



Vascepa® (icosapent ethyl) – First-time generic

- On November 5, 2020, [Hikma Pharmaceuticals USA](#) launched an [AB-rated](#) generic version of Amarin's [Vascepa \(icosapent ethyl\)](#) 1 gram capsules.
 - Initially, Hikma will be releasing limited quantities to ensure a consistent supply for customers. Hikma is working to increase availability as soon as possible.
 - Dr. Reddy's received FDA approval of an [AB-rated](#) generic version of Vascepa 1 gram capsules on August 7, 2020. Launch plans are pending.
 - Teva received FDA approval of [AB-rated](#) generic versions of Vascepa 500 mg and 1 gram capsules on September 11, 2020. Launch plans are pending.
- Vascepa is approved:
 - As an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization in adult patients with elevated triglyceride (TG) levels (≥ 150 mg/dL) and established cardiovascular (CV) disease or diabetes mellitus and 2 or more additional risk factors for CV disease
 - As an adjunct to diet to reduce TG levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia.
- Hikma's generic Vascepa is only approved as an adjunct to diet to reduce TG levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia.
- Vascepa is also available as a brand 500 mg capsule.



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