

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at <https://www.tga.gov.au/reporting-problems>.

DEFITELIO®

defibrotide

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DEFITELIO. It does not contain all the available information. It does not take the place of talking to your doctor.

All medicines have risks and benefits. Your doctor has weighed the risks of you using DEFITELIO against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor.

Keep this leaflet.

You may need to read it again.

What DEFITELIO is used for

DEFITELIO is a medicine that contains the active substance defibrotide.

DEFITELIO is used to treat a condition called hepatic veno-occlusive disease (or VOD), in which the blood vessels in the liver become damaged and obstructed by blood clots. This can be caused by medicines that are given prior to a stem cell transplantation.

DEFITELIO works by protecting the cells of the blood vessels and preventing or breaking down the blood clots.

This medicine can be used in adults, and in adolescents, children and infants over one month of age.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

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

This medicine is not expected to affect your ability to drive a car or operate machinery.

Before you are given DEFITELIO

When you must not be given this medicine

You must not be given DEFITELIO if you:

- are allergic to defibrotide or any of the other ingredients listed in this leaflet
- are using other medicines to break down blood clots such as tissue plasminogen activators (e.g. alteplase, reteplase).

Before you are given this medicine

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you:

- are taking medicine that thins your blood or increases the risk of bleeding
- have heavy bleeding and need a blood transfusion
- are undergoing surgery
- have problems with blood circulation because your body cannot maintain a constant blood pressure.

DEFITELIO is not recommended in children less than 1 month of age.

If you are not sure if you should be given DEFITELIO talk to your doctor.

Taking other medicines

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

Tell your doctor if you are taking any of the following:

- medicines to break down blood clots, such as tissue plasminogen activators (e.g. alteplase, reteplase).
- medicines used to thin your blood such as aspirin, heparin sodium, warfarin, dabigatran etexilate, rivaroxaban, apixaban
- non-steroidal anti-inflammatory medicines such as ibuprofen, naproxen, diclofenac and other non-steroidal anti-inflammatory medicines.

Pregnancy

If you are pregnant, think you may be pregnant or are planning to have a baby, tell your doctor.

Defitelio should not be used during pregnancy unless there is a definite need. Your doctor will discuss with you the risk and benefit involved in using DEFITELIO during pregnancy.

If you are sexually active and you or your partner could become pregnant, you both must use effective contraception during treatment with DEFITELIO and for 1 week after stopping the treatment.

Breastfeeding

If you are breastfeeding, tell your doctor.

Your doctor can discuss with you the risk and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you are given DEFITELIO.

How DEFITELIO is given

The treatment with DEFITELIO can be initiated and continuously supervised only by an experienced doctor in a hospital or in a specialised centre for stem cell transplantation.

How much is given

The total dose of DEFITELIO that is given is calculated based on your body weight. The calculation of the dose in children from one month to 18 years of age is the same as in adults.

How it is given

DEFITELIO will be given via a drip (a slow injection into your veins) over a 2-hour period. This is also called an intravenous infusion.

When it is given

You will receive this treatment four times a day for at least 21 days or until your symptoms resolve.

If you miss a dose

Tell your doctor or nurse immediately if you think you have missed a dose of DEFITELIO.

As you will be given this medicine by a doctor or a nurse it is unlikely that a dose will be missed. You must not be given a double dose to make up for a missed dose.

If you are given too much (overdose)

As DEFITELIO is given to you under the supervision of your doctor it is unlikely that you will be given too much. However, if you experience any side effects after being given DEFITELIO, tell your doctor immediately.

Side effects

Like all medicines, DEFITELIO can cause side effects, although not everybody gets them. Your doctor will discuss these with you and explain the risks and benefits of your treatment.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or nurse immediately if you notice any of the following as you may require medical attention:

- signs of increased or unusual bleeding or bruising during or after treatment
- nosebleeds
- passing of blood in the urine or faeces
- dark coloured faeces
- bloody diarrhoea
- vomiting blood or material that looks like coffee grounds
- bleeding from the infusion line or catheter
- bleeding at the site of injection
- bleeding from the mouth
- bleeding from the eye
- chest pain
- shortness of breath
- rapid heart beat
- fever or high temperature
- dizziness or light-headedness

- sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing.
- feeling sick, also called nausea
- vomiting
- diarrhoea
- rash
- red or purple, flat, pinhead spots under the skin
- itching.

Other side effects not listed above may also occur in some people.

After you are given DEFITELIO

Storage

It is unlikely that you will be asked to store DEFITELIO yourself. It will usually be stored in the pharmacy or on the ward.

DEFITELIO is stored below 25°C. It must not be frozen.

Keep this medicine out of reach and sight of children.

Do not use DEFITELIO after the expiry date which is stated on the carton and vial label after 'EXP'.

The expiry date refers to the last day of the month.

Product description

What it looks like

DEFITELIO is a clear light yellow to brown concentrated solution for infusion, free from particulate matter or turbidity.

One carton contains 10 glass vials, each with 2.5 mL of concentrated solution for infusion.

Ingredients

The active substance in DEFITELIO is defibrotide. Each 2.5 mL vial contains 200 mg defibrotide and each mL of concentrated solution contains 80 mg defibrotide.

DEFITELIO also contains:

- sodium citrate dihydrate
- hydrochloric acid
- sodium hydroxide
- water for injections.

Name and address of the sponsor

DEFITELIO is distributed in Australia by:

Link Medical Products Pty Ltd
5 Apollo Street
Warriewood NSW 2102
AUSTRALIA

Australian registration number:
AUST R 319221

Date of preparation

July 2020.