Prescribing Information

Defitelio® ▼ 80 mg/mL concentrate for solution for infusion
(Defibrotide)
Please refer to the Summary of Product Characteristics before Prescribing.

Presentation: Each 2.5 mL vial contains 200 mg defibrotide. Concentrate for solution for infusion. **Indication:** Defitelio® is indicated in the treatment of severe hepatic veno-occlusive disease (VOD) in haematopoietic stem-cell transplantation (HSCT) therapy. **Dosage and administration:** For adults and children over 1 month of age. Defitelio® must be prescribed and administered by specialised physicians experienced in the diagnosis and treatment of complications of HSCT. The recommended dose is 6.25 mg/kg body weight every 6 hours (recommended max: 25 mg/kg/day) administered over a 2-hour intravenous infusion. Defitelio® must always be diluted with 5% glucose solution for infusion or sodium chloride 9 mg/mL (0.9%) solution for infusion prior to use. Defitelio® should be administered for a minimum of 21 days and continued until symptoms and signs of severe VOD resolve. Renal impairment: Dose adjustment is not required for patients with renal impairment or who are on intermittent haemodialysis. Hepatic impairment: no dose adjustment recommended but careful monitoring of the patients should be undertaken. Paediatric population: The use of Defitelio® in children aged less than one month is not recommended. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. Concomitant use of thrombolytic therapy (e.g.t-PA). **Warnings and precautions:** Use of medicinal products that increase the risk of haemorrhage within 24 hours of Defitelio® administration (within 12 hours in the case of unfractionated heparin) is not recommended. Concomitant systemic anticoagulant therapy (e.g. heparin, warfarin, direct thrombin inhibitors and direct factor Xa inhibitors), except for routine maintenance or reopening of central venous line, requires careful monitoring. Medicinal products that affect platelet aggregation (e.g. non–steroidal anti-inflammatory agents) should be administered with care. In patients who have or develop clinically significant acute bleeding requiring blood transfusion, Defitelio® is not recommended or should be discontinued. Temporary discontinuation of Defitelio® is recommended in patients who undergo surgery or invasive procedures at significant risk of major bleeding. Administration of Defitelio® to patients who have haemodynamic instability, defined as inability to maintain mean arterial pressure with single pressor support, is not recommended. A bolus administration of Defitelio® may cause flushing or a sensation of "generalised heat". **Fertility, Pregnancy and Lactation:** No data on use in pregnant women. Not to be used during pregnancy unless benefits outweighs risk. It is not known if Defitelio is excreted in human milk. Risk to infant not expected. It may be used in breast feeding. **Undesirable effects:** ***Please refer to the full SmPC for the complete list of undesirable effects.*** Very common (≥1/10): hypotension. Common (≥1/100 to <1/10): coagulopathy, haemorrhage including cerebral, pulmonary, mouth and gastrointestinal haemorrhage, catheter site haemorrhage, epistaxis, haematemesis, haematuria, petechiae, rash, pruritus, pyrexia, diarrhoea, nausea, vomiting. Uncommon (≥1/1000 to < 1/100): hypersensitivity, anaphylactic reaction, cerebral haematoma, conjunctival and injection site haemorrhage, haemothorax, melaena, ecchymosis. **Overdose:** There is no specific antidote for overdose and treatment should be symptomatic. Defibrotide is not removed by dialysis. **Storage and Handling:** This medicinal product does not need any special storage condition. Do not freeze. Defitelio® is for single use only. Shelf life of unopened vials: 3 years. Any unused medicinal product or waste material should be disposed of in accordance with local requirements. **Legal category:** POM. Package Quantity and Cost**:** 10 x 2.5mL vials. **UK:** £3650**. IE:** Price on Application. **Marketing authorisation number:** EU/1/13/878/001. **Marketing Authorisation Holder:** Gentium Srl., Piazza XX Settembre 2, 22079 Villa Guardia (Co)- Italy Tel +39 0315373200. **Date of preparation:** February 2019. **Job Code:** EURW-UKIREDEF-0001.

▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.

Adverse events should be reported. Healthcare professionals are asked to report any suspected adverse reactions.

For the UK, reporting forms and information can be found at: www.mhra.gov.uk/yellowcard.

For Ireland, reporting forms and information can be found at: www.hpra.ie.

Adverse events should also be reported by email: AEreporting@jazzpharma.com or by fax to +44 (0) 1865 598765.