ONCOLOGY

Gemcitabine Kabi 38 mg/ml

Trusted Generics: Total Care

Gemcitabine Kabi 38 mg/ml
powder for solution for infusion

FRESENIUS
KABI

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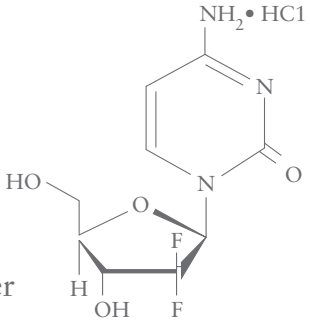
Gemcitabine Kabi

Therapeutic class

Pyrimidine antimetabolite



Indications

- Locally advanced or metastatic bladder cancer in combination with cisplatin
- Locally advanced or metastatic adenocarcinoma of the pancreas
- First line treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) in combination with cisplatin. Gemcitabine Kabi monotherapy can be considered in elderly patients or those with performance status 2
- Locally advanced or metastatic epithelial ovarian carcinoma, in combination with carboplatin, in patients with relapsed disease following a recurrence-free interval of at least 6 months after platinum-based, first-line therapy
- Treatment of patients with unresectable, locally recurrent or metastatic breast cancer who have relapsed following adjuvant/neoadjuvant chemotherapy in combination with paclitaxel. Prior chemotherapy should have included an anthracycline unless clinically contraindicated

Please refer to the Gemcitabine Kabi SPC for full details

Gemcitabine Kabi is available as follows:

	200 mg	10 ml	Vial
	1 g	50 ml	Vial
	2 g	100 ml	Vial
Composition	1 ml of reconstituted solution contains gemcitabine 38 mg		
Pharmaceutical form	Powder for solution for infusion, white to off-white powder		
Excipients	Mannitol, sodium acetate trihydrate, hydrochloric acid (for pH-adjustment), sodium hydroxide (for pH-adjustment)		
Shelf life	2 years (before opening the vial)		

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

Gemcitabine Kabi in focus

- Cell cycle specific pyrimidine antimetabolite that inhibits DNA synthesis
- Proven survival benefits in pancreatic, non-small cell lung, bladder, ovarian and metastatic breast cancers

Stability

Chemical and physical in-use stability has been demonstrated for 35 days at 25 °C. From a microbiological point of view, the product should be used immediately. Gemcitabine Kabi does not require any special storage condition. Do not refrigerate the reconstituted solution as crystallisation may occur.

Infusions made with Gemcitabine Kabi are stable for up to 120 day. Please contact your local Fresenius Kabi representative for more details.

Manufacturing and safety

Gemcitabine 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.

Abridged SPC of Gemcitabine Kabi 38 mg/ml powder for solution for infusion (gemcitabine)

Composition: One vial contains gemcitabine hydrochloride equivalent to 200 mg gemcitabine. One vial contains gemcitabine hydrochloride equivalent to 1,000 mg gemcitabine. After reconstitution, the solution contains 38 mg/ml of gemcitabine. Each 200 mg vial contains 3.5 mg (<1 mmol) sodium. Each 1,000 mg vial contains 17.5 mg (<1 mmol) sodium. Each 2,000 mg vial contains 35 mg (<1 mmol) sodium. Powder for solution for infusion. White to off-white powder. ***Mechanism of action:*** Gemcitabine (dFdC), which is a pyrimidine antimetabolite, is metabolised intracellularly by nucleoside kinase to the active diphosphate (dFdCDP) and triphosphate (dFdCTP) nucleosides. The cytotoxic effect of gemcitabine is due to inhibition of DNA synthesis by two mechanisms of action by dFdCDP and dFdCTP. First, dFdCDP inhibits ribonucleotide reductase, which is uniquely responsible for catalysing the reactions that produce deoxynucleoside triphosphates (dCTP) for DNA synthesis. Inhibition of this enzyme by dFdCDP reduces the concentration of deoxynucleosides in general and, in particular, dCTP. Second, dFdCTP competes with dCTP for incorporation into DNA (self-potentiation). ***Indications:*** Non-small cell lung cancer (NSCLC): Gemcitabine in combination with cisplatin is indicated for the first line treatment of patients with locally advanced or metastatic NSCLC. Gemcitabine monotherapy can be considered in elderly patients or those with performance status 2. Pancreatic cancer: Gemcitabine is indicated for treatment of patients with locally advanced or metastatic adenocarcinoma of the pancreas. Bladder cancer: Gemcitabine is indicated for the treatment of locally advanced or metastatic bladder cancer in combination with cisplatin. Breast cancer: Gemcitabine, in combination with paclitaxel, is indicated for the treatment of patients with unresectable, locally recurrent or metastatic breast cancer who have relapsed following adjuvant/neoadjuvant chemotherapy. Prior chemotherapy should have included an anthracycline unless clinically contraindicated. Ovarian cancer: Gemcitabine is indicated for the treatment of patients with locally advanced or metastatic epithelial ovarian carcinoma, in combination with carboplatin, in patients with relapsed disease following a recurrence-free interval of at least 6 months after platinum-based, first-line therapy. ***Dosage and administration:*** Gemcitabine should only be prescribed by a physician qualified in the use of anti-cancer chemotherapy. Standard dosing: Non-Small Cell Lung Cancer: (Monotherapy): Adults – the recommended dose of gemcitabine is 1000 mg/m², given by 30-minute intravenous infusion. This should be repeated once weekly for three weeks, followed by a one-week rest period. This four-week cycle is then repeated. Dosage reduction with each cycle or within a cycle may be applied based upon the amount of toxicity experienced by the patient. Non-Small Cell Lung Cancer: (Combination Use): Adults – The recommended dose for gemcitabine is 1250 mg/m² body surface area given as a 30-minute intravenous infusion on day 1 and 8 of the treatment cycle (21 days). Dosage reduction with each cycle or within a cycle may be applied based upon the grade of toxicity experienced by the patient. Cisplatin has been used at doses between 75–100 mg/m² once every 3 weeks. Pancreatic Cancer: Adults – the recommended dose of gemcitabine is 1000 mg/m², given by 30-minute intravenous infusion. This should be repeated once weekly for up to 7 weeks followed by a week of rest. Subsequent cycles should consist of injections once weekly for 3 consecutive weeks out of every 4 weeks. Dosage reduction with each cycle or within a cycle may be applied based upon the amount of toxicity experienced by the patient. Bladder Cancer: (Combination use): Adults – the recommended dose for gemcitabine is 1000 mg/m², given by 30-minute infusion. The dose should be given on days 1, 8 and 15 of each 28-day cycle in combination with cisplatin. Cisplatin is given at a recommended dose of 70 mg/m² on day 1 following gemcitabine or day 2 of each 28-day cycle. This 4-week cycle is then repeated. Dosage reduction with each cycle or within a cycle may be applied based upon the amount of toxicity experienced by the patient. Breast Cancer: (Combination Use): Adults- gemcitabine in combination with paclitaxel is recommended using paclitaxel (175 mg/m²) administered on day 1 over approximately 3 hours as an intravenous infusion, followed by gemcitabine (1250 mg/m²) as a 30-minute intravenous infusion on days 1 and 8 of each 21-day cycle. Dose reduction with each cycle or within a cycle may be applied based upon the amount of toxicity experienced by the patient. Patients should have an absolute granulocyte count of at least 1,500 (x106/l) prior to initiation of gemcitabine + paclitaxel combination. Ovarian Cancer: (Combination Use): Adults – gemcitabine in combination with carboplatin is recommended using gemcitabine 1000 mg/m² administered on days 1 and 8 of each 21-day cycle as a 30-minute intravenous infusion. After gemcitabine, carboplatin will be given on day 1 consistent with a target Area under curve (AUC) of 4.0 mg/ml min. Dosage reduction with each cycle or within a cycle may be applied based upon the grade of toxicity experienced by the patient. Monitoring, Dose Adjustment or Titration, Methods of Terminating Treatment Patients receiving gemcitabine should be monitored prior to each dose for platelet, leukocyte and granulocyte counts and, if necessary, the dose of gemcitabine may be either reduced or withheld in the presence of haematological toxicity. Periodic physical examination and checks of renal and hepatic function should be made to detect non-haematologic toxicity. Dosage reduction with each cycle or within a cycle may be applied based on the amount of toxicity experienced by the patient. Doses should be withheld until toxicity has resolved in the opinion of the physician. ***Method of administration:*** Gemcitabine is tolerated well during infusion and may be administered ambulant. If extravasation occurs, generally the infusion must be stopped immediately and started again in another blood vessel. The patient should be monitored carefully after the administration. ***Special population:*** Elderly population (>65 years): Gemcitabine has been well tolerated in patients over the age of 65. Renal and hepatic impairment: Gemcitabine should be used with caution in patients with impaired renal function or hepatic insufficiency. Paediatric population (<18 years): Gemcitabine is not recommended for use in children under 18 years of age due to insufficient data on safety and efficacy. ***Contraindications:*** Hypersensitivity to the active substance gemcitabine or to any of the excipients. Breast-feeding during treatment with gemcitabine. ***Special warnings and precautions for use:*** Prolongation of the infusion time and increased dosing frequency have been shown to increase toxicity. Gemcitabine can suppress bone marrow function as manifested by leukopenia, thrombocytopenia and anaemia. However, myelosuppression is short-lived and usually does not result in dose reductions and rarely in discontinuation. ***Pregnancy and lactation:*** Pregnancy: Gemcitabine should not be used during pregnancy unless clearly necessary. Women should be advised not to become pregnant during treatment with gemcitabine and to warn their attending physician immediately, should this occur after all. Lactation: Breast-feeding must be discontinued during gemcitabine therapy. Fertility: In fertility studies gemcitabine caused hypospermatogenesis in male mice. Therefore, men being treated with gemcitabine are advised not to father a child during and up to 6 months after treatment and to seek further advice regarding cryoconservation of sperm prior to treatment because of the possibility of infertility due to therapy with gemcitabine. ***Undesirable effects:*** The most commonly reported adverse drug reactions associated with gemcitabine treatment include: nausea with or without vomiting, raised liver transaminases (AST/ALT) and alkaline phosphatase, reported in approximately 60% of patients; proteinuria and haematuria reported in approximately 50% patients; dyspnoea reported in 10–40% of patients (highest incidence in lung cancer patients); allergic skin rashes occur in approximately 25% of patients and are associated with itching in 10% of patients. ***Overdose:*** There is no known antidote for overdose of gemcitabine. Doses as high as 5700 mg/m² have been administered by intravenous infusion over 30-minutes every 2 weeks with clinically acceptable toxicity. In the event of suspected overdose, the patient should be monitored with appropriate blood counts and receive supportive therapy, as necessary. ***List of excipients:*** Mannitol (E421), sodium acetate trihydrate (E262), hydrochloric acid (E507) (for pH-adjustment), sodium hydroxide (E524) (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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