

Liqrev[®] (sildenafil) – New drug approval

- On April 28, 2023, the <u>FDA approved</u> CMP Pharma's <u>Liqrev (sildenafil)</u> oral suspension, for the treatment of pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group I) in adults to improve exercise ability and delay clinical worsening.
- Sildenafil is available generically as <u>oral 25 mg, 50 mg and 100 mg tablets</u>, <u>oral 20 mg tablet</u>, <u>oral powder for suspension</u>, and <u>injection</u>.
 - Sildenafil oral 25 mg, 50 mg, and 100 mg tablets are approved for the treatment of erectile dysfunction.
 - Sildenafil oral 20 mg tablet, oral powder for suspension, and injection carry the same indication as Liqrev.
 - <u>Revatio[®] (sildenafil)</u> brand product carries the indication for PAH treatment in pediatric patients 1 to 17 years of age.
- The approval of Ligrev was based on efficacy trials conducted with Revatio.
- Liqrev is contraindicated in patients with concomitant use of organic nitrates in any form, either
 regularly or intermittently, because of the greater risk of hypotension; concomitant use of
 <u>Adempas[®] (riociguat)</u>. Phosphodiesterase-5 (PDE-5) inhibitors, including sildenafil, may potentiate
 the hypotensive effects of Adempas; and known hypersensitivity to sildenafil or any component of
 the oral suspension.
- Warnings and precautions for Liqrev include hypotension, worsening pulmonary vascular occlusive disease, epistaxis, visual loss, hearing loss, combination with other PDE-5 inhibitors, priapism, and vaso-occlusive crisis in patients with pulmonary hypertension secondary to sickle cell disease.
- The most common adverse reactions with Liqrev use were headache, dyspepsia, flushing, pain in limb, myalgia, back pain and diarrhea.
- The recommended dosage of Liqrev is 20 mg orally three times a day.
- CMP Pharma's launch plans for Liqrev are pending. Liqrev will be available as a 10 mg/mL oral suspension.



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