

In pulmonary arterial hypertension (PAH) WHO Class III or IV

When initiating PAH therapy

	Tracleer	Sildenafil
Indicated to reduce the risk of clinical worsening?	YES ¹	<u>NO</u> ²
Over 2 years of follow-up data in PAH clinical trials?	YES ¹	<u>NO</u>
Prescribed to over 40,000 PAH patients, and over 5 years of clinical PAH experience?	YES ³	<u>NO</u>
Blocks the devastating effects of endothelin?*	YES	<u>NO</u>

Don't take NO for an answer

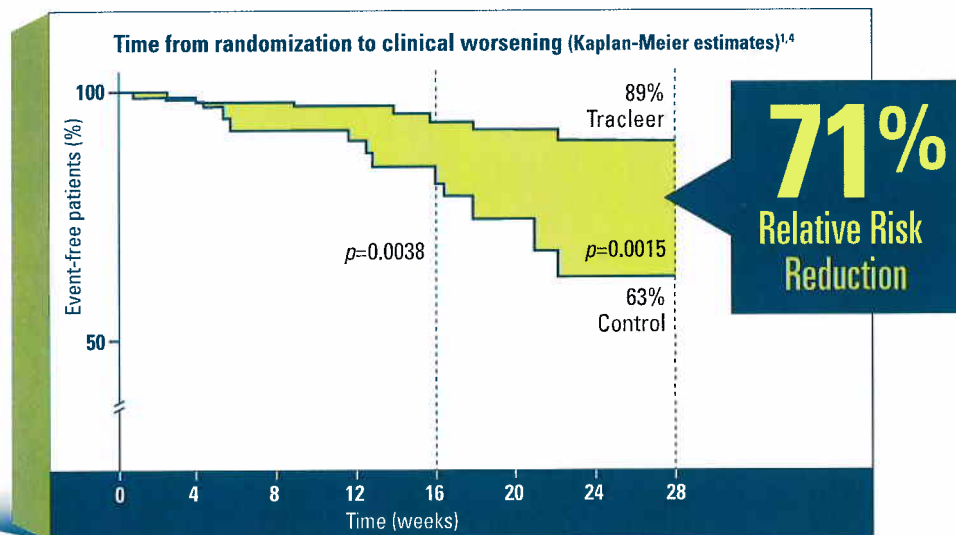
*Statement is based on observations reported from in vitro or animal trials. The clinical significance in humans is unknown.

THE DUAL ENDOTHELIN
RECEPTOR ANTAGONIST



In pulmonary arterial hypertension WHO Class III or IV

Tracleer is proven to reduce the risk of clinical worsening*



BREATHE-1 Multicenter, randomized, double-blind, placebo-controlled study to assess the efficacy and safety of Tracleer (125 mg BID, 250 mg BID) in patients with WHO functional class III-IV pulmonary arterial hypertension (N=213). All patients (n=144 in the Tracleer group and n=69 in the control group) participated in the first 16 weeks. A subset of this population (n=35 in the Tracleer group and n=13 in the control group) continued for up to 28 weeks.

*Defined in bosentan clinical trials as the combined endpoint of death, hospitalization for treatment related to PAH, discontinuation of therapy due to worsening PAH, or initiation of epoprostenol therapy.⁴

Liver and Pregnancy Warnings

Requires attention to two significant concerns: Potential for serious liver injury (including, after prolonged treatment, rare cases of liver failure and unexplained hepatic cirrhosis in a setting of close monitoring)—Liver monitoring of all patients is essential prior to initiation of treatment and monthly thereafter.

High potential for major birth defects—Pregnancy must be excluded and prevented by two forms of birth control; monthly pregnancy tests should be obtained. Because of these risks, Tracleer may only be prescribed through the Tracleer Access Program.

Please see accompanying full prescribing information.

References: 1. Tracleer (bosentan) full prescribing information. Actelion Pharmaceuticals US, Inc. 2007. 2. Revatio™ (sildenafil citrate) full prescribing information. Pfizer Inc. 2006. 3. Data on file, Actelion Pharmaceuticals. 4. Rubin LJ, Badesch DB, Barst RJ, et al. Bosentan therapy for pulmonary arterial hypertension. *N Engl J Med.* 2002;346:896-903.



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THE DUAL ENDOTHELIN
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Tracleer
BOSENTAN TABLETS