

Opsumit approved for pulmonary arterial hypertension

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(HealthDay)—Opsumit (macitentan) has been approved by the U.S. Food and Drug Administration to treat adults with pulmonary arterial hypertension, a debilitating disease characterized by high blood pressure in the lung arteries.

Pulmonary hypertension causes the heart to overwork, which can limit exercise, cause shortness of breath and create the need for a lung transplant. Opsumit relaxes the lung arteries, decreasing <u>blood pressure</u> in the vessels, the FDA said in a news release.

The drug's safety and effectiveness were evaluated in clinical studies involving 742 people. The medication was found effective in "delaying disease progression," the agency said.

The most common side effects included anemia, cold-like symptoms, bronchitis, headache, flu and urinary tract infection.

Opsumit's label includes a boxed warning that the medication could harm a developing fetus, so the drug should not be taken by pregnant women, the FDA said.

The drug is marketed by Actelion Pharmaceuticals US, based in San Francisco.

More information: To learn more about PAH, visit the U.S. <u>National Heart, Lung and Blood Institute</u>.



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