IRINOCAN INJECTION 20 MG/ML

For Intravenous Use Only

DESCRIPTION

Irinotecan Injection (Irinotecan Hydrochloride Injection) is an antineoplastic agent of the topoisomerase I inhibitor class. Irinotecan hydrochloride was clinically investigated as CPT-11.

Irinotecan hydrochloride is a semisynthetic derivative of camptothecin, an alkaloid extract from plants such as Camptotheca acuminata. The chemical name is (S)-4,11-diethyl-3,4,12,14-tetrahydro-4-hydroxy-3,14-dioxo1H-pyrano[3',4':6,7]-indolizino[1,2-b]quinolin-9-yl-[1,4'bipiperidine]-1'-carboxylate, monohydrochloride, trihydrate.

Irinotecan hydrochloride is a pale yellow to yellow crystalline powder, with the empirical formula C 33H38N4O6•HCl•3H2O and a molecular weight of 677.19. It is slightly soluble in water and organic solvents.

COMPOSITION

Irinotecan Injection is supplied as a sterile, pale yellow, clear, aqueous solution.

It is available in two single-dose sizes: 2 mL-fill vials contain 40 mg irinotecan hydrochloride and 5 mL-fill vials contain 100 mg irinotecan hydrochloride. Each milliliter of solution contains 20 mg of irinotecan hydrochloride (on the basis of the trihydrate salt).

Inactive ingredients include lactic acid Ph. Eur./USP, sorbitol Ph. Eur., and water for injection Ph. Eur. The pH of the solution has been adjusted to 3.0 (range, 3.0 to 3.8) with hydrochloric acid (37%) Ph. Eur./BP/NF and sodium hydroxide Ph. Eur./BP/NF.

Irinotecan Injection is intended for dilution with 5% Dextrose Injection, (D5W), or 0.9% Sodium Chloride Injection, prior to intravenous infusion. The preferred diluent is 5% Dextrose Injection.

CLINICAL PHARMACOLOGY

Irinotecan is a derivative of camptothecin. Camptothecins interact specifically with the enzyme topoisomerase I which relieves torsional strain in DNA by inducing reversible single-strand breaks. Irinotecan and its active metabolite SN-38 bind to the topoisomerase I-DNA complex and prevent religation of these single-strand breaks. Current research suggests that the cytotoxicity of irinotecan is due to double-strand DNA damage produced during DNA synthesis when replication enzymes interact with the ternary complex formed by topoisomerase I, DNA, and either irinotecan or SN-38. Mammalian cells cannot efficiently repair these double-strand breaks.

Irinotecan serves as a water-soluble precursor of the lipophilic metabolite SN-38. SN- 38 is formed from irinotecan by carboxylesterase-mediated cleavage of the carbamate bond between the camptothecin moiety and the dipiperidino side chain. SN-38 is approximately 1000 times as potent as irinotecan as an inhibitor of topoisomerase purified from human and rodent tumor cell lines. In vitro cytotoxicity assays show that the potency of SN-38 relative to irinotecan varies from 2- to 2000-fold. However, the plasma area under the concentration versus time curve (AUC) values for SN-38 are 2% to 8% of irinotecan and SN-38 is 95% bound to plasma proteins compared to approximately 50% bound to plasma proteins for irinotecan. The precise contribution of SN-38 to the activity of irinotecan is thus unknown. Both irinotecan and SN-38 exist in an active lactone form and an inactive hydroxy acid anion form. A pH-dependent equilibrium exists between the two forms such that an acid pH promotes the formation of the lactone, while a more basic pH favors the hydroxy acid anion form. Administration of irinotecan has resulted in antitumor activity in mice bearing cancers of rodent origin and in human carcinoma xenografts of various histological types.

Pharmacokinetics

After intravenous infusion of irinotecan in humans, irinotecan plasma concentrations decline in a multiexponential manner, with a mean terminal elimination half-life of about 6 to 12 hours. The mean terminal elimination half-life of the active metabolite SN-38 is about 10 to 20 hours. The half-lives of the lactone (active) forms of irinotecan and SN-38 are similar to those of total irinotecan and SN-38, as the lactone and hydroxy acid forms are in equilibrium.

Over the recommended dose range of 50 to 350 mg/m2, the AUC of Irinotecan increases linearly with dose; the AUC of SN-38 increases less than proportionally with dose. Maximum concentrations of the active metabolite SN-38 are generally seen within 1 hour following the end of a 90-minute infusion of Irinotecan.

Irinotecan exhibits moderate plasma protein binding (30% to 68% bound). SN-38 is highly bound to human plasma proteins (approximately 95% bound). The plasma protein to which irinotecan and SN-38 predominantly binds is albumin.

Metabolism and Excretion: The metabolic conversion of irinotecan to the active metabolite SN-38 is mediated by carboxylesterase enzymes and primarily occurs in the liver. SN-38 is subsequently conjugated predominantly by the enzyme UDP-glucuronosyl transferase 1A1 (UGT1A1) to form a glucuronide metabolite. UGT1A1 activity is reduced in individuals with genetic polymorphisms that lead to reduced enzyme activity such as the UGT1A1*28 polymorphism. The disposition of irinotecan has not been fully elucidated in humans. The urinary excretion of irinotecan is 11% to 20%; SN-38, <1%; and SN-38 glucuronide, 3%. The cumulative biliary and urinary excretion of irinotecan and its metabolites (SN-38 and SN-38 glucuronide) over a period of 48 hours following administration of irinotecan in patients ranged from approximately 25% (100 mg/m2) to 50% (300 mg/m2).

Pharmacokinetics in Special Populations

Geriatric: In studies using the weekly schedule, the terminal half-life of irinotecan was 6.0 hours in patients who were 65 years or older and 5.5 hours in patients younger than 65 years. Dose- normalized AUC0-24 for SN-38 in patients who were at least 65 years of age is higher than in patients younger than 65 years. No change in the starting dose is recommended for geriatric patients receiving the weekly dosage schedule of irinotecan. The pharmacokinetics of irinotecan given once every 3 weeks has not been studied in the geriatric population; a lower starting dose is recommended in patients 70 years or older based on clinical toxicity experience with this schedule.

Gender: The pharmacokinetics of irinotecan do not appear to be influenced by gender.

Race: The influence of race on the pharmacokinetics of irinotecan has not been evaluated.

Hepatic Insufficiency: Irinotecan clearance is diminished in patients with hepatic dysfunction while exposure to the active metabolite SN-38 is increased relative to that in patients with normal hepatic function. The magnitude of these effects is proportional to the degree of liver impairment as measured by elevations in total bilirubin and transaminase concentrations. However, the tolerability of irinotecan in patients with hepatic dysfunction (bilirubin greater than 2 mg/dl) has not been assessed sufficiently, and no recommendations for dosing can be made.

Renal Insufficiency: The influence of renal insufficiency on the Pharmacokinetic of irinotecan has not been evaluated.

INDICATIONS AND USAGE

Irinotecan Injection 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-fluoroucil containing treatment regimen

CONTRAINDICATIONS

Irinotecan Injection is contraindicated in patients with

- A history of severe hypersensitivity reactions to irinotecan hydrochloride trihydrate or to one of the excipients of Irinotecan Injection
- A chronic inflammatory bowel disease and/or a bowel obstruction
- In pregnant or breast feeding women
- In patients with bilirubin > 3 times the ULN
- In patients with a severe bone marrow failure
- In patients presenting a risk factor, particularly those with a WHO performance > 2

WARNINGS & PRECAUTIONS

The use of irinotecan injection should be confined to units specialized 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. Given the nature and incidence of adverse events, irinotecan injection will only be prescribed in the following cases after the expected benefits have been weighed against the possible therapeutic risks:

In patients presenting a risk factor, particularly those with a WHO performance status =2

In a few rare instances where patients are deemed unlikely to observe recommendations regarding management of adverse events (need for immediate and prolonged antidiarrheal treatment combined with high fluid intake at onset of delayed diarrhea). Strict hospital supervision is recommended for such patients.

When irinotecan injection 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 Diarrhea

Patients should be made aware of the risk of delayed diarrhea occurring more than 24 hours after the administration of irinotecan injection and at any time before the next cycle. In monotherapy, the median time of onset of the first liquid stool was on day 5 after the infusion of irinotecan injection. Patients should quickly inform their physician of its occurrence and start appropriate therapy immediately. Patients with an increased risk of diarrhea are those who had previous abdominal/pelvic radiotherapy, those with baseline hyperleucocytosis, those with performance status ≥ 2 and women. If not properly treated, diarrhea can be life threatening, especially if the patient is concomitantly neutropenic.

As soon as the first liquid stool occurs, the patient should start drinking large volumes of beverages containing electrolytes and an appropriate therapy must be initiated immediately. The antidiarrhea treatment will be prescribed by the department where irinotecan injections have been administered. After discharge from the hospital, the patients should obtain the prescribed drugs so that they can treat the diarrhea as soon as it occurs. In addition, they must inform their physician or the department administering irinotecan when/if diarrhea is occurring. The currently recommended antidiarrhea treatment consists of high doses of loperamide (4mg for the first intake and then 2mg every 2 hours). This therapy should continue for 12 hours after the last liquid stool and should not be modified. In no instance should loperamide be administered for more than 48 consecutive hours at these doses, because of the risk of paralytic ileus, nor for less than 12 hours. In addition to the antidiarrhea treatment, a prophylactic broad-spectrum antibiotics should be given, when diarrhea is associated with severe neutropenia (neutrophils count < 500cells/mm3).

In addition to the antibiotic treatment, hospitalization is recommended for management of the diarrhea in following cases: diarrhea associated with fever, severe diarrhea (requiring intravenous hydration), and diarrhea persisting beyond 48 hours following the initiation of high-dose loperamide therapy. Loperamide should not be given prophylactically, even in patients who experienced delayed diarrhea at previous cycle. In patients who experienced severe diarrhea, a reduction in dose is recommended for subsequent cycles.

Nausea and Vomiting

A prophylactic treatment with antiemetics is recommended before each treatment with irinotecan. Nausea and vomiting have been frequently reported. Patients with vomiting associated with delayed diarrhea should be hospitalized as soon as possible for treatment.

Acute cholinergic syndrome

If acute cholinergic syndrome appears (defined as early diarrhea 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. In patients who experienced an acute and severe cholinergic syndrome, the use of prophylactic atropine sulphate is recommended with subsequent doses of irinotecan.

Hematology

Weekly monitoring of complete blood cell counts is recommended during irinotecan treatment. Patients should be aware of the risk of neutropenia and the significance of fever. Febrile neutropenia (temperature > 380C and neutrophil count ≤ 1000 cells/mm3) should be urgently treated in the hospital with broad-spectrum intravenous antibiotics. In patients who experienced severe hematological events, a dose reduction is recommended for subsequent administration. There is an increased risk of infections and hematological toxicity in patients with severe diarrhea. In patients with severe diarrhea, complete blood cells counts should be performed.

Liver impairment

Liver function tests should be performed at baseline and before each cycle. In patients with hyperbilirubinemia, the clearance of irinotecan hydrochloride is decreased and therefore the risk hematotoxicity is increased. Thus, frequent monitoring of complete blood counts should be conducted in this patient population. Irinotecan should not be used in patients with a bilirubin > 3 times the ULN.

Elderly

Due to the greater frequency of decreased biological functions, in particular hepatic function, in elderly patients, dose selection with irinotecan should be cautions in this population.

Patients with bowel obstruction

Patients must not be treated with irinotecan until resolution of the bowel obstruction

Patients with Impaired Renal function

Studies in this population have not been conducted.

Others

Since this medicine contains sorbitol, it is unsuitable in hereditary fructose intolerance. Infrequent cases of renal insufficiency, hypotension or circulatory failure have been observed in patients who experienced episodes of dehydration associated with diarrhea and/or vomiting, or sepsis. Contraceptive measures must be taken during and for at least three months after cessation of therapy.

DRUG INTERACTIONS

Interaction between irinotecan hydrochloride and neuromuscular blocking agents cannot be ruled out. Since irinotecan injection has anticholinesterase activity, drugs with anticholinesterase activity may prolong the neuromuscular blocking effects of suxamethonium and the neuromuscular blockade of non-depolarising drugs may be antagonized.

Carcinogenesis, Mutagenesis & Impairment of Fertility

Long-term carcinogenicity studies with irinotecan were not conducted. Neither irinotecan nor SN-38 was mutagenic in the in vitro Ames assay. Irinotecan was clastogenic both in vitro (chromosome aberrations in Chinese hamster ovary cells) and in vivo (micronucleus test in mice). No significant adverse effects on fertility and general reproductive performance were observed after intravenous administration of irinotecan in doses of up to 6 mg/kg/day to rats and rabbits.

PREGNANCY AND LACTATION Pregnancy

There is no information on the use of irinotecan in pregnant women

Irinotecan has been shown to be embryotoxic, foetotoxic and teratogenic in rabbits and rats. Therefore, irinotecan must not be used during pregnancy.

Women of child-bearing potential

Women of child bearing age receiving irinotecan should be advised to avoid becoming pregnant, and to inform the treating physician immediately should this occur.

Lactation

It is not known whether irinotecan is excreted in human milk. Consequently, because of the potential for adverse reactions in nursing infants, breast-feeding must be discontinued for the duration of irinotecan therapy.

DOSAGE AND ADMINISTRATION

For Adults only

- In monotherapy (for previously treated patient):The recommended dosage of Irinotecan Injection is 350 mg/m2 administered as an intraveneous infusion over a 30-to-90 minutes period every three weeks
- In combination therapy (for previously untreated patient)Safety and efficacy of Irinotecan Injection in combination with 5-fluorouracil (5FU) and folinic acid (FA) have been assessed with the following schedule:Irinotecan Injection plus 5FU/FA in every 2 weeks schedule. The recommended dose of Irinotecan Injection is 180 mg/ m2 administered once every 2 weeks as an intravenous infusion over a 30-to 90 –minutes period, followed by infusion with folinic acid anf 5-fluorouracil.

Dosage Adjustments

Irinotecan Injection should be administered after appropriate recovery of all adverse events to grade 0 or 1 NCI-CTC grading (National Cancer Institute Common Toxicity Criteria) and when treatment – related diarrhea is fully resolved. At the start of a subsequent infusion of therapy, the dose of irinotecan Injection, 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 Injection and/or 5FU when applicable: hematological toxicity (neutropenia grade 4, febrile neutropenia (neutropenia grade 3-4 and fever grade 2-4), thrombocytopenia and leucopenia (grade 4), non hematological toxicity (grade 3-4).

Treatment duration

Treatment with Irinotecan Injection should be continued until there is an objective progression of the disease or an unacceptable toxicity.

Irinotecan - 20 mg - Lab-PIL

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Colour : Pantone Black

Date : 23*05*16 (1), 05*02*22 (1)

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Signature				
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Special Population

Elderly

No specific pharmacokinetics studies have been performed in elderly. However, the dose should be chosen carefully in this population due to their greater frequency of decreased biological functions. This population should require more intensive surveillance.

Patients with Impaired Hepatic Function

In monotherapy: in patients with hyperbilirubinemia and prothrombin time greater than 50%, the clearance of irinotecan is decreased and therefore the risk of hematotoxicity is increased. Thus, frequent 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 injection is 350 mg/m2,

-In patients with bilirubin ranging from 1.5 to 3 times the ULN, the recommended dosage of irinotecan injection is 200 mg/m2

-Patients with bilirubin beyond to 3 times the ULN should not be treated with irinotecan injection

No data are available in patients with hepatic impairment treated by irinotecan injection in combination.

Patients with impaired renal function

Irinotecan injection is not recommended for use in patients with impaired renal function, as studies in this population have not been conducted.

Preparation & Administration Precautions

As with other potentially toxic anticancer agents, care should be exercised in the handling and preparation of infusion solutions prepared from irinotecan Injection. The use of glasses, mask and gloves is recommended. If a solution of irinotecan contacts the skin, wash the skin immediately and thoroughly with soap and water. If irinotecan contacts the mucous membranes, flush thoroughly with water.

Preparation for intravenous infusion administration

As with any other injectable drugs, the irinotecan solution must be prepared aseptically. If any precipitate is observed in the vials or after reconstitution, the product should be discarded according to standard procedures for cytotoxic agents. Aseptically withdraw the required amount of irinotecan solution from the vial with a calibrated syringe and inject into a 250 ml infusion bag or bottle containing either 0.9% sodium chloride solution or 5% dextrose solution. The infusion should then be thoroughly mixed by manual rotation. Irinotecan Injection must be diluted prior to infusion. Irinotecan should be diluted in 5% Dextrose Injection, (preferred) or 0.9% Sodium Chloride Injection, to a final concentration range of 0.12 to 2.8 mg/mL. In most clinical trials, irinotecan was administered in 250 mL to 500 mL of 5% Dextrose Injection.

For single use only. Discard any unused solution.

Other drugs should not be added to the infusion solution. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit.

Administration

Irinotecan solution for infusion should be infused into a peripheral or central vein. Irinotecan solution should not be delivered as an intravenous bolus or an intravenous infusion shorter than 30 minutes or longer than 90 minutes.

Disposal

All materials used for dilution and administration should be disposed of according to hospital standard procedure applicable to cytotoxic agents.

ADVERSE REACTIONS

Undesirable effects detailed in this section refer to irinotecan. There is no evidence that the safety profile of irinotecan is influenced by cetuximab or vice versa. In combination with cetuximab, additional reported undesirable effects were those expected with cetuximab. Therefore also refer to the product information of cetuximab.

For information on adverse reactions in combination with bevacizumab, refer to the bevacizumab summary product of characteristics.

The following adverse reactions considered to be possibly or probably related to the administration of irinotecan have been reported at the recommended dose of 350 mg/m2 in monotherapy, and in combination therapy with 5FU/FA in every 2 weeks schedule at the recommended dose of 180 mg/m2.

Gastrointestinal Disorders

Delayed diarrhea

Diarrhea (occurring more than 24 hours after administration) is a dose-limiting toxicity of irinotecan.

In monotherapy:

Severe diarrhea was observed in patients who follow recommendations for the management of diarrhea. The median time of onset of the first liquid stool was on day 5 after the infusion of irinotecan.

In combination therapy:

Severe diarrhea was observed who follow recommendations for the management of diarrhea.

Uncommon cases of pseudo-membranous colitis have been reported, one of which has been documented bacteriologically (Clostridium difficile)

Nausea and Vomiting

In monotherapy:

Nausea and vomiting were severe in patients treated with antiemetic.

In combination therapy:

A lower incidence of severe nausea and vomiting was observed..

Dehydration

Episodes of dehydration commonly associated with diarrhea and/or vomiting have been reported.

Infrequent cases of renal insufficiency, hypotension or cardio-circulatory failure have been observed in patients who experienced episodes of dehydration associated with diarrhea and/or vomiting.

Other gastrointestinal disorders

In frequent cases of intestinal obstruction, ileus, or gastrointestinal haemorrhage and rare cases of colitis, including typhlitis, ischemic and ulcerative colitis, were reported. Rare cases of intestinal perforation were reported. Other mild effects include anorexia, abdominal pain and mucositis.

Rare cases of symptomatic or asymptomatic pancreatitis have been associated with irinotecan therapy.

Blood disorders

Neutropenia is a dose-limiting toxic effect. Neutropenia was reversible and not cumulative; the median day to nadir was 8 days whatever the use in monotherapy or in combination therapy.

In monotherapy:

Neutropenia was observed and was severe in some patients.

Infectious episodes occurred in patients and were associated with severe neutropenia in patients and resulted in death in 2 cases.

Anemia was reported in patients.

Thrombocytopenia (< 100 000 cells/mm^3) was observed in patients.

Nearly all the patients showed a recovery by day 22

In combination therapy:

Neutropenia was observed in patients and was severe (neutrophil count < 500 cells/mm^3) some patient.

Total recovery was usually reached within 7-8 days

Fever with severe neutropenia was reported in some patients.

Infectious episodes occurred in patients and were associated with severe neutropenia in few of patients and resulted in death in 1 case.

Anemia was reported in some patients.

Thrombocytopenia was observed in patients. No severe thrombocytopenia (< 50 000 cells/mm^3) has been observed.

One case of peripheral thrombocytopenia with antiplatelet antibodies has been reported in the post-marketing experience.

Infection and infestation

Infrequent cases of renal insufficiency, hypotension or cardio-circulatory failure have been observed in patients who experienced sepsis.

General disorders and infusion site reactions

Acute cholinergic syndrome

Severe transient acute cholinergic syndrome was observed in patients treated in monotherapy and in patients treated in combination therapy. The main symptoms were defined as early diarrhea and various other symptoms such as abdominal pain, conjunctivitis, rhinitis, hypotension, vasodilatation, sweating, chills, malaise, dizziness, visual disturbances, myosis, lacrimation and increased salivation occurring during or within the first 24 hours after the infusion of irinotecan. These symptoms disappear after atropine administration.

Asthenia was severe in patients treated in monotherapy and in patients treated in combination therapy. The causal relationship to irinotecan has not been clearly established. Fever in the absence of infection and without concomitant severe neutropenia, occurred in patients treated in monotherapy and in patients treated in combination therapy.

Mild infusion site reactions have been reported although uncommonly.

Cardiac disorders

Rare cases of hypertension during or following the infusion have been reported.

Respiratory Disorders

Interstitial pulmonary disease presenting as pulmonary infiltrates in uncommon during irinotecan therapy. Early effects such as dyspnoea have been reported

Skin and Subcutaneous Tissue Disorders

Alopecia was very common and reversible. Mild cutaneous reactions have been reported although uncommonly.

Immune system Disorders

Uncommon mild allergy reactions and rare cases of anaphylactic / anaphylactoid reactions have been reported.

Musculoskeletal disorders

Early effects such as muscular contraction or cramps and paresthesia have been reported.

Laboratory Tests

In monotherapy, transient and mild to moderate increases in serum levels of either transaminases, alkaline phosphatase or bilirubin were observed in the absence of progressive liver metastasis.

Transient and mild to moderate increases of serum levels of creatinine have been observed in the patients.

In combination therapy transient serum levels (grades 1 and 2) of either SGPT, SGOT, alkaline phosphatase or bilirubin were observed in the absence of progressive liver metastasis. Transient grade 3 were observed. No grade 4 was observed.

Increase of amylase and/or lipase have been very rarely reported.

Rare cases of hypokalemia and hyponatremia mostly related with diarrhea and vomiting have been reported.

Nervous System Disorders

There have been very rare postmarketing reports of transient speech disorders associated with irinotecan infusions.

Driving

Patients should be warned about the potential for dizziness or visual disturbances which may occur within 24 hours following the administration of irinotecan, and advised not to drive or operate machinery if these symptoms occur.

INCOMPATIBILITIES

None known

Do not admix with other medications

OVERDOSAGE

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 diarrhea. There is no known antidote for overdosage of irinotecan. Maximum supportive care should be instituted to prevent dehydration due to diarrhea and to treat any infectious complications.

HOW SUPPLIED

Each mL of Irinotecan Injection contains 20 mg Irinotecan (on the basis of the trihydrate salt); When necessary, pH has been adjusted to 3.5 (range, 3.0 to 3.8) with sodium hydroxide or hydrochloric acid.

Irinotecan Injection is available in single-dose amber glass vials in 2 mL and 5 mL. This is packaged in a backing/plastic blister to protect against inadvertent breakage and leakage. The vial should be inspected for damage and visible signs of leaks before removing the backing/plastic blister. If damaged, incinerate the unopened package.

SHELF LIFE

Two years from the date of Manufacturing

STORAGE

Store below 30°C. Protect from light.

Manufactured by:

INTAS Logo

INTAS PHARMACEUTICALS LIMITED

Plot No: 457-458, Sarkhej- Bavla Highway,
Matoda, Sanand, Dist- Ahmedabad,
Gujarat, India- 382 210.

Product Registration Holder:

Jetpharma Sdn Bhd
No.13, Jalan Rajawali 2,
Bandar Puchong Jaya
47100 Puchong
Selangor, Malaysia

Irinotecan - 20 mg - Lab-PIL

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