

## 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.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details. [Include if applicable]

### 1. Why am I being given DEFITELIO?

DEFITELIO contains the active ingredient 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.

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

### 2. What should I know before I am given DEFITELIO?

Do not use if you have ever had an allergic reaction to defibrotide or any of the ingredients listed at the end of the CMI.

Do not use if are using other medicines to break down blood clots such as tissue plasminogen activators (e.g. alteplase, reteplase).

**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 DEFITELIO?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with DEFITELIO and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How is DEFITELIO 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.
- The total dose of DEFITELIO that is given is calculated based on your body weight.

More instructions can be found in Section [4. How is DEFITELIO given?](#) in the full CMI.

### 5. What should I know while being given DEFITELIO?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using DEFITELIO.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• DEFITELIO is not expected to affect your ability to drive a car or operate machinery.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• It is unlikely that you will be asked to store DEFITELIO yourself. It will usually be stored in the pharmacy or on the ward.</li><li>• DEFITELIO is stored below 25°C. It must not be frozen.</li></ul>

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

### 6. Are there any side effects?

Possible side effects include 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 heartbeat, 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, nausea, vomiting, diarrhoea, rash, red or purple, flat, pinhead spots under the skin, and itching.

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.

▼ 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 [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). [Include if applicable]

# DEFITELIO®

Active ingredient(s): defibrotide

## Consumer Medicine Information (CMI)

This leaflet provides important information about using DEFITELIO. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using DEFITELIO.**

Where to find information in this leaflet:

1. [Why am I being given DEFITELIO?](#)
2. [What should I know before I am given DEFITELIO?](#)
3. [What if I am taking other medicines?](#)
4. [How is DEFITELIO given?](#)
5. [What should I know while being given DEFITELIO?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

## 1. Why am I being given DEFITELIO?

DEFITELIO contains the active ingredient 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.

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

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

## 2. What should I know before I am given DEFITELIO?

### Warnings

**Do not use DEFITELIO if:**

- you are allergic to defibrotide, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- are using other medicines to break down blood clots such as tissue plasminogen activators (e.g. alteplase, reteplase).

**Check with your doctor if you:**

- have any other medical conditions
- 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
- have allergies to any other medicines, foods, preservatives, or dyes.

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?](#)

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

## Pregnancy and breastfeeding

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

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.**

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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

## 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.

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.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect DEFITELIO.**

## 4. How is DEFITELIO 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 and 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 DEFITELIO

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.

## 5. What should I know while being given DEFITELIO?

### Things you should do

Remind any doctor, dentist or pharmacist you visit that you are using DEFITELIO.

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how DEFITELIO affects you.**

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

### Looking after your medicine

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.
- **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.

**Keep it where young children cannot reach or see it.**

## 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.

### Serious side effects

Serious side effects	What to do
<p><b>Bleeding-related:</b></p> <ul style="list-style-type: none"> <li>• signs of increased or unusual bleeding or bruising during or after treatment</li> <li>• nosebleeds</li> <li>• passing of blood in the urine or faeces</li> <li>• dark coloured faeces</li> <li>• bloody diarrhoea</li> <li>• vomiting blood or material that looks like coffee grounds</li> <li>• bleeding from the infusion line or catheter</li> <li>• bleeding at the site of injection</li> <li>• bleeding from the mouth</li> <li>• bleeding from the eye</li> </ul> <p><b>Heart-related:</b></p> <ul style="list-style-type: none"> <li>• chest pain</li> <li>• rapid heartbeat</li> </ul> <p><b>Breathing-related:</b></p> <ul style="list-style-type: none"> <li>• shortness of breath</li> </ul> <p><b>General:</b></p> <ul style="list-style-type: none"> <li>• fever or high temperature</li> </ul> <p><b>Head-related:</b></p> <ul style="list-style-type: none"> <li>• dizziness or light-headedness</li> </ul> <p><b>Allergy related:</b></p> <ul style="list-style-type: none"> <li>• 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.</li> </ul> <p><b>Gastrointestinal-related:</b></p> <ul style="list-style-type: none"> <li>• feeling sick, also called nausea</li> <li>• vomiting</li> <li>• diarrhoea</li> </ul> <p><b>Skin-related:</b></p> <ul style="list-style-type: none"> <li>• rash</li> <li>• red or purple, flat, pinhead spots under the skin</li> <li>• itching</li> </ul>	<p><b>Tell your doctor or nurse immediately if you notice any of the following as you may require medical attention.</b></p>

**Tell your doctor 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](http://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 DEFITELIO contains**

<b>Active ingredient (main ingredient)</b>	Defibrotide Each 2.5 mL contains 200 mg defibrotide and each mL of concentrated solution contains 80 mg defibrotide.
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>• sodium citrate dihydrate</li><li>• hydrochloric acid</li><li>• sodium hydroxide</li><li>• water for injections</li></ul>
<b>Potential allergens</b>	N/A

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

### **What DEFITELIO 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.

(AUST R 319221).

### **Who distributes DEFITELIO**

Jazz Pharmaceuticals ANZ Pty Ltd

Suite 214, Level 2

165 Phillip Street

Sydney, NSW, 2000

Australia

Phone: 1800 577 422

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