Prescribing Information (UK)

ACTILYSE® Cathflo® 2 mg (alteplase)

Each constituted vial with powder will deliver 2 mg alteplase (corresponding to 1,160,000 IU). **Indication:** Thrombolytic treatment of occluded central venous access devices including those used for haemodialysis (2 mg vial is the only recommended presentation for use in this indication). **Dose and Administration:** Give as soon as possible after occlusion. For all patients, a dose of up to 2 mg alteplase can be administered up to two times for any one occlusion to restore the function of central venous access devices (CVADs) which became dysfunctional due to thrombotic occlusion. Reconstitution to a final concentration of 1 mg alteplase per ml is recommended. In patients with a body weight ≥ 30 kg, a total dose of 2 mg alteplase in 2 ml of reconstituted solution should be instilled into the dysfunctional CVAD. In patients with a body weight < 30 kg, the volume of reconstituted solution to be instilled into the dysfunctional CVAD should be 110% of the internal lumen volume of the device, with the total dose of alteplase not exceeding 2 mg. If CVAD function is not restored at 120 minutes after the first dose, a second dose of equal amount may be used. If CVAD function is not restored after a second dose, consider device replacement. **Contraindications:** Hypersensitivity to the active substance alteplase, gentamicin (a trace residue from the manufacturing process) or to any of the excipients. **Warnings and Precautions:** *2 mg presentation of alteplase is not indicated for use in acute myocardial infarction, acute pulmonary embolism or acute ischaemic stroke (due to risk of massive under dosing). Only 10, 20 or 50 mg vials are indicated for use in these indications.* For the thrombolytic treatment of occluded CVAD including those used for haemodialysis, the co-administration of heparin is not recommended. Catheter dysfunction may be caused by a variety of conditions other than thrombus formation, such as catheter malposition, mechanical failure, constriction by a suture, and lipid deposits or drug precipitates within the catheter lumen. Vigorous suction should not be applied in order to determine the reason for catheter occlusion and excessive pressure should be avoided. Caution needed if syringes ≤ 1 ml are used, especially with use in the paediatric population. Use with caution in patients who have active internal bleeding or who have had any of the following within 48 hours: surgery, obstetrical delivery, percutaneous biopsy of viscera or deep tissues, or puncture of non-compressible vessels. In addition, caution should be exercised with patients who have thrombocytopenia, other haemostatic defects (including those secondary to severe hepatic or renal disease), or any condition for which bleeding constitutes a significant hazard or would be particularly difficult to manage because of its location, or who are at high risk for embolic complications (e.g. venous thrombosis in the region of the catheter). Death and permanent disability have been reported in patients who have experienced stroke and other serious bleeding episodes when receiving pharmacologic doses of a thrombolytic. In case of serious bleeds in a critical location (e.g. intracranial, GI, retroperitoneal, pericardial) occur, treatment with Actilyse Cathflo should be stopped and withdrawn from the catheter. Care should be taken to avoid causing infection whilst restoring the function of the CVAD by maintaining aseptic technique and use of antibiotic treatment if necessary. Hypersensitivity reactions associated with the administration of Actilyse Cathflo can be caused by the active substance alteplase, gentamicin (a trace residue from the manufacturing process), any of the excipients, or the stopper of the glass vial with Actilyse Cathflo powder which contains natural rubber (a derivative of latex). If a severe hypersensitivity reaction occurs, the instillation should be discontinued and appropriate treatment should be promptly initiated. **Interactions:** The risk of haemorrhage is increased if coumarine derivatives, oral anticoagulants, platelet aggregation inhibitors, heparins or other agents inhibiting coagulation that are administered before, during or within the first 24 hours after treatment with Actilyse Cathflo. Concomitant treatment with ACE inhibitors may enhance the risk of suffering a hypersensitivity reaction. **Fertility, pregnancy and lactation:** Experience is very limited; studies in animals have shown reproductive toxicity. It is not known if alteplase is excreted into human milk. **Undesirable effects:** In clinical trials investigating treatment of occluded catheters with Actilyse Cathflo the following were observed. Uncommon (≥1/1,000 to <1/100): sepsis, catheter related complications. Rare (≥1/10,000 to <1/1,000): pyrexia. Under systemic application of alteplase (i.e. high dose in thrombo-embolic indications) the following were observed. Rare (≥1/10,000 to <1/1,000): hypersensitivity reactions (e.g. rash, urticaria, bronchospasm, angio-oedema, hypotension, shock). Very rare (<1/10,000): serious anaphylaxis. In principle, all undesirable effects as found for the systemic use of Actilyse (10, 20 and 50 mg alteplase) may also occur during treatment of occluded catheters in cases where Actilyse Cathflo (2 mg alteplase) reaches the systemic circulation (e.g. haemorrhage, embolism, hypersensitivity reactions, blood pressure decreased, nausea, vomiting, body temperature increased). Prescribers should consult the Summary of Product Characteristics for further information on side effects. **Pack size and NHS price:** 5 x Actilyse Cathflo 2 mg £225.00. **Legal category:** POM **MA number:** PL 00015/0325. **Marketing Authorisation Holder:** Boehringer Ingelheim Limited, Ellesfield Avenue, Bracknell, RG12 8YS. Prescribers should consult the Summary of Product Characteristics for full prescribing information. **Prepared in April 2018**.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Boehringer Ingelheim Drug Safety on 0800 328 1627 (freephone).

Boehringer Ingelheim

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rt-PA FOR VENOUS CATHETER OCCLUSION

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