Pemetrexed

Concentrate for Solution for Infusion

MADE IN GERMANY

Pemetrexed EVER Pharma is provided as three ready to dilute liquid formulation that can be stored at room temperature and is available in 3 vial sizes for economy and convenience.

Pemetrexed is an antineoplastic chemotherapy drug. It is used in the treatment of malignant mesothelioma and locally advanced or metastatic nonsquamous non-small cell lung cancer.

- **Available as a ready to dilute liquid formulation** – does not require reconstitution from powder saving time and costs. It can be stored at room temperature.
- **Available in three presentations** – providing greater flexibility and convenience when preparing patient specific doses
- **All vial presentations come in CytoWrap®** – for safer handling and transportation

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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 m^2)[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 prepared[3]

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Indications

In combination with cisplatin is indicated for the treatment of chemotherapy naive patients with unresectable malignant pleural mesothelioma.

In combination with cisplatin is indicated for the first line treatment of patients with locally advanced or metstatic NSCLC other than predominantly squamous cell histology.

Monotherapy for the maintenance treatment of locally advanced or metastatic NSCLC other than predominantly squamous cell histology in patients whose disease has not progressed immediately following platinum-based chemotherapy.

Monotherapy for the second line treatment of patients with locally advanced or metastatic NSCLC 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

One ml of concentrate contains 25 mg pemetrexed (as pemetrexed disodium hemipentahydrate).

Stability

- **Unopened:** 36 months at room temperature (do not freeze)
- **After dilution:** Chemical and physical in-use stability of infusion solution of pemetrexed was demonstrated for 28 days at refrigerated temperature (2 °C to 8 °C) and for 7 days at 20 °C to 30 °C.

Primary Packaging

Colourless glass vial (type I) with a bromobutyl rubber stopper with fluoropolymer coating and an aluminium cap with plastic flip-off.

Pack sizes

1 vial per pack. Vials may or may not be sheathed in a protective sleeve.

Cyto Wrap®

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 ad-justment), 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 fi rst 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 lo-cally 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 clea-rance 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, Aalanine aminotransferase increased, Aspartate aminotransferase increased, Hyperpigmentation, Pruritus, Erythema multiforme, Alopecia, Urtic, Renal failure, Glomerular fi ltration rate decrea-sed, Pyrexia, Pain, Oedema, Chest pain, Mucosal infl ammation, 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: Dermohypodermitis, 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 Valinject GmbH, Oberburgau 3, 4866 Unterach am Attersee, Austria.

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