1 in100 people):
• Allergic reactions (Hypersensitivity)
• Rash
• Eczema

The following side effects have been reported but it is **not known** how many people may be affected;
• Development of neutralising antibodies (inhibitors) to IDELVION

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 [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of IDELVION
- *Storage*

Keep out of the reach and sight of children.

Do not store above 25°C. Do not freeze.

Do not use this medicine after the expiry date, which is stated on the label and carton.

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 be longer than 4 hours at room temperature (below 25 °C).

- *Disposal*

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.

Product Description
- *What it looks like*

IDELVION is presented as a paleyellow to white powder and is supplied with water for injections as solvent.
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 containany obvious particles.

Immediate containers
Powder (250/500/1000 IU) in a 6 ml vial (type I glass), with a stopper (rubber) a disc (plastic) and a cap (aluminium).
2.5 ml of solvent in a vial (type I glass), with a stopper (rubber) a disc (plastic) and a cap (aluminium).
Powder (2000 IU) in a 10 ml vial (type I glass), with a stopper (rubber) a disc (plastic) and a cap (aluminium).
5 ml of solvent in a vial (type I glass), with a stopper (rubber) a disc (plastic) and a cap (aluminium).

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
1 non-sterile plaster

Box with 2000 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
1 non-sterile plaster

Not all pack sizes may be marketed.

- *Ingredients*
  - Active ingredient
    Albutrepenonacog alfa

  - Inactive ingredients
    Tri-sodium citrate dihydrate, polysorbate 80, mannitol, sucrose, and HCl (for pH adjustment)
    Solvent: Water for injections

- *MAL numbers:*
- **IDELVION 250IU powder and solvent for solution for injection**
  MAL18046017ARZ

- **IDELVION 500IU powder and solvent for solution for injection**
  MAL18046018ARZ

- **IDELVION 1000IU powder and solvent for solution for injection**
  MAL18046019ARZ

- **IDELVION 2000IU powder and solvent for solution for injection**
  MAL18046020ARZ

Manufacturer
CSL Behring GmbH
Emil-von-Behring-Str. 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, Malaysia.

Date of revision
10/05/2024

Serial Number
NPRA(R3/01)10052024/0305