NOVARTIS

# **HYCAMTIN™** (topotecan)

0.25 mg and 1 mg Hard capsules for oral administration

## Basic Succinct Statement (BSS)

## Code: BSS RD 22 May 17; APPR 22 JUL 19

**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 (as hydrochloride). ♦Hard capsules for oral administration: 0.25 mg and 1 mg.

**Indications:** ♦ Treatment of adult patients with relapsed small cell lung cancer (SCLC) for whom re-treatment with the first-line regimen is not considered appropriate.

**Dosage and administration: ♦Initial dose** ♦ 2.3 mg/m$^2$ daily for 5 consecutive days every 21 days. **♦Subsequent doses:** To be adjusted based on neutrophil count, platelet count and diarrhoea.

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

**♦Renal impairment:** Monotherapy*:* ♦ A dose of 1.9 mg/m$^2$/day is recommended in patients with a creatinine clearance of 30 to 49 mL/min. **♦Hepatic impairment**: ♦ Not studied.

**Contraindications:** ♦ Severe hypersensitivity reactions to the active substance or to any of the excipients. ♦Breast-feeding. ♦Severe bone marrow depression prior to starting first course.

**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.

**Capsules:** ♦Diarrhoea: Higher incidence in patients receiving oral topotecan. Higher risk of severe diarrhoea and subsequent hospitalization in patients >65 years of age. Ensure proactive and aggressive management. Diarrhoea can occur at the same time as drug-related neutropenia and its sequelae.
**Adverse drug reactions: ♦Very common (≥10%):** infection, febrile neutropenia, neutropenia, thrombocytopenia, anaemia, leucopenia, anorexia (which may be severe), nausea, vomiting and diarrhoea (all of which may be severe), which may lead to dehydration, alopecia, fatigue. **♦Common (1 to 10%):** sepsis[1], pancytopenia, hypersensitivity reaction including rash, abdominal pain[2], constipation, mucositis, dyspepsia, hyperbilirubinaemia, pruritis, asthenia, pyrexia, malaise. **♦Rare (0.01 to 0.1%):** anaphylactic reaction, angioedema, urticaria, interstitial lung disease (some cases have been fatal). **♦Not known:** severe bleeding (associated with thrombocytopenia), gastrointestinal perforation, mucosal inflammation.
[1] Fatalities due to sepsis have been reported in patients treated with topotecan.
[2] Neutropenic colitis, including fatal neutropenic colitis, has been reported to occur as a complication of topotecan-induced neutropenia

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

**Packs and prices**: Country-specific**.**

**Legal classification:** Country-specific.