

## Indocin<sup>®</sup> (indomethacin) – First-time generic

- On January 16, 2024, [ANI Pharmaceuticals launched](#) an [AB-rated](#) 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 [capsule](#), an [extended-release capsule](#), a [rectal suppository](#) and an [injection](#).
  - 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.