ONCOLOGY

Irinotecan Kabi 20 mg/ml

Trusted Generics: Total Care

Irinotecan Kabi 20 mg/ml
concentrate for
solution for infusion

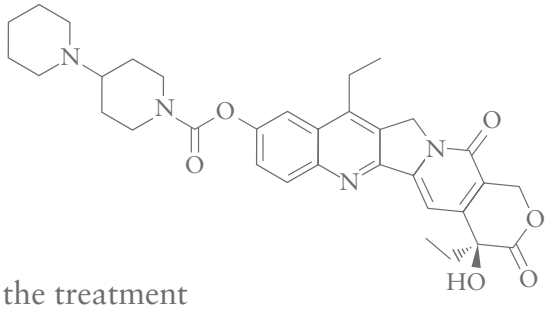
FRESENIUS KABI

caring for life

Irinotecan Kabi

Therapeutic class

Topoisomerase I inhibitor



Indications

Irinotecan Kabi is indicated for the treatment of patients with advanced colorectal cancer:

- In combination with 5-fluorouracil and folinic acid in patients without prior chemotherapy for advanced disease
- As a single agent in patients who have failed an established 5-fluorouracil containing treatment regimen

Please refer to the Irinotecan 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.

Irinotecan Kabi is available as follows:

	40 mg	2 ml	Vial
	100 mg	5 ml	Vial
	300 mg	15 ml	Vial
	500 mg	25 ml	Vial

Composition	1 ml of solution contains irinotecan hydrochloride trihydrate 20 mg
Pharmaceutical form	Concentrate for solution for infusion, light yellow coloured solution
Excipients	Sorbitol, lactic acid, water for injections, sodium hydroxide (for pH-adjustment)
Shelf life	2 years (before opening the vial)

Irinotecan Kabi in focus

- Cell cycle non-specific cytotoxic agent
- Exerts its anti-tumor activity on cancerous cells, throughout their life cycle
- Proven survival benefits in colorectal cancers

Stability

The unopened vials of Irinotecan Kabi injection are stable until the date indicated on the package when stored under recommended storage condition in the original package. Solution for infusion prepared as recommended are stable at ambient temperature (approx. 25°C).
Additional stability information is available from your local Fresenius Kabi representative.

Compatibility

Solution should be prepared in glass, polyethylene or polypropylene containers.

Manufacturing and safety

Irinotecan 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 Irinotecan Kabi 20 mg/ml concentrate solution for infusion (irinotecan)

Composition: The solution contains 20 mg/ml irinotecan hydrochloride trihydrate (equivalent to 17.33 mg/ml irinotecan). Each vial of 2 ml contains 40 mg and each vial of 5 ml contains 100 mg of irinotecan hydrochloride trihydrate. ***Mechanism of action:*** Irinotecan is a semi-synthetic derivative of camptothecin. It is an antineoplastic agent which acts as a specific inhibitor of DNA topoisomerase I. The inhibition of DNA topoisomerase I by irinotecan or SN-38 induces single-strand DNA lesions which blocks the DNA replication fork and are responsible for the cytotoxicity. This cytotoxic activity was found time-dependent and was specific to the S phase. ***Indications:*** Irinotecan is indicated for the treatment of patients with advanced colorectal cancer in combination with 5-fluorouracil and folinic acid in patients without prior chemotherapy for advanced disease, as a single agent in patients who have failed an established 5-fluorouracil containing treatment regimen. ***Dosage and administration:*** For adults only. After dilution, irinotecan concentrate for solution for infusion should be infused into a peripheral or central vein. In monotherapy (for previously treated patient): The recommended dosage of irinotecan is 350 mg/m² administered as an intravenous infusion over a 30 to 90 minute period every three weeks. In combination therapy (for previously untreated patient): Safety and efficacy of Irinotecan in combination with 5-fluorouracil (5FU) and folinic acid (FA) have been assessed with the following schedule: Irinotecan plus 5FU/FA in every 2 weeks schedule. The recommended dose of Irinotecan is 180 mg/m² administered once every 2 weeks as an intravenous infusion over a 30 to 90 minute period, followed by infusion with folinic acid and 5-fluorouracil. Dosage adjustments: At the start of a subsequent infusion of therapy, the dose of irinotecan, and 5FU when applicable, should be decreased according to the worst grade of adverse events observed in the prior infusion. Treatment should be delayed by 1 to 2 weeks to allow recovery from treatment-related adverse events. With the following adverse events a dose reduction of 15% to 20% should be applied for irinotecan and/or 5FU when applicable: Haematological toxicity (neutropenia grade 4, febrile neutropenia (neutropenia grade 3 to 4 and fever grade 2 to 4), thrombocytopenia and leukopenia (grade 4)), non haematological toxicity (grade 3 to 4). Treatment Duration: Treatment with irinotecan should be continued until there is an objective progression of the disease or an unacceptable toxicity. ***Special populations:*** Patients with impaired hepatic function: In monotherapy: Blood bilirubin levels (up to 3 times the upper limit of the normal range (UNL)) in patients with performance status ÷2, should determine the starting dose of Irinotecan. In these patients with hyperbilirubinemia and prothrombin time greater than 50%, the clearance of irinotecan is decreased and therefore the risk of haematotoxicity is increased. Thus, weekly monitoring of complete blood counts should be conducted in this patient population. In patients with bilirubin up to 1.5 times the upper limit of the normal range (ULN), the recommended dosage of Irinotecan is 350 mg/m², in patients with bilirubin ranging from 1.5 to 3 times the ULN, the recommended dosage of Irinotecan is 200 mg/m², patients with bilirubin beyond to 3 times the ULN should not be treated with irinotecan. Patients with impaired renal function: Irinotecan is not recommended for use in patients with impaired renal function. Elderly: The dose should be chosen carefully in this population due to their greater frequency of decreased biological functions. This population should require more intense surveillance. ***Contraindications:*** Chronic inflammatory bowel disease and/or bowel obstruction. History of severe hypersensitivity reactions to irinotecan hydrochloride trihydrate or to one of the excipients of Irinotecan Kabi. Pregnancy and lactation. Bilirubin >3 times the upper limit of the normal range. Severe bone marrow failure. WHO performance status >2. Concomitant use with St John's Wort. ***Special warnings and precautions for use:*** The use of irinotecan should be confined to units specialised in the administration of cytotoxic chemotherapy and it should only be administered under the supervision of a physician qualified in the use of anticancer chemotherapy. When irinotecan is used in monotherapy, it is usually prescribed with the every-3-week dosage schedule. However, the weekly-dosage schedule may be considered in patients who may need a closer follow-up or who are at particular risk of severe neutropenia. Delayed diarrhoea: Patients should be made aware of the risk of delayed diarrhoea occurring more than 24 hours after the administration of irinotecan and at any time before the next cycle. Patients should quickly inform their physician of its occurrence and start appropriate therapy immediately. Haematology: Weekly monitoring of complete blood cell counts is recommended during Irinotecan treatment. In patients who experienced severe haematological events, a dose reduction is recommended for subsequent administration. Liver impairment: Liver function tests should be performed at baseline and before each cycle. Nausea and vomiting: A prophylactic treatment with antiemetics is recommended before each treatment with irinotecan. Acute cholinergic syndrome: If acute cholinergic syndrome appears (defined as early diarrhoea and various other symptoms such as sweating, abdominal cramping, lacrimation, myosis and salivation), atropine sulphate (0.25 mg subcutaneously) should be administered unless clinically contraindicated. Caution should be exercised in patients with asthma. Elderly: Due to the greater frequency of decreased biological functions, in particular hepatic function, in elderly patients, dose selection with Irinotecan should be cautious in this population. Patients with bowel obstruction: Patients must not be treated with irinotecan until resolution of the bowel obstruction. ***Pregnancy and lactation:*** Pregnancy: Contraceptive measures must be taken during and for at least three months after cessation of therapy. Irinotecan has been shown to be embryotoxic, foetotoxic and teratogenic in rabbits and rats. Therefore, irinotecan must not be used during pregnancy. Women of childbearing potential: Women of childbearing age receiving irinotecan should be advised to avoid becoming pregnant, and to inform the treating physician immediately should this occur. Lactation: Breast-feeding must be discontinued for the duration of irinotecan therapy. ***Undesirable effects:*** The most serious and/or most frequently occurring adverse events of irinotecan, both in monotherapy and in combination therapy, were gastrointestinal (diarrhoea, nausea, vomiting constipation), haematological (neutropenia, anaemia, thrombocytopenia), fever, asthenia, Acute Cholinergic Syndrome, infections and alopecia. ***Overdose:*** There have been reports of overdosage at doses up to approximately twice the recommended therapeutic dose, which may be fatal. The most significant adverse reactions reported were severe neutropenia and severe diarrhoea. There is no known antidote for irinotecan. Maximum supportive care should be instituted to prevent dehydration due to diarrhoea and to treat any infectious complications. ***List of excipients:*** Sorbitol, lactic acid, water for injections, sodium hydroxide (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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