

Package leaflet: Information for the user

Defitelio® 80 mg / ml concentrate for solution for infusion defibrotide

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Defitelio® is and what it is used for
2. What you need to know before you are administered Defitelio®
3. How you will be given Defitelio®
4. Possible side effects
5. How to store Defitelio®
6. Contents of the pack and other information

1. What Defitelio® is and what it is used for

Defitelio® is a medicine that contains the active substance defibrotide.

It 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 that are given prior to a stem cell transplantation.

Defibrotide 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.

2. What you need to know before you are administered Defitelio®

Do not use Defitelio®

- if you are allergic to defibrotide or any of the other ingredients of this medicine (listed in section 6)
- if you are using other medicines to break down blood clots such as tissue plasminogen activator.

Warnings and precautions

- Talk to your doctor before using Defitelio®:
- if you are taking medicine that increases the risk of bleeding.
- 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.

Children and adolescents

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

Other medicines and Defitelio®

Tell your doctor if you are taking medicines to prevent blood clotting such as acetylsalicylic acid, heparins, warfarin, dabigatran, rivaroxaban or apixaban or if you are taking anti-inflammatory medicines (e.g., ibuprofen, naproxen, diclofenac and other non-steroidal anti-inflammatory medicines).

Pregnancy and breast-feeding

Do not use Defitelio[®] if you are pregnant unless your disease requires treatment with Defitelio[®]. 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.

Driving and using machines

It is not expected that Defitelio[®] will affect your ability to drive and operate machines.

Defitelio[®] contains sodium

This medicine contains 20.4 mg sodium (main component of cooking/table salt) in each vial. This is equivalent to 1.02% of the recommended maximum daily dietary intake of sodium for an adult.

3. How you will be given Defitelio[®]

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 cells transplantation.

It 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. The recommended dose in children from one month to 18 years of age is the same as in adults.

If a dose of Defitelio[®] has been forgotten

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. If you have any further questions on the use of this medicine, ask your doctor, nurse or pharmacist.

4. Possible side effects

Like all medicines, Defitelio[®] can cause side effects, although not everybody gets them. For patients treated with Defitelio[®] the following side effects were reported.

If you experience any of these side effects, you should **contact your doctor immediately**.

Very Common (may affect more than 1 in 10 people)

- low blood pressure

Common (may affect up to 1 in 10 people)

- bleeding in general
- bleeding from the nose
- bleeding in the brain
- bleeding in the gut
- vomiting blood
- bleeding in the lungs
- bleeding from the infusion line
- blood in the urine
- bleeding from the mouth

- bleeding into the skin
- coagulopathy (disturbance of blood clotting)
- nausea
- vomiting
- diarrhoea
- rash
- itching
- fever

Uncommon (may affect up to 1 in 100 people)

- bleeding from the eye
- blood in the stool
- bleeding at the site of injection
- localized blood collection out of the vessel (hematoma) in the brain
- haemothorax (accumulation of blood in the area between the heart and the lung)
- bruising
- severe allergic reaction (you might experience swelling of the hands, face, lips, tongue or throat, difficulty in breathing).

Children and adolescents

Side effects in children (1 month to 18 years old) are expected to be similar in type, severity and frequency and no other special precautions are needed.

Reporting of side effects

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

The National Pharmacovigilance Centre (NPC):

Fax: +966-11-205-7662

SFDA Call Center: 19999

E-mail: npc.drug@sfd.gov.sa

Website: <https://ade.sfd.gov.sa>

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Defitelio®

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 vial label after EXP. The expiry date refers to the last day of that month.

Store below 30°C. Do not freeze.

Once diluted for use the infusion storage should not exceed 24 hours at 2°C -8°C unless dilution has taken place in controlled and validated aseptic conditions.

Defitelio® should not be used if the solution is cloudy or contains particles.

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Defitelio® contains

- The active substance is defibrotide. Each 2.5 ml vial contains 200 mg defibrotide and each ml solution contains 80 mg defibrotide.
- The other ingredients are sodium citrate dihydrate, hydrochloric acid and sodium hydroxide (both for pH-adjustment) and water for injections (see section 2 ‘Defitelio® contains Sodium’).

What Defitelio® looks like and contents of the pack

Defitelio® is a clear light yellow to brown concentrate for solution for infusion, free from particulate matter or turbidity.

One carton contains 10 glass vials with 2.5 ml of concentrate each.

Marketing Authorisation Holder

Jazz Pharmaceuticals Ireland Ltd
5th Floor
Waterloo Exchange
Waterloo Road
Dublin
D04 E5W7
Ireland

Manufacturer

Patheon Italia S.p.A.
2 Trav. SX Via Morolense 5 - 03013
Ferentino (FR), Italy

Batch release site

Gentium S.r.l
Piazza XX Settembre, 2
Villa Guardia
22079 Italy

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

Biologix Pharmacovigilance Department
E-mail: Pharmacovigilance-KSA@blgx.net
Tel + 966 11 4646 955 Ext 286
Mobile: + 966 55 9994 037

This leaflet was last revised in: November 2020**This is a Medication**

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor’s prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not, by yourself, interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers
Union of Arab Pharmacists