

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using IDELVION®?

IDELVION® contains the active ingredient albutrepenonacog alfa (recombinant fusion protein linking coagulation factor IX with albumin (rIX-FP)). IDELVION® is used to prevent and treat bleeding, occurring either spontaneously or due to injury, and bleeding during emergency and surgical procedures, by temporarily providing additional factor IX.

For more information, see Section [1. Why am I using IDELVION®?](#) in the full CMI.

2. What should I know before I use IDELVION®?

Do not use if you have ever had an allergic reaction to IDELVION® or any of the ingredients listed at the end of the CMI including hamster proteins.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use IDELVION®?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with IDELVION® and affect how it works.

For more information, see Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use IDELVION®?

- Your doctor will determine what dose is required and the duration of your treatment.
- Treatment should be started and supervised by a doctor experienced in the treatment of blood clotting disorders.
- Training will be provided for preparation and administration of IDELVION® prior to use (if applicable).
- If IDELVION® is not used immediately after reconstitution it must be stored at room temperature (at or below 25°C) and used within 4 hours of preparation. The reconstituted solution should not be stored in the refrigerator.

More instructions can be found in Section [4. How do I use IDELVION®?](#) in the full CMI.

5. What should I know while using IDELVION®?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using IDELVION®.• Notice any signs of a side effect – this may indicate that the use of IDELVION® needs to be stopped immediately.
Things you should not do	<ul style="list-style-type: none">• Do not give or share your medicine with anyone else, even if they have the same condition.• Do not mix IDELVION® with other medicines or diluents either before or during administration.
Driving or using machines	<ul style="list-style-type: none">• IDELVION® does not affect your ability to drive and use machines.
Looking after your medicine	<ul style="list-style-type: none">• Store IDELVION® at 2°C to 25°C. Do not freeze.• Keep IDELVION® in the outer carton, in order to protect from light.

For more information, see Section [5. What should I know while using IDELVION®?](#) in the full CMI.

6. Are there any side effects?

All medicines can have side effects. sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects. The most common side effects are headache, dizziness, rash, or an allergic reaction. The more serious side effects include skin rash, breathlessness, wheezing or difficulty breathing, tightness of the chest, fall in blood pressure, dizziness, bleeding and vomiting.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

IDELVION®

Active ingredient(s): *Albutrepenonacog alfa (recombinant fusion protein linking coagulation factor IX with albumin (rIX-FP))*

Consumer Medicine Information (CMI)

This leaflet provides important information about using IDELVION®. **You should also speak to your doctor, pharmacist or Haemophilia Treatment Centre if you would like further information or if you have any concerns or questions about using IDELVION®.**

Where to find information in this leaflet:

- [1. Why am I using IDELVION®?](#)
- [2. What should I know before I use IDELVION®?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use IDELVION®?](#)
- [5. What should I know while using IDELVION®?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using IDELVION®?

IDELVION® contains the active ingredient albutrepenonacog alfa (recombinant fusion protein linking coagulation factor IX with albumin (rIX-FP)).

IDELVION® is used to prevent and treat bleeding, occurring either spontaneously or due to injury, and bleeding during emergency and surgical procedures, by temporarily providing additional factor IX.

Factor IX is involved in blood clotting. Lack of this factor means that blood does not clot as quickly as it should and there is an increased tendency to bleed.

IDELVION® works by replacing factor IX in patients with haemophilia B (also called congenital factor IX deficiency or Christmas disease).

2. What should I know before I use IDELVION®?

IDELVION® treatment will be initiated at a Haemophilia Treatment Centre under the supervision of a doctor experienced and trained in the diagnosis and management of haemophilia B.

If your doctor thinks that you could take IDELVION® on your own (home treatment), appropriate instructions and training will be provided to you by your doctor or Haemophilia Treatment Centre.

Warnings

Do not use IDELVION® if:

- you have an allergy or hypersensitivity reaction to albutrepenonacog alfa (recombinant fusion protein linking coagulation factor IX with albumin) or any of the ingredients listed at the end of this leaflet
- you have an allergy to hamster proteins (trace amounts present in medicine).

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- tightness of the chest
- wheezing or difficulty breathing
- fall in blood pressure
- dizziness
- rash, itching or hives on the skin.

Check with your doctor if you:

- have previously had an allergic or hypersensitivity reaction to other factor IX products.
- have allergies to any medicines
- have, or have had, any other medical conditions (including pre-existing blood clotting conditions), or are currently taking any medications, including non-prescription medicines, health supplements and herbal remedies.

Discuss the risks and benefits of this medicine with your doctor.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant, think you are pregnant, intend to become pregnant or are breastfeeding.

During pregnancy and breastfeeding, IDELVION® should be given only if it is clearly needed.

Experience regarding the use of IDELVION® during pregnancy and during breastfeeding is not available because of the rare occurrence of haemophilia B in women.

Inhibitors

Treatment with factor IX products such as IDELVION® may sometimes lead to the formation of antibodies (inhibitors) which neutralise factor IX and reduce the effectiveness of the treatment or even stop the medicine from working properly (uncontrolled bleeding). If your bleeding is not being controlled with IDELVION®, tell your doctor immediately or contact your Haemophilia Treatment Centre.

Your doctor will monitor you for development of these inhibitors and if they suspect that an inhibitor is present, the level of inhibitor will be measured using the appropriate laboratory tests.

Thromboembolism

Factor IX products such as IDELVION® may increase the risk of thromboembolism (abnormal blood clots) in your body if you have risk factors for developing blood clots.

All medicines have benefits and risks. Your doctor has weighed the benefits that IDELVION® will have for you against this risk.

Record of use

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

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with IDELVION® and affect how it works.

You should avoid taking medicines that increase the risk of bleeding.

Check with your doctor, Haemophilia Treatment Centre or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect IDELVION®.

4. How do I use IDELVION®?

IDELVION® is used for intravenous (into the vein) injection.

Treatment with IDELVION® should be started and supervised by a doctor at a Haemophilia Treatment Centre who is experienced in the treatment of haemophilia B.

If your doctor decides that treatment at home is appropriate, detailed instructions and training will be provided by your doctor or Haemophilia Treatment Centre on how to use IDELVION®.

If you do not understand the instructions, ask your doctor.

How much to use

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

- the severity of the 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.

Use in children and adolescents

IDELVION® can be used in children and adolescents of all ages.

When to use IDELVION®

Always take IDELVION® exactly as your doctor has told you. Check with your doctor if you are not sure.

How to prepare IDELVION® for injection

General Instructions

- The powder must be mixed with the solvent (liquid) and withdrawn from the vial under sterile conditions.
- IDELVION® must not be mixed with other medicines, diluents or solvents.
- 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.

The following instructions are intended as a guide only for those patients who have been instructed by their doctor or Haemophilia Treatment Centre on the proper way to self-administer IDELVION®.

You will need one 2.5 mL Water for Injections (WFI) for each 250 IU, 500 IU or 1000 IU vial of IDELVION®, or one 5 mL Water for Injections (WFI) for each 2000 IU or 3500 IU vial of IDELVION® (supplied).

If multiple vials of IDELVION® are to be given, a separate Mix2Vial™ (supplied) must be used for each vial.







The following components are required

- One carton of IDELVION® containing:
 - 1 vial of IDELVION®
 - 1 vial of Water for Injections (WFI)
 - 1 Mix2Vial™ filter transfer set
 - One administration pack with:
 - 1 disposable syringe
 - 1 venipuncture set
 - 2 alcohol swabs.

You may also require the following items that are not included in the pack:

- sharps container
- waste container for discarding biological material
- adhesive tape
- cotton balls
- gloves.

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| 1. Check the expiry of each vial. Do not use if expired. |
| 2. Allow the vial of IDELVION® and diluent (Water for Injections; WFI) to reach room temperature prior to use, which may take up to one hour. Do not warm the WFI in hot water. |
| 3. Remove jewellery, watches, rings, etc, and wash hands with soap and water and dry hands thoroughly with a clean towel. |

4. Find a clean, flat working surface such as a table, where you can prepare IDELVION®.	
5. Using a clean cloth or paper towel, clean the preparation area with methylated spirits.	
6. Remove the flip top caps from the IDELVION® and WFI vials.	
7. Wipe the rubber stoppers of both the product and diluent vials with an alcohol swab and allow to dry for two minutes. Do not touch the rubber stoppers with your fingers.	
8. Open the Mix2Vial™ package by peeling off the lid. Do not remove the Mix2Vial™ from the blister package.	
9. Place the WFI 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 end straight down through the WFI stopper.	
10. 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™ itself.	
11. Place the IDELVION® vial on an <u>even and firm surface</u> . Invert the WFI vial with the Mix2Vial™ set attached and push the transparent adapter straight down through the IDELVION® vial stopper. The WFI will automatically flow into the IDELVION® vial.	
<p>If WFI does not flow into the vial, it means that there is no vacuum in the vial and the seal may be faulty. Do not use the product but return it to your Haemophilia Treatment Centre.</p> <p>Note: The Mix2Vial™ is intended to filter the contents of a single vial of IDELVION® only. If multiple vials of IDELVION® are to be given, a separate Mix2Vial™ must be used for each vial.</p>	
12. With one hand, hold the IDELVION® side of the Mix2Vial™ set, hold the WFI side with the other hand and unscrew the set carefully anti-clockwise into two pieces. Discard the WFI vial with the blue Mix2Vial™ end attached.	
13. Gently swirl the IDELVION® vial until the substance is fully dissolved. Do not shake as this could damage the product.	

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.

Do not use solutions that are cloudy or contain flakes or particles.

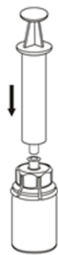


This medicine does not contain an antimicrobial preservative.

Use IDELVION® as soon as you can after reconstitution.

If the IDELVION® solution is not used immediately after reconstitution it must be stored at room temperature (at or below 25°C) and used within 4 hours of preparation.

Do not refrigerate IDELVION® once it has been prepared.

The reconstituted solution should only be stored in the vial. Any unused portion remaining in the vial must be discarded appropriately.

14. Draw air into an empty, sterile, syringe. Use the syringe provided with the product. While the IDELVION® vial is upright, connect the syringe to the Mix2Vial™'s Luer Lock fitting by screwing clockwise. Inject air into the IDELVION® vial.	
15. While keeping the syringe plunger pressed, turn the system upside down and draw the solution into the syringe by pulling the plunger back slowly.	
16. When the solution has been transferred into the syringe, firmly hold on to the barrel of the syringe in one hand (keeping the syringe plunger facing down), and with the other hand disconnect the Mix2Vial™ set and IDELVION® vial from the syringe by unscrewing anti-clockwise.	

How to administer IDELVION® injection

IDELVION® should be used for one person on one occasion only.

Should any of the symptoms listed under Section 6. [Are there any side effects?](#) develop, stop the injection immediately and contact your doctor or Haemophilia Treatment Centre.

1. Wash hands with soap and water, dry with a clean towel.
2. Put on gloves.
3. Apply tourniquet. Select the injection site.

4.	Wipe the skin area with an alcohol swab, allow to dry.
5.	Using the venipuncture set supplied with the product, insert the needle into the vein. Let blood flow back to the end of the tube.
6.	Secure the needle with adhesive tape.
7.	Attach the syringe containing IDELVION® to the end of the tube. Care should be taken that no blood enters the syringe filled with IDELVION® as there is a risk blood could clot in the syringe.
8.	Release the tourniquet.
9.	Administer the IDELVION® solution slowly (usually within 5 minutes, or as tolerated).
10.	Carefully remove the adhesive tape.
11.	Carefully remove the intravenous needle with the syringe attached and place directly into the sharps container.
12.	Apply pressure to the injection site using a cotton ball for one to two minutes. Apply dressing if necessary.
13.	Discard all used sharps into the sharps container, and dispose of the other used components appropriately.
14.	Wash hands with soap and water, dry with a clean towel.

It is recommended that treatment details and the lot number from the IDELVION® vial label are recorded every time you use IDELVION®.

If you forget to use IDELVION®

IDELVION® should be used as prescribed by your doctor. If you miss a dose, follow your doctor's instructions or contact your doctor or Haemophilia Treatment Centre.

If you use too much IDELVION®

No symptoms of overdose with IDELVION® have been reported. If you think that you have used too much IDELVION®, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor or Haemophilia Treatment Centre, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using IDELVION®?

Things you should do

Call your doctor straight away if you:

- Notice signs or symptoms of a serious side effect. This may be a sign of a serious allergy or anaphylactic reaction. The administration of IDELVION® should be stopped immediately.
- Remind any doctor, dentist or pharmacist you visit that you are using IDELVION®.

Things you should not do

- Do not stop using this medicine suddenly unless instructed by your doctor.
- Do not give or share your medicine with anyone else, even if they have the same condition as you.
- Do not mix IDELVION® with other medicines or diluent either before or during administration.

Driving or using machines

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

Be careful before you drive or use any machines or tools until you know how IDELVION® affects you.

Looking after your medicine

- Store IDELVION® at 2°C to 25°C. Do not freeze.
- Keep IDELVION® in the outer carton, in order to protect from light.
- Do not use after the expiry date.
- IDELVION® does not contain a preservative so the reconstituted solution should preferably be used immediately. If the medicine is not used immediately, store (in the vial) at room temperature (below 25°C) and use within 4 hours.

Follow the instructions in the carton on how to take care of your medicine properly.

Keep it out of sight and reach of children.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy or Haemophilia Treatment centre for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• a local reaction around the site of the injection (e.g. a burning sensation, or transient reddening of the skin)• nausea• headache.	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">• skin rashes, itching, eczema• breathlessness• wheezing or difficulty breathing• tightness of the chest• decreased blood pressure• dizziness (feeling faint)• uncontrolled bleeding• vomiting.	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor, Haemophilia Treatment Centre or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What IDELVION® contains

Active ingredient (main ingredient)	Albutepeonacog alfa (recombinant fusion protein linking coagulation factor IX with albumin).
Other ingredients (inactive ingredients)	Sodium citrate dihydrate Polysorbate 80 Mannitol

	Sucrose Hydrochloric acid (pH adjustment).
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IDELVION® also contains trace amount of hamster protein.

Do not take this medicine if you are allergic to any of these ingredients.

What IDELVION® looks like

IDELVION® is a pale yellow to white powder before reconstitution and is supplied with Water for Injections as solvent.

The 250 IU vial, 500 IU vial and 1000 IU vial of IDELVION® comes in a pack containing:

- a vial of diluent (2.5 mL of Water for Injections) used to dissolve the powder
- a Mix2Vial™ filter transfer set
- an administration pack with:
 - a disposable 5 mL syringe
 - a venipuncture set (butterfly)
 - 2 alcohol swabs.

The 2000 IU vial and 3500 IU vial of IDELVION® comes in a pack containing:

- a vial of diluent (5 mL of Water for Injections) used to dissolve the powder
- a Mix2Vial™ filter transfer set
- an administration pack with:
 - a disposable 10 mL syringe
 - a venipuncture set (butterfly)
 - 2 alcohol swabs.

Not all dose strengths may be available.

250 IU AUST R 255552

500 IU AUST R 259938

1000 IU AUST R 259939

2000 IU AUST R 259940

3500 IU AUST R 324220

Who distributes IDELVION®

IDELVION® is supplied in Australia by

CSL Behring (Australia) Pty Ltd

ABN 48 160 734 761

189-209 Camp Road

Broadmeadows VIC 3047

Australia

For Medical / Technical Enquiries

TOLL FREE: 1800 642 865

For Customer Service Enquiries

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