

PRESCRIBING INFORMATION (prepared September 2018.)

Moventig 12.5mg and 25mg film-coated tablets®
▼ (naloxegol oxalate)

Consult Summary of Product Characteristics (SmPC) before prescribing.

Indication: Opioid-induced constipation (OIC) in adult patients who have had an inadequate response to laxative(s) (concurrent OIC symptoms of at least moderate severity while taking at least one laxative class for a minimum of four days during the previous 2 weeks).

Dosage and administration: Recommended 25 mg once daily. Take on empty stomach at least 30 minutes prior to first meal of day or 2 hours after first meal of day. Crushed tablets can be mixed with water (120ml) and drunk immediately or administered via a nasogastric tube (CH8 or greater). **Renal impairment:** Moderate or severe renal impairment starting dose 12.5mg. Discontinue if side effects impact tolerability. Increase to 25mg if well tolerated. **Hepatic impairment:** Use in severe hepatic impairment not recommended. **Moderate CYP3A4 inhibitors:** Starting dose 12.5mg, can be increased to 25mg if well tolerated. **Paediatric population (<18 years):** Safety and efficacy not yet established. **Adverse effects:** Consult SmPC for full list of side effects.

Very Common: Abdominal pain, diarrhoea. *Common:* Nasopharyngitis, headache, flatulence, nausea, vomiting, hyperhidrosis. *Uncommon:* Opioid withdrawal syndrome. Not known: Hypersensitivity. **Contraindications:** Hypersensitivity to active substance or any of the excipients or any other opioid antagonist. Patients with known or suspected gastrointestinal (GI) obstruction or patients at increased risk of recurrent obstruction. Patients with underlying cancer who are at heightened risk of GI perforation, such as those with underlying malignancies of gastrointestinal tract or peritoneum, recurrent or advanced ovarian cancer or vascular endothelial growth factor (VEGF) inhibitor treatment. Concomitant use with strong CYP3A4 inhibitors. **Warnings and precautions:** Use with caution in patients with any condition which might result in impaired integrity of the gastrointestinal tract wall. Advise patients to discontinue therapy and promptly report if unusually severe or persistent abdominal pain develops. Use with caution in patients with clinically important disruptions to the blood brain barrier and observe for potential CNS effects. Discontinue if interference with opioid-mediated analgesia or opioid

withdrawal syndrome occurs. Use with caution in patients taking methadone. If opioid withdrawal syndrome is suspected the patient should discontinue Moventig and contact their physician. Use with caution in patients with a recent history of myocardial infarction, symptomatic congestive heart failure, overt cardiovascular (CV) disease or with a QT interval of ≥ 500 msec. Use with caution in OIC patients with cancer-related pain. **Use in pregnancy and lactation:** Not recommended. **Legal category:** POM. **Marketing Authorisation numbers:** Moventig 12.5mg x 30 tablets EU/1/14/962/001; Moventig 12.5mg x 30 x 1 film-coated tablets EU/1/14/962/008; Moventig 25mg x 30 tablets EU/1/14/962/005; Moventig 25mg x 30 x 1 film-coated tablets EU/1/14/962/010. **Further information available on request from the Marketing Authorisation holder:** Kyowa Kirin Holdings B.V., Bloemlaan 2, 2132NP Hoofddorp, The Netherlands.

For the United Kingdom:

NHS cost: Moventig 12.5mg, 30 tablets, £55.20; Moventig 25mg, 30 tablets, £55.20.

Adverse Events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse Events should also be reported to Kyowa Kirin Ltd. on +44 (0)1896 664000, email medinfo@kyowakirin.com

For the Republic of Ireland:

Adverse Events should be reported. Information about adverse event reporting can be found at www.hpra.ie. Adverse Events should also be reported to Kyowa Kirin Ltd. on +44 (0)1896 664000, email medinfo@kyowakirin.com