MOVENTIG® (naloxegol) FACT SHEET

MOVENTIG® (naloxegol) is the first once-daily oral peripherally acting mu-opioid receptor antagonist (PAMORA) for the treatment of opioid-induced constipation (OIC) in adult patients who have had an inadequate response to laxative(s).[1]

The European Commission (EC) marketing authorisation of MOVENTIG applies to all 28 European Union member countries as well as Iceland, Norway and Liechtenstein.

OIC is a condition caused by prescription opioid pain medicines.[2,3] Millions of patients are treated with opioids each year.[4] Opioids play an important role in chronic pain relief[5] and work by binding to mu-receptors in the central nervous system (CNS), but they can also bind to mu-receptors in the bowel, which can result in patients suffering from OIC.[2,4,6]

Unlike conventional laxatives[2], naloxegol binds to mu-receptors in the bowel, targeting the underlying cause of OIC.[6] MOVENTIG treats OIC at its source in the bowel without impacting opioid-mediated analgesic effects on the CNS.[1]

Once-daily MOVENTIG 25 mg starts to work quickly for most patients — often within a day of first dose.[1,7]

For patients with an inadequate response to laxative(s), once-daily **MOVENTIG 25 mg** provides efficacious and sustained relief for OIC.[1]

MOVENTIG 25 mg* should be taken:[1]

- **Once daily in the morning[1]**
- **On an empty stomach at least 30 minutes prior to the first meal of the day or 2 hours after the first meal of the day[1]**
- **When initiating naloxegol therapy, it is recommended that all currently used maintenance laxative therapy be halted, until the clinical effect of naloxegol is determined[1]**

Pivotal Trials Demonstrated Consistent Efficacy and Safety Profile

The safety profile and tolerability of MOVENTIG were investigated in the KODIAC clinical programme, which was comprised of four studies: KODIAC-4[8], -5[8], -7[9] and -8[10], enrolling more than 2000 patients. KODIAC-4[8] and -5[8] were identically designed, placebo controlled, double-blind, 12 week studies assessing safety and efficacy, while KODIAC-7[9] was a 12 week safety extension to KODIAC-4[8], and KODIAC-8[10] was a 52 week long-term safety study.

The efficacy and durability of the effect of MOVENTIG were measured in the primary end-point as response over the 12-week treatment period in KODIAC-4[8] and KODIAC-5[8], where a responder is defined as having at least 3 spontaneous bowel movements (SBMs)/week**, with at least 1 SBM/week increase over baseline, for at least 9 out of 12 weeks, and at least 3 out of the last 4 weeks.[1] The first of three secondary endpoints was the 12-week responder rate in the laxative inadequate responder (LIR) subgroup. There was a statistically significant difference for the 25 mg dose versus placebo for the LIR subgroup responder rate in KODIAC-4 and KODIAC-5.[1]

In the pooled data from clinical trials, the most commonly reported adverse reactions with MOVENTIG (≥5%) were abdominal pain, diarrhea, nausea, headache, and flatulence.[1] In KODIAC-8[10], there were no important unexpected differences in safety and tolerability findings between patients who received MOVENTIG and patients receiving usual care (i.e., laxative regimen decided by clinician).[1***]

Regulatory Action in the EU, US, Canada and Switzerland

The EC approval on 8 December 2014 of MOVENTIG® (naloxegol) is applicable to all 28 European Union member countries plus Iceland, Norway and Liechtenstein.

The therapy was also approved, under the trade name MOVANTIK™ (naloxegol) tablets, on 16 September 2014 by the US Food and Drug Administration (FDA) as the first once-daily PAMORA for the treatment of OIC in adult patients with chronic non-cancer pain in the United States.[11]

MOVANTIK™ (naloxegol) tablets is under regulatory review by Health Canada and SwissMedic.

*Reduced dosing at 12.5 mg once daily is recommended for certain patient types. The MOVENTIG Summary of Product Characteristics should be referred to for specific dosing information.

**SBM was defined as a bowel movement without rescue laxative taken within the past 24 hours.

***In addition to KODIAC 4 and KODIAC 5, the safety and tolerability of MOVENTIG were studied in KODIAC 7 and KODIAC 8. KODIAC 7 (a 12-week safety study that was an extension of KODIAC 4) and KODIAC 8 (a phase 3, 52-week, multicenter, open-label, randomised, parallel group study of MOVENTIG vs usual care in the treatment of OIC in patients with non-cancer pain) were designed to evaluate the long-term safety profile and tolerability of MOVENTIG.

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