Isopto® Atropine (atropine sulfate) – New Drug Approval

- On December 1, 2016, the FDA approved Alcon's Isopto Atropine (atropine sulfate) 1% ophthalmic solution, indicated for mydriasis, cycloplegia, and penalization of the healthy eye in the treatment of amblyopia.
    - Previously, Isopto Atropine was available as an unapproved drug. Alcon stopped distribution of the product.
- Isopto Atropine is a muscarinic antagonist. It causes dilation of the pupil and paralysis of the ciliary muscle which controls accommodation.
- Atropine sulfate is also available as a 1% ophthalmic solution by Akorn.
- The efficacy of Isopto Atropine has been demonstrated in adults and children for mydriasis and/or cycloplegia.
    - The maximum effect for mydriasis is achieved in about 30 – 40 minutes after administration, with recovery after approximately 7 – 10 days.
    - The maximum effect for cycloplegia is achieved within 60 – 180 minutes after administration, with recovery after approximately 7 – 12 days.
- Warnings and precautions of Isopto Atropine include photophobia and blurred vision, elevation of blood pressure, and increased adverse drug reaction susceptibility with certain central nervous system conditions.
- The most common adverse events with Isopto Atropine use were eye pain and stinging on administration, blurred vision, photophobia, superficial keratitis, decreased lacrimation, drowsiness, increased heart rate and blood pressure.
- The recommended dose of Isopto Atropine for individuals from ≥ 3 months of age is 1 drop topically to the cul-de-sac of the conjunctiva, 40 minutes prior to the intended maximal dilation time.
    - In individuals ≥ 3 years of age, doses may be repeated up to twice daily as needed.
- Alcon immediately launched Isopto Atropine. Isopto Atropine is available as a 1% ophthalmic solution in 8 mL and 15 mL bottles.