ONCOLOGY

Paclitaxel Kabi 6 mg/ml

Trusted Generics: Total Care

Paclitaxel Kabi 6 mg/ml
concentrate for
solution for infusion

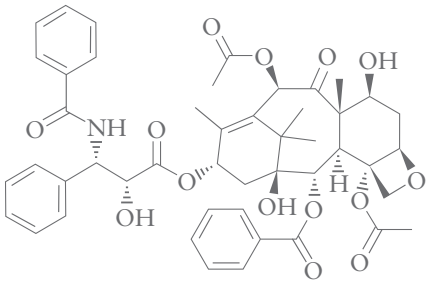
FRESENIUS KABI

caring for life

Paclitaxel Kabi

Therapeutic class

Taxane – mitotic inhibitor



Indications

- Ovarian carcinoma
- Breast carcinoma
- Advanced non-small cell lung carcinoma
- AIDS-related Kaposi's sarcoma

Please refer to the Paclitaxel Kabi SPC for full details.

The colour of the packaging is designed to improve patient and user safety and to distinguish between different products in our range.

Paclitaxel Kabi is available as follows:

	30 mg	5 ml	Vial
	100 mg	16.7 ml	Vial
	150 mg	25 ml	Vial
	300 mg	50 ml	Vial
	600 mg	100 ml	Vial
Composition	1 ml of concentrate for solution for infusion contains 6 mg paclitaxel		
Pharmaceutical form	Concentrate for solution for infusion, clear, slightly yellowish solution		
Excipients	Ethanol, anhydrous; macrogolglycerol ricinoleate; citric acid, anhydrous (for pH adjustment)		
Shelf life	2 years (before opening the vial)		

Paclitaxel Kabi in focus

- Antimicrotubule agent that promotes the assembly of microtubules from tubulin dimers and stabilises microtubules by preventing depolymerisation
- Established choice in ovarian cancer, breast cancer and advanced non-small cell lung cancer (NSCLC)

Stability

The unopened vials of Paclitaxel Kabi injection are stable until the date indicated on the package when stored under recommended storage conditions in the original package. Freezing does not adversely affect the product. Solutions for infusion prepared as recommended are stable at ambient and refrigerated temperatures. Extended stability data is available from your local Fresenius Kabi representative.

Compatibility

Solution should be prepared in glass, polyethylene or polypropylene containers, use of PVC is not recommended.

Manufacturing and safety

Paclitaxel Kabi is made by Fresenius Kabi from our own raw materials, giving us full control of the manufacturing and supply chain*. Our state of the art cleaning process for finished vials guarantees the removal of all external contamination.

Fresenius Kabi sleeved vials (OncoShield®) offers maximum protection for people working with cytotoxic drugs.

* The source of active pharmaceutical ingredient may vary in different countries.

OncoShield®

Abridged SPC of Paclitaxel Kabi 6 mg/ml concentrate for solution for infusion (paclitaxel)

Composition: Each vial contains paclitaxel 6 mg per 1 ml of concentrate for solution for infusion. A vial contains 5 ml of paclitaxel (corresponding to 30 mg paclitaxel). A vial contains 16.7 ml of paclitaxel (corresponding to 100 mg paclitaxel). A vial contains 50 ml of paclitaxel (corresponding to 300 mg paclitaxel). ***Mechanism of action:*** Paclitaxel is a novel antimicrotubule agent that promotes the assembly of microtubules from tubulin dimers and stabilises microtubules by preventing depolymerisation. This stability results in the inhibition of the normal dynamic reorganisation of the microtubule network that is essential for vital interphase and mitotic cellular functions. In addition, paclitaxel induces abnormal arrays or bundles of microtubules throughout the cell cycle and multiple asters of microtubules during mitosis. ***Indications:*** Paclitaxel is indicated for the primary treatment of ovarian cancer in combination with other chemotherapeutic agents. Paclitaxel is indicated for the treatment of metastatic carcinoma of the ovary after failure of standard therapy. Paclitaxel is indicated for the treatment of metastatic carcinoma of the breast after failure of anthracycline containing therapy or where anthracycline therapy is contraindicated. Paclitaxel is indicated for the treatment of non-small cell lung cancer (NSCLC) in patients who are not candidates for potentially curative surgery and/or radiation therapy. Paclitaxel is indicated for the second-line treatment of AIDS-related Kaposi's Sarcoma (KS). ***Dosage and administration:*** All patients must be premedicated with corticosteroids, antihistamines, and H_2 antagonists prior to paclitaxel. Paclitaxel concentrate for solution for infusion must be diluted before use and should only be administered intravenously. First-line chemotherapy of ovarian carcinoma: a combination regimen of paclitaxel and cisplatin is recommended. According to duration of infusion, two doses of paclitaxel are recommended: Paclitaxel 175 mg/m² administered intravenously over 3 hours, followed by cisplatin at a dose of 75 mg/m² every three weeks or paclitaxel 135 mg/m², in a 24-hour infusion, followed by cisplatin 75 mg/m², with a 3-week interval between courses. Second-line chemotherapy of ovarian carcinoma: the recommended dose of paclitaxel is 175 mg/m² administered over a period of 3 hours, with a 3-week interval between courses. Adjuvant chemotherapy in breast carcinoma: the recommended dose of paclitaxel is 175 mg/m² administered over a period of 3 hours every 3 weeks for four courses, following AC therapy. First-line chemotherapy of breast carcinoma: when used in combination with doxorubicin (50 mg/m²), paclitaxel should be administered 24 hours after doxorubicin. The recommended dose of paclitaxel is 220 mg/m² administered intravenously over a period of 3 hours, with a 3-week interval between courses. When used in combination with trastuzumab, the recommended dose of paclitaxel is 175 mg/m² administered intravenously over a period of 3 hours, with a 3-week interval between courses. Paclitaxel infusion may be started the day following the first dose of trastuzumab or immediately after the subsequent doses of trastuzumab if the preceding dose of trastuzumab was well tolerated. Second-line chemotherapy of breast carcinoma: the recommended dose of paclitaxel is 175 mg/m² administered over a period of 3 hours, with a 3-week interval between courses. Treatment of advanced NSCLC: the recommended dose of paclitaxel is 175 mg/m² administered over a period of 3 hours, followed by cisplatin 80 mg/m², with a 3 week interval between courses. Treatment of AIDS-related KS: the recommended dose of paclitaxel is 100 mg/m² administered as a 3-hour intravenous infusion every two weeks. Subsequent doses of paclitaxel should be administered according to individual patient tolerance. Paclitaxel should not be readministered until the neutrophil count is ≥1.5x10⁹/l (≥.0x10⁹/l for KS patients) and the platelet count is ≥100x10⁹/l (≥75x10⁹/l for KS patients). Patients who experience severe neutropenia (neutrophil count <0.5x10⁹/l for ≥7 days) or severe peripheral neuropathy should receive a dose reduction of 20% for subsequent courses (25% for KS patients). Paediatric patients: Paclitaxel is not recommended for paediatric patients. Hepatic impairment: Patients with severe hepatic impairment should not be treated with paclitaxel. Renal impairment: Studies in patients with impaired renal function have not been performed and there are insufficient data to permit dosage recommendations. ***Contraindications:*** Paclitaxel is contraindicated in patients with severe hypersensitivity to paclitaxel or to any excipient, especially macrogolglycerol ricinoleate. Paclitaxel is contraindicated during pregnancy and lactation, and should not be used in patients with baseline neutrophils <1.5x10⁹/l (<1.0x10⁹/l for KS patients). In KS patients, paclitaxel is also contraindicated in patients with concurrent, serious, uncontrolled infections. ***Special warnings and precautions for use:*** Paclitaxel should be administered under the supervision of a physician experienced in the use of cancer chemotherapeutic agents. Appropriate management of complications is possible only when adequate diagnostic and treatment facilities are readily available. Paclitaxel should be administered as a diluted infusion. Patients must be pretreated with corticosteroids, antihistamines and H_2 antagonists (such as dexamethasone, diphenhydramine, and cimetidine and ranitidine) before receiving paclitaxel. Paclitaxel should be given before cisplatin when used in combination. Paclitaxel infusion should be discontinued immediately if severe hypersensitivity (anaphylactoid) reactions characterised by dyspnea flushing, chest pain and tachycardia occur. Bone marrow suppression (primarily neutropenia) is the dose-limiting toxicity. Frequent monitoring of blood counts should be instituted during paclitaxel treatment. Severe cardiac conduction abnormalities have been reported rarely during paclitaxel therapy. If patients develop significant, appropriate therapy should be administered and continuous electrocardiographic monitoring should be performed during subsequent therapy with paclitaxel. ***Pregnancy and lactation:*** Pregnancy: As with other cytotoxic drugs, paclitaxel may cause foetal harm, and is therefore contraindicated during pregnancy. Women should be advised to avoid becoming pregnant during therapy with paclitaxel. Sexually active female and male patients of fertile age, and/or their partners, should use contraceptives for at least 6 months after treatment with paclitaxel. Lactation: Paclitaxel is contraindicated during lactation. Breast-feeding should be discontinued for the duration of therapy. ***Undesirable effects:*** The most frequent significant undesirable effect was bone marrow suppression. Severe neutropenia (<0.5x10⁹ cells/l) occurred in 28% of patients, but was not associated with febrile episodes. Only 1% of patients experienced severe neutropenia for ≥7 days. Thrombocytopenia was reported in 11% of patients. Three percent of patients had a platelet count nadir <50x10⁹/l at least once while on study. Anaemia was observed in 64% of patients, but was severe (Hb <5 mmol/l) in only 6% of patients. Incidence and severity of anaemia is related to baseline haemoglobin status. ***Overdose:*** There is no known antidote for paclitaxel overdose. The primary anticipated complications of overdose would consist of bone marrow suppression, peripheral neurotoxicity and mucositis. In case of overdose, the patient should be closely monitored. Treatment should be directed to the major anticipated toxicities. ***List of excipients:*** Ethanol, anhydrous, macrogolglycerol ricinoleate, citric acid, anhydrous (for pH adjustment). ***Shelf life:*** 2 years.

Registered product information may differ in your country. Before prescribing refer to nationally approved Prescribing Information. Before prescribing please refer to nationally registered and approved Summary of Product Characteristics.

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