

## Vyzulta<sup>™</sup> (latanoprostene bunod) – New drug approval

- On November 2, 2017, <u>Bausch and Lomb/Valeant</u> and <u>Nicox announced</u> the FDA approval of <u>Vyzulta (latanoprostene bunod)</u> for the reduction of intraocular pressure (IOP) in patients with openangle glaucoma or ocular hypertension.
- Vyzulta is a prostaglandin analog that is metabolized into latanoprost acid and butanediol
  mononitrate. Latanoprost acid works primarily within the uveoscleral pathway to increase aqueous
  humor outflow, and butanediol mononitrate releases nitric oxide to increase outflow through the
  trabecular meshwork and Schlemm's canal.
  - Both of these mechanisms are thought to lower IOP. Lowering IOP, can delay, or even prevent damage to optic nerves. Reduction of IOP reduces the risk of glaucomatous visual field loss.
- The safety and efficacy of Vyzulta have been demonstrated in multiple clinical studies.
  - In clinical studies up to 12 months duration, patients with open-angle glaucoma or ocular hypertension with average baseline IOPs of 26.7 mmHg, the IOP-lowering effect of Vyzulta once daily was up to 7 to 9 mmHg.
- Warnings and precautions of Vyzulta include pigmentation, eyelash changes, intraocular inflammation, macular edema, bacterial keratitis, and use with contact lens.
- The most common adverse reactions (≥ 2%) with Vyzulta use were conjunctival hyperemia, eye irritation, eye pain, and instillation site pain.
- The recommended dose of Vyzulta is one drop in the conjunctival sac of the affected eye(s) once daily in the evening.
- Valeant plans to launch Vyzulta by the end of this year. Vyzulta will be available as a topical ophthalmic solution containing 0.24 mg/mL latanoprostene bunod (0.024%).



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