

Formulary Drug Listing Decisions

TAPENTADOL Extended Release, TAPENTADOL Immediate Release

Indication(s)

Nucynta® ER is indicated for the management of pain that is severe enough to require daily, continuous, long-term opioid treatment, opioid-responsive; and for which alternative treatment options are inadequate.

Nucynta® IR (tapentadol immediate-release) is indicated for the management of moderate to severe acute pain in adults.

Formulary Status

The Drug Advisory Committee (DAC) recommended tapentadol extended release (ER) and tapentadol immediate release (IR) not be listed on any WSIB formulary as clinical trials did not provide sufficient evidence demonstrating an advantage to comparators currently listed on the WSIB formularies.

The WSIB has decided to accept the DAC recommendation.

Tapentadol ER and tapentadol IR are not listed on any WSIB formularies.

Overview

- Tapentadol is a centrally acting opioid analgesic with a dual mechanism of action. In addition to mu-opioid receptor agonism, it weakly inhibits reuptake of norepinephrine.
- An external, independent review of RCTs showed that tapentadol offers analgesia that appears to be equal in magnitude to that provided by oxycodone in the treatment of osteoarthritis and lower back pain. Tapentadol may be associated with lower rates of opioid-related gastrointestinal side effects (eg. nausea, vomiting and constipation) than oxycodone; however, it has not been determined whether differences in rates of adverse effects between tapentadol and oxycodone translate into meaningful improvements in functional ability or quality of life.

- There are no long-term trials (beyond 15 weeks) investigating the efficacy or safety of tapentadol ER in chronic pain.
- There are no RCTs or pharmacoeconomic analyses comparing tapentadol with less costly opioid formulary alternatives such as codeine, morphine, or hydromorphone. The Canadian Expert Drug Advisory Committee (CEDAC) has recommended tapentadol CR not be listed by participating provincial plans. The Ontario Drug Benefit Program does not list tapentadol ER or IR as a general benefit.
- No pharmacoeconomic studies relevant to the WSIB were located.
- Therefore, the DAC concluded that there is no evidence to indicate any therapeutic or non-therapeutic advantage of tapentadol over appropriate comparators in the treatment of chronic noncancer pain.

Original date: 23 March 2012

Updated: 29 Jan 2013

Updated: 10 May 2016

Drug Profile

Products available in
Canada:

Nucynta® ER (Tapentadol
Extended Release), Nucynta®
IR (Tapentadol Immediate
Release)

Manufacturer: Janssen Inc.