NOVARTIS

HYCAMTIN® (topotecan)

1 mg and 4 mg; Powder for solution for infusion

Basic Succinct Statement (BSS)

Code: BSS RD 10 Sept 18; APPR 25 Mar 20

HYCAMTIN®

Important note: Before prescribing, consult full prescribing information of topotecan. When used in combination with cisplatin, consult full prescribing information of both products.

Presentation: Topotecan hydrochloride. ♦Powder for solution for infusion: 1 mg and 4 mg.

Indications: ♦Powder for i.v. infusion: Treatment of patients with small cell lung carcinoma, ovarian carcinoma. Combination with cisplatin: Treatment of patients with histologically confirmed Stage IV-B, recurrent, or persistent carcinoma of the cervix, which is not amenable to curative treatment with surgery and/or radiation therapy.

Dosage and administration: ♦Initial dose ♦*Powder for i.v. infusion*: Ovarian and small cell lung carcinoma: Initial dose 1.5 mg/m^2 for 5 consecutive days every 21 days. Cervical Cancer: 0.75 mg/m^2 on days 1, 2 and 3. **♦Subsequent doses:** To be adjusted based on neutrophil count and platelet count.

Special populations: ♦Children: Not recommended. **♦Elderly (>65 years):** No overall differences in effectiveness with younger adult patients.

♦Renal impairment: Monotherapy*:* ♦*Powder for i.v. infusion*: The recommended dose in patients with creatinine clearance between 20 and 39 mL/min is 0.75 mg/m^2/day. No dose adjustment required in patients with a creatinine clearance ≥40 mL/min. Combination therapy*:* ♦*Powder for i.v infusion*: combination with cisplatin for the treatment of cervical cancer can only be initiated in patients with serum creatinine ≤ 1.5 mg/dL.

♦Hepatic impairment: Monotherapy*:* ♦*Powder for i.v. infusion*: No dose adjustment required, although a small reduction in topotecan clearance was observed.

Contraindications: ♦Severe hypersensitivity reactions to topotecan and/or its excipients. ♦Pregnancy or breast-feeding. ♦Severe bone marrow depression prior to treatment.

Warnings and precautions: ♦Monitoring of full blood count including platelets. ♦Myelosuppression leading to sepsis. ♦Fever, neutropenia and a compatible pattern of abdominal pain to be considered for neutropenic colitis. ♦Monitor pulmonary symptoms indicative of interstitial lung disease (ILD) (e.g. cough, fever, dyspnea and/or hypoxia), and discontinue if a new diagnosis of ILD is confirmed. ♦Dose adjustment may be necessary in combination with other cytotoxic agents.

Adverse drug reactions: ♦Very common (≥10%): infection, anemia, febrile neutropenia, leucopenia, neutropenia (neutropenic colitis, including fatal neutropenic colitis, has been reported to occur as a complication of topotecan-induced neutropenia), thrombocytopenia, anorexia (which may be severe), diarrhoea, nausea and vomiting (all of which may be severe), abdominal pain, constipation, stomatitis, alopecia, asthenia, fatigue, pyrexia. **♦Common (1 to 10%):** sepsis, pancytopenia, hypersensitivity, including rash, hypocalcemia, hyperbilirubinemia, malaise. **♦Rare (0.01 to 0.1%):** interstitial lung disease. **♦Very rare (≤0.01%):** Extravasation (i.v. formulation only). **♦Frequency not known:** severe bleeding (associated with thrombocytopenia), gastrointestinal perforation, mucosal inflammation, anaphylactic reaction.

For a complete list of ADRs, consult full prescribing information.