

Indocin® (indomethacin) – First-time generic

- On January 16, 2024, <u>ANI Pharmaceuticals launched</u> an <u>AB-rated</u> generic version of Zyla Life Sciences' Indocin (indomethacin) oral suspension.
 - ANI Pharmaceuticals was granted 180-days of Competitive Generic Therapy exclusivity.
- Indocin is approved for:
 - Moderate to severe rheumatoid arthritis including acute flares of chronic disease
 - Moderate to severe ankylosing spondylitis
 - Moderate to severe osteoarthritis
 - Acute painful shoulder (bursitis and/or tendinitis) and
 - Acute gouty arthritis.
- Indocin carries a boxed warning for risk of serious cardiovascular and gastrointestinal events.
- Indomethacin is also available generically as a <u>capsule</u>, an <u>extended-release capsule</u>, a <u>rectal suppository</u> and an <u>injection</u>.
 - Indomethacin capsule and rectal suppository carry the same indications as Indocin oral suspension.
 - Indomethacin extended-release capsule carries the same indications as Indocin oral suspension with the exception of acute gouty arthritis.
 - Indomethacin injections is indicated to close a hemodynamically significant patent ductus arteriosus in premature infants weighing between 500 and 1,750 g when 48 hours usual medical management (eg, fluid restriction, diuretics, digitalis, respiratory support, etc.) is ineffective.
- According to IQVIA data, Indocin oral suspension had annual sales of \$4.1 million.



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