
Produk Baru

Paxus®

Quantitative Composition (per ml)

Each ml Paxus® injection contains 6 mg of paclitaxel, 527 mg of purified Cremophor® (polyoxyl 35 castor oil) and 49.7% (v/v) of dehydrated alcohol.

Indications

- Paxus® is indicated as first-line and subsequent therapy for the treatment of advanced carcinoma of the ovary. As first-line therapy Paxus® is indicated in combination with cisplatin.
- Paxus® is indicated for the treatment of breast cancer after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy. Prior therapy should have included an anthracycline unless clinically contraindicated.

Contraindications

- Paclitaxel is contraindicated in patients who have a history of severe hypersensitivity reactions to paclitaxel or other drugs formulated in polyoxyl 35 castor oil.
- Paclitaxel should not be used in patients with baseline neutrophil count of less than 1,500 cells/mm³ or in patients with AIDS related Kaposi's sarcoma with baseline neutrophil counts of < 1000 cells/mm³.

Storage

Store the vials in original cartons between 21-30°C. Retain in the original package to protect from light.

Packag

1 Box @ 1 vial (5 ml)

Registration

Reg. No. DKL0303300143A1

Dosage and Administration

1) Premedication

Following sequence of premedication shall be done to prepare patient for infusion with Paxus® injection.

12 hours before treatment..... Dexamethasone 20 mg P.O.
6 hours before treatment..... Dexamethasone 20 mg P.O.
30-60 minutes before treatment..... Diphenhydramine 50 mg I.V.

Cimetidine 300 mg or
Ranitidine 50 mg I.V.
→ PAXUS Inj

2) Preparation

Prior to infusion to patients, Paxus® injection shall be diluted in any of following injection solutions to get a final concentration of 0.3-1.2 mg of paclitaxel/ml.

- 0.9% Sodium Chloride Injection
- 5% Dextrose Injection
- 5% Dextrose/0.9% Sodium Chloride Injection
- 5% Dextrose in Ringer Injection solution

3) Dose schedule

Intravenous (i.v.) infusion at a dose of 175 mg/m² over a 3 hour period. The treatment may be repeated every 3 weeks.

4) Repeat dosage

Subsequent treatment shall not be given to patients until neutrophil count is at least 1,500 cells/mm³ and platelet count is at least 100,000 cells/mm³. For patients who experienced severe neutropenia (neutrophil < 500 cells/mm³) for a week or longer or moderate to severe peripheral neuropathy during Paxus® injection treatment, dosage shall be reduced by 20% for subsequent courses of Paxus® therapy.

5) Stability of diluted solutions

Physically and chemically stable for up to 27 hours at ambient temperature (15-30°C).

6) Infusion set

- Undiluted concentrate shall not come in contact with plasticized PVC equipments during preparation. To minimize patients' exposure to the plasticizer DHEP, which may be leached from PVC infusion bags or sets, diluted Paxus® solutions shall preferably be stored in bottles (glass, propylene) or plastic bags (polypropylene, polyolefin) and administered with polyethylene-lined administration sets.
- Paxus® shall be administered through an in-line filter with a microporous membrane not greater than 0.22 microns. Use of filter devices such as IVEX-2 filters which incorporate short inlet and outlet PVC-coated tubing has not resulted in significant leaching of DHEP.



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