

## Tracleer® (bosentan) – First-time generic

- Amneal and Par/Endo launched AB-rated generic versions of Actelion's Tracleer (bosentan) 62.5 mg and 125 mg tablets.
  - Alvogen, <u>Lupin/Natco</u>, <u>Sun</u>, <u>Teva/Watson</u>, <u>West-Ward</u>, and <u>Zydus</u> have also received FDA approval of AB-rated generic versions of Tracleer tablets. Launch plans are pending for these generics.
- Tracleer is approved for the treatment of pulmonary arterial hypertension (WHO Group 1).
- Tracleer is also available as a brand 32 mg tablet for oral suspension and carries the same indication as the tablets.
- Tracleer carries a boxed warning for risks of hepatotoxicity and embryo-fetal toxicity.



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