Kytril® (granisetron) film-coated tablets and solution for injection Prescribing Information

Please consult the full Summary of Product Characteristics (SmPC) before prescribing

Presentation: *Kytril tablets* contain 1 mg or 2 mg granisetron (hydrochloride) and *Kytril solution for injection* granisetron (hydrochloride) 1 mg/ml is available in 1 ml and 3 ml ampoules. Solution for injection requires dilution prior to delivery as either intravenous injection or infusion.

Indication: *Kytril tablets* are indicated in adults for the prevention and treatment of acute nausea and vomiting and prevention of delayed nausea and vomiting associated with chemotherapy and radiotherapy (CINV & RINV). *Kytril solution for injection* is indicated for the prevention of delayed nausea and vomiting associated with CINV and RINV. It is also indicated in adults for the prevention and treatment of acute nausea and vomiting associated with CINV & RINV and post-operative nausea and vomiting (PONV), and in children aged 2 years and above for the prevention and treatment of acute nausea and vomiting associated with chemotherapy (CINV).

Dosage and administration: *Kytril tablets dose for adults only*: 1 mg twice a day or 2 mg once a day for up to one week following radiotherapy or chemotherapy, swallowed whole with water. The first dose of Kytril should be administered within 1 hour before the start of therapy. Dexamethasone has been used concomitantly at doses up to 20 mg once a day orally. *Kytril solution for injection adults in CINV and RINV:* Prevention (acute and delayed nausea): 1-3 mg (10-40 µg/kg) of Kytril solution for injection should be administered either as a slow intravenous injection or as a diluted intravenous infusion (dilute to 5 ml per mg) 5 minutes prior to the start of chemotherapy. Treatment (acute nausea): 1-3 mg (10-40 µg/kg) of Kytril solution for injection should be administered either as a slow intravenous injection or as a diluted intravenous infusion (dilute to 5ml per mg) and administered over 5 minutes. Further maintenance doses of Kytril solution for injection may be administered at least 10 minutes apart with a maximum dose of 9 mg over 24 hours. Combination with adrenocortical steroid: The efficacy of parenteral granisetron may be enhanced by an additional intravenous dose of an adrenocortical steroid. Please refer to SmPC for details. PONV: 1 mg (10 µg/kg) administered by slow intravenous injection with a maximum dose of 3 mg over 24 hours. For the prevention of PONV, administration should be completed prior to induction of anaesthesia. *Kytril solution for injection in children:* Prevention (acute and delayed) and treatment (acute): 10-40 µg/kg body weight (up to 3 mg) should be administered as an i.v. infusion, diluted in 10-30 ml infusion fluid and administered over 5 minutes prior to the start of chemotherapy. One additional dose may be administered within a 24 hour-period if required. This must be at least 10 minutes after the initial infusion. Administration of Kytril solution for injection may be as slow intravenous injection (over 30 seconds) or as an intravenous infusion diluted in 20 to 50 ml of compatible infusion fluid administered over 5 minutes.

Contraindications: Hypersensitivity to the active substance or to any of the excipients.

Special warnings and precautions: As granisetron may reduce lower bowel motility, patients with signs of sub-acute intestinal obstruction should be monitored following its administration. Use with certain amount of caution in patients with hepatic impairment. ECG changes including QT interval prolongation have been reported with granisetron as with other 5-HT_3 antagonists. Caution should be exercised in patients with cardiac co-morbidities, on cardiotoxic chemotherapy and/or with concomitant electrolyte abnormalities. Cross-sensitivity between 5-HT_3 antagonists (e.g. dolasteron, ondansetron) has been reported. Patients with rare hereditary problems of galactose intolerance, lactase deficiency or glucose-galactose malabsorption should not take these tablets. Reports of serotonin syndrome with the use of 5-HT_3 antagonists either alone, but mostly in combination with other serotonergic drugs (including selective serotonin reuptake inhibitors (SSRIs), and serotonin noradrenaline reuptake inhibitors (SNRIs). Appropriate observation of patients for serotonin syndrome-like symptoms is advised. Kytril is essentially 'sodium free' as the tablets contain less than 1 mmol sodium (23 mg) per dose (2 mg) and the solutions contains less than 1 mmol sodium (23 mg) per dose (3 mg). **Pregnancy and lactation**: It is preferable to avoid the use of granisetron during pregnancy and breastfeeding is not advised during treatment with Kytril.

Undesirable effects: The most frequently reported adverse reactions for Kytril are headache and constipation, which may be transient. ECG changes including QT prolongation have been reported with Kytril. *Very common: ≥1/10;* Headache and constipation. *Common ≥1/100 to <1/10*; Insomnia, diarrhoea and elevated hepatic transaminases. *Serious adverse reactions:* As for other 5-HT_3 antagonists, ECG changes including QT prolongation have been reported with granisetron and cases of serotonin syndrome following the concomitant use of Kytril and other serotonergic drugs. **Refer to SmPC for full details.**

Legal category: POM. **Presentation and Cost:** 1 mg tablets (10) €48.88, 2 mg tablets (5) €57.47, 1 mg/ml solution (5) €55.88 3 mg/3 ml (5) €90.34 **Marketing authorisation holder and numbers:** Atnahs Pharma Netherlands B.V. Strawinskylaan 3127, Netherlands. Ampoules PA22657/003/001-002. Tablets PA22657/003/003-004 Further information is available from Atnahs Pharma UK Limited, Sovereign House, Miles Gray Road, Basildon SS14 3FR, UK. **Date of last revision:** February 2020.

Adverse events should be reported. Healthcare professionals are asked to report any suspected adverse reactions to HPRA Pharmacovigilance, Earlsfort Terrace, IRL-Dublin 2. Tel +353 1 6764971. Website: www.hpra.ie email: medsafety@hpra.ie . Adverse events should also be reported to Atnahs Pharma UK Ltd on 0044 (0) 1279 406759 or by email to atnahspv@diamondpharmaservices.com