

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

^{Pr}DEFITELIO™ (defibrotide sodium)

Read this carefully before you start taking **DEFITELIO**. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **DEFITELIO**.

Serious Warnings and Precautions

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

You should not take anticoagulant medications such as heparin, warfarin, or alteplase at the same time as DEFITELIO because of an increased risk of bleeding.

What is DEFITELIO used for?

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

This medicine can be used in:

- adults;
- adolescents;
- children;
- infants over one month of age.

How does DEFITELIO work?

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

What are the ingredients in DEFITELIO

Medicinal ingredients: defibrotide sodium

Non-medicinal ingredients: sodium citrate dihydrate, hydrochloric acid and/or sodium hydroxide and water for injection.

DEFITELIO comes in the following dosage forms:

Each 2.5 mL vial contains 200 mg of defibrotide sodium and each millilitre (1 mL) of solution contains 80 mg defibrotide sodium.

Do not use DEFITELIO if:

- if you are allergic to defibrotide sodium or other ingredients of this medicine;
- if you are using other medicines to break down blood clots such as tissue plasminogen activator (t-PA).

To help avoid side effects and ensure proper use, talk to your healthcare professional before you receive DEFITELIO. Talk about any health conditions or problems you may have, including if you:

- if you have heavy bleeding and need a blood transfusion;
- if you are undergoing surgery;
- if you have problems with blood circulation because your body cannot maintain a constant blood pressure.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**The following may interact with DEFITELIO:**

- medicines to prevent blood clotting such as acetylsalicylic acid (aspirin), heparins, warfarin, dabigatran, rivaroxaban or apixaban;
- anti-inflammatory medicines (e.g., ibuprofen, naproxen, diclofenac and other non-steroidal anti-inflammatory medicines).

How to take DEFITELIO

DEFITELIO will be slowly injected (over a 2-hour period) into one of your veins. This is called an “intravenous infusion” or drip.

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

Usual dose:

The recommended dose is based on the body weight (25 mg/kg/day). The dosage is the same in children from one month to 18 years of age as in adults.

Overdose:

If you think you have received too much DEFITELIO contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

As you will be given this medicine by a doctor or a nurse it is unlikely that a dose will be missed. However, tell your doctor or healthcare professional if you think that a dose has been forgotten. You must not be given a double dose to make up for a missed dose.

What are possible side effects from using DEFITELIO?

These are not all the possible side effects you may feel when taking DEFITELIO. If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:

- Hypotension (low blood pressure)
- Diarrhea;
- Vomiting;
- Nausea;
- Epistaxis (nose bleeds).

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON Bleeding: from nose, in the brain, in the gut, in the lungs, from the infusion line, blood in urine, disturbance in blood clotting			✓
Low blood pressure (hypotension): dizziness, light-headedness, blurred vision, weakness, fatigue, nausea, palpitations, headache, cold and/or pale skin		✓	
UNCOMMON Bleeding: from the eye, vomiting blood, blood in the stool, bleeding from the mouth, bleeding at the site of injection, localized blood collection out of the vessel (hematoma) in the brain			✓
Haemothorax (accumulation of blood around the lungs): chest pain, shortness of breath, rapid heart beat			✓
Severe allergic reaction: swelling of the hands, face, lips, tongue or throat, difficulty breathing			✓
Skin conditions: rash, itching, bruising, red spots on the body caused by broken blood vessels		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at [MedEffect](#);
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
 - Fax to 1-866-678-6789 (toll-free), or
 - Mail to: Canada Vigilance Program
Health Canada, Postal Locator 0701E
Ottawa, ON
K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at [MedEffect](#).

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Keep this medicine out of the sight and reach of children.

Do not use DEFITELIO after the expiry date which is stated on the carton and label after EXP. The expiry date refers to the last day of that month. Do not freeze.

Once diluted for use the infusion storage should not exceed 24 hours at 2-8°C. DEFITELIO should not be used if the solution is cloudy or contains particles.

If you want more information about DEFITELIO:

- Talk to your healthcare professional;
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the [Health Canada website](#); the manufacturer's website <https://www.jazzpharma.com>, or by calling 1-800-520-5568.

This leaflet was prepared by Jazz Pharmaceuticals Ireland Limited

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