

Pemetrexed

MADE IN GERMANY

Concentrate for Solution for Infusion



Pemetrexed EVER Pharma is available in three presentations (100 mg, 500 mg and 1000 mg) as a ready-to-dilute liquid formulation that can be stored at room temperature, supplied in CytoWrap® for safer handling and transportation.

Indicated, in combination with cisplatin, for malignant pleural mesothelioma and first-line non-squamous NSCLC, and as monotherapy for maintenance and second-line treatment of non-squamous NSCLC.

- **Ready-to-dilute liquid formulation** – no reconstitution from powder, saving preparation time and costs; can be stored at room temperature
- **Available in three presentations** – providing greater flexibility and convenience when preparing patient specific doses and minimising wastage
- **Supplied in CytoWrap®** – for safer handling and transportation



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EVER
PHARMA

LIQUID READY-TO-DILUTE FORMULATION

Pemetrexed EVER Pharma is supplied as a liquid formulation ready to dilute to the required patient dose



100 mg
4 ml



500 mg
20 ml



1000 mg
40 ml

- **Available in three presentations** to provide greater flexibility and convenience when preparing patient specific doses and minimizing wastage
- **1000 mg/4 ml vial provides a single patient dose from one vial** for average male lung cancer patients (BSA 1.92 m²)^{1,2}

1. Sacco JJ1, Botten J, Macbeth F, Bagust A, Clark P. The average body surface area of adult cancer patients in the UK: a multicentre retrospective study. PLoS One. 2010 Jan 28;5(1):e8933. doi: 10.1371/journal.pone.0008933.

2. Wallington M, Variations in Body Surface Area of Patients Receiving Chemotherapy Treatment in England, Poster: Chemotherapy Intelligence Unit, Oxford

3. Practical information for medical or healthcare professionals on preparation, administration and handling of Alimta® 100mg powder for concentrate for solution for infusion – Eli Lilly SmPC

ROOM TEMPERATURE STORAGE



Less preparation time, wastage and costs



Patient dose stable for 28 days at 2-8°C and 7 days at 20-30°C
providing greater working flexibility and less wasted product



Faster preparation time compared to powder forms - it takes at least 5 minutes, or even longer where multiple vials are required, to reconstitute from a powder before a patient specific dose can be prepared³

Indications	In combination with cisplatin is indicated for the treatment of chemotherapy-naïve patients with unresectable malignant pleural mesothelioma. In combination with cisplatin is indicated for the first-line treatment of patients with locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology. As monotherapy for the maintenance treatment of locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology in patients whose disease has not progressed immediately following platinum-based chemotherapy. As monotherapy for the second-line treatment of patients with locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology.
Active Ingredient	Pemetrexed
Excipients	Trometamol, Monothioglycerol, Citric acid, Sodium hydroxide, Hydrochloric acid (for pH adjustment), Water for injections
Presentations	■ 100 mg/4 ml, concentrate for solution for infusion ■ 500 mg/20 ml concentrate for solution for infusion ■ 1000 mg/40 ml concentrate for solution for infusion
Strength	Each 1 ml of concentrate contains 25 mg pemetrexed (as pemetrexed disodium hemipentahydrate or disodium heptahydrate).
Stability	■ Unopened: 36 months. Store at room temperature (do not freeze). ■ After dilution: Chemical and physical in-use stability of the infusion solution has been demonstrated for 28 days at 2 °C to 8 °C and for 7 days at 20 °C to 30 °C.
Primary Packaging	Type I colourless glass vial with a bromobutyl rubber stopper with fluoropolymer coating, sealed with an aluminium crimp cap, covered with a plastic flip-off cap.
Pack sizes	1 vial per pack. Vials may or may not be sheathed in a protective sleeve.
Density	1.017 g/cm ³



Plastic sleeving for safer handling

Pemetrexed EVER Pharma 25 mg/ml concentrate for solution for infusion. Composition: One ml of concentrate contains 25 mg pemetrexed (as pemetrexed disodium hemipentahydrate). List of excipients: Trometamol, Monothioglycerol, Citric acid, Sodium hydroxide (for pH adjustment), Hydrochloric acid (for pH adjustment), Water for injections. Therapeutic indications: 1. Malignant pleural mesothelioma: Pemetrexed in combination with cisplatin is indicated for the treatment of chemotherapy naïve patients with unresectable malignant pleural mesothelioma. 2. Non-small cell lung cancer: Pemetrexed in combination with cisplatin is indicated for the first line treatment of patients with locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology (see section 5.1). Pemetrexed is indicated as monotherapy for the maintenance treatment of locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology in patients whose disease has not progressed immediately following platinum-based chemotherapy (see section 5.1). Pemetrexed is indicated as monotherapy for the second line treatment of patients with locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology (see section 5.1). Contraindications: Hypersensitivity to the active substance or to any of the excipients listed in section 6.1. Breast-feeding (see section 4.6). Concomitant yellow fever vaccine (see section 4.5). Side effects: very common: Infection, Pharyngitis, Neutropenia, Leukopenia, Haemoglobin decreased, Stomatitis, Anorexia, Vomiting, Diarrhoea, Nausea, Rash Skin exfoliation, Creatinine clearance decreased, Blood creatinine increased, Fatigue, common: Sepsis, Febrile neutropenia, Platelet count decreased, Hypersensitivity, Dehydration, Taste disorder, Peripheral motor neuropathy, Peripheral sensory neuropathy, Dizziness, Conjunctivitis, Dry eye, Lacrimation increased, Keratoconjunctivitis sicca, Eyelid oedema, Ocular surface disease, Cardiac failure, Arrhythmia, Dyspepsia, Constipation, Ab-dominal pain, Alanine aminotransferase increased, Aspartate aminotransferase increased, Hyperpigmentation, Pruritus, Erythema multiforme, Alopecia, Urtic, Renal failure, Glomerular filtration rate decreased, Pyrexia, Pain, Oedema, Chest pain, Mucosal inflammation, Gamma-glutamyltransferase increased, uncommon: Pancytopenia, Cerebrovascular accident, Ischaemic stroke, Haemorrhage intracranial, Angina, Myocardial infarction, Coronary artery disease, Arrhythmia supraventricular, Peripheral ischaemia, Pulmonary embolism, Interstitial pneumonitis, Rectal haemorrhage, Gastrointestinal haemorrhage, Intestinal perforation, oesophagitis, Colitis, Radiation oesophagitis, Radiation pneumonitis, rare: Autoimmune haemolytic anaemia, Anaphylactic shock, Hepatitis, Erythema, Recall phenomenon, very rare: Dermohypodermatitis, Stevens-Johnson syndrome, Toxic epidermal necrolysis, Pemphigoid, Dermatitis bullous, Acquired epidermolysis bullosa, Erythematous oedema, Pseudocellulitis, Dermatitis, Eczema, Prurigo, unknown: Nephrogenic diabetes insipidus, Renal tubular necrosis. More information available in the summary of product characteristics. Only available on prescription. Last update: November 2020. Marketing Authorisation Holder: EVER Valinect GmbH, Oberburgau 3, 4866 Unterach am Attersee, Austria.