Decitabine

Powder for Concentrate for Solution for Infusion

50 mg

Decitabine EVER Pharma is indicated for the treatment of adult patients with newly diagnosed de novo or secondary acute myeloid leukaemia (AML), according to the World Health Organisation (WHO) classification, who are not candidates for standard induction chemotherapy.

- **Available in CytoWrap® protected vials** – ensuring safer handling and transportation

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Indications

Indicated for the treatment of adult patients with newly diagnosed de novo or secondary acute myeloid leukaemia (AML), according to the World Health Organisation (WHO) classification, who are not candidates for standard induction chemotherapy.

Active Ingredient

Decitabine

Excipients

Potassium dihydrogen phosphate, Sodium hydroxide, Hydrochloric acid (for pH adjustment)

Presentations

- **50 mg** powder for concentrate for solution for infusion

Strengths

Each vial of powder for concentrate for solution for infusion contains 50 mg decitabine. After reconstitution with 10 ml of water for injections, each 1 ml of concentrate contains 5 mg decitabine.

Stability

- **Unopened:** 24 months. Do not store above 30°C.
- **Reconstituted & Diluted Solution:** Within 15 minutes of reconstitution, the concentrate (in 10 ml of sterile water for injections) must be further diluted with cold (2 °C to 8 °C) infusion fluids. The prepared diluted solution for intravenous infusion may be stored at 2 °C to 8 °C for up to 7 hours, followed by up to 3 hours at room temperature (20 °C to 25 °C) before administration.

Primary Packaging

- Type I colourless 20 ml glass vial with a rubber stopper, sealed with an aluminium seal, covered with a flip-off cap.

Pack sizes

1 vial per pack. Vials may be sheathed in a protective sleeve.

Density

1.005 g/cm^3 when reconstituted according to the instructions in the package insert.

Cyto Wrap®

Plastic sleeving for safer handling

Decitabine EVER Pharma 50 mg powder for concentrate for solution for infusion. Composition: Each vial of powder for concentrate for solution for infusion contains 50 mg decitabine. List of excipients: Potassium dihydrogen phosphate (E340), Sodium hydroxide (E524), Hydrochloric acid (for pH adjustment). Therapeutic indications: for the treatment of adult patients with newly diagnosed de novo or secondary acute myeloid leukaemia (AML), according to the World Health Organisation (WHO) classification, who are not candidates for standard induction chemotherapy. Contraindications: Hypersensitivity to decitabine or to any of the excipients, listed in section 6.1. Breast-feeding (see section 4.6). Side effects: Very common: pneumonia, urinary tract infection, All other infections (viral, bacterial, fungal), febrile neutropaenia, neutropaenia, thrombocytopaenia, anaemia, leukopaenia, hyperglycaemia, headache, epistaxis, diarrhoea, vomiting, nausea, hepatic function abnormal, pyrexia, Common: septic shock, sepsis, sinusitis, hypersensitivity including anaphylactic reaction, stomatitis, hyperbilirubinaemia, Uncommon: pancytopaenia, cardiomyopathy, acute febrile neutrophilic dermatosis (Sweet's syndrome), Not known: differentiation syndrome, interstitial lung disease. More information available in the summary of product characteristics. Only available on prescription. Last update: December 2025. Marketing Authorisation Holder: EVER Valinject GmbH, Oberburgau 3, 4866 Unterach am Attersee, Austria.

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