

Intro Time: 1 minutes**Generic vs. Brandname****When does it really matter?**

Marc R Bloomenstein, OD, FAAO

Marc R. Bloomenstein

- Speaker's Panel: Alcon, J&J, Allergan, B&L, BioTissue, Bruder, Reichert, OcuSoft, Sun, Tariusus, Dompe', Tear Science
- President of MRB Eye Consultants
- Past President OCRT
- VE Director of Education
- No Financial Interest in any product

Generic Time: 5 minutes**Generics**

- According to the FDA website- " A generic is identical - or bioequivalent- to a brand-name drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use."

Making of a Generic

- Drug companies must submit an abbreviated new drug application (ANDA)
- The Drug Price Competition and Patent Term Restoration Act of 1984, more commonly known as the Hatch-Waxman Act, made ANDAs possible by creating a compromise in the drug industry.
- Generic drug companies gained greater access to the market for prescription drugs, and innovator companies gained restoration of patent life of their products lost during FDA's approval process.

Same as in "Ways that Matter"

- in their price,
- Color
- size
- shape
- place of manufacture
- The specific dyes used to create them,
- Filling agents
- The chemical binders that hold their active components together,
- The lacquered coatings that they employ

Generic Information

- Generic drugs must have systemic bioavailability similar to that of the original drugs
- Similar Therapeutic bioequivalence
- FDA requires that you get 80-125% of the drug into your blood stream from a generic medication, compared to the original
- 1984 < 19% of all Rx's in US
- Today 54% of all Rx's in US

Generic Information

- **Many different generics and not all the same**
- **As stated Not all generics have the same buffer or vehicles**
- **Generics are NOT tested like name brands**
- **Labels on most generics can be misleading and incorrect**

More generic Information

- **Yes, the active ingredients are regulated and they do have to show bioequivalence**
- **BUT... the inactive ingredients**
 - **(Buffers, preservatives, viscosity agents)**
- **Are NOT regulated...**

Generics can be Scary...

- 2005 J. Ophthalmol reported that 20% of generic ciprofloxacin in India was under-potent
- The sufficiently low antibiotic content could have potentially lead to resistant isolates in patients
- **Generics are not tested the same as brand name and thus may fall short**
- **Manufacturing may impede efficacy**
 - **Particles in Pred Forte were smaller and more uniform**
 - **Staying in the suspension longer resulting in greater drop homogeneity**
 - **Providing better bioavailability**
- **Overseas manufacturing plants are rarely inspected by USFDA (less than 10%)**
- **Generic companies can not be held liable for adverse reactions caused by their product!!!**

Generics can be inconsistent...

- **The composition, packaging and manufacturing of brand products are strictly controlled in the manufacturing process**
- **That is not the case for generic counterparts**

These differences are particularly magnified in ophthalmic meds

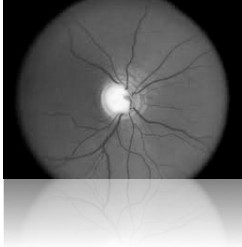
- **Size (of the drop) does matter**
- **Preservatives matter**
- **Ability of drop to get to desired receptor sites is affected by inactive ingredients**
- **Tolerability is affected by inactive ingredients**
- **Up to 99% of an ophthalmic drug can be the inactive ingredient**

When to consider a Generic

- **NOT an extended release medication**
- **When you can ID the manufacturer to get the consistency**
- **When you know there is an authorized generic**
- **When there are few manufacturers of the generic product**
- **When you gain clinical proof that a generic is comparable**


Glaucoma Time: 14 minutes

Glaucoma
 Glaucoma meds are uniquely affected by the inactive ingredient differences



Beta Blockers

- Excretion into human milk detected-PI
- Timolol OK for nursing
 Tarascon
 Pharmacopeia
 \$8.50



Xalatan

- 0.005% latanoprost
- Prostaglandin analog
- Generic: \$18.19
- Branded: \$67.00



Lumigan

- 0.01%
- Bimatoprost
- Prostaglandin analog
- 5ml \$127.07



Travatan

- 0.004% travoprost
- Prostaglandin analog
- Travatan Z
- 5ml \$114.78



XLT Study - Parrish, Palmberg, et. al. (AJO, May 2003, Vol. 135, No.5)

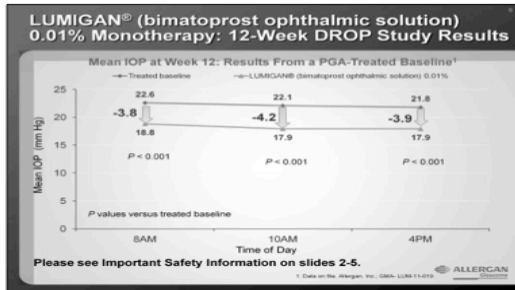
- Multicenter study to compare IOP lowering efficacy of Bimatoprost vs Latanoprost vs Travoprost
- Also compared safety profiles of the 3 drugs
- Conclusions: All 3 drugs were comparable in their ability to lower IOP at all time periods.
 - Latanoprost exhibited greater ocular tolerability

The Branded PGAs are similar in efficacy and side effects

- But how do they compare to the Generics?

DROP Study - Meyer, 2014

- All pts were started on Latanoprost
- Avg IOP dropped to 22.6 in 1 month
- Half were then switched to Lumigan .01%,
- Switch group IOP reduced by 4mm Hg (19%) (17.9mm Hg) at 12 weeks



Zioptan

- 0.0015% tafluprost
- Preservative free
- Unit dose
- Prostaglandin analog
- Zioptan 1 X 30 \$116.53 qd



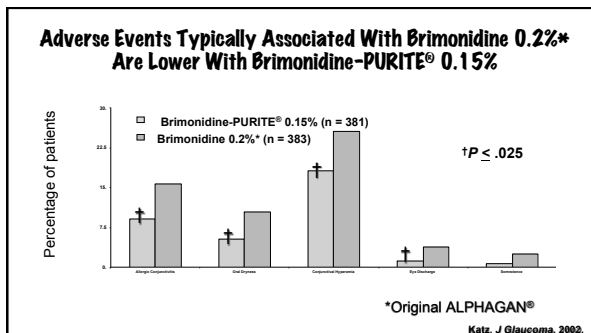
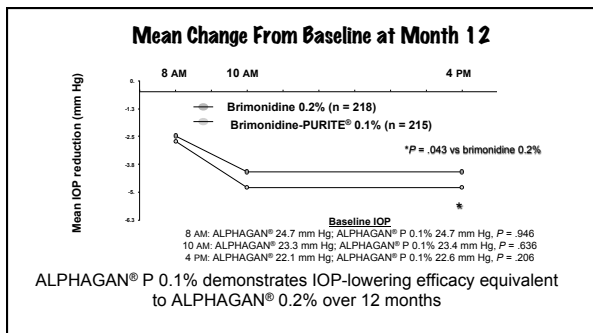
Brimonidine

- Alphagan P 0.15%
- Bromonidine Tartrate 0.2%
- Generic
- \$23.10



Brimonidine Formulation Comparison

	ALPHAGAN® P		ALPHAGAN®
Concentration of Brimonidine	0.1%	0.15%	0.2%
pH	7.7	7.2	6.3-6.5
Preservative	PURITE®		BAK
Viscosity agent	Carboxymethylcellulose		Polyvinyl alcohol
Electrolytes	Potassium chloride, calcium chloride dihydrate, magnesium chloride hexahydrate		-



Effect of Brimonidine-PURITE® 0.1% Formulation on Safety

- Ocular surface exposed to 50% less drug with new formulation
 - Less allergy, redness, irritation
- Lower concentration also means fewer systemic effects as less drug enters nasolacrimal duct

Katz. J Glaucoma. 2002.

Combigan

- Brimonidine 0.2%/timolol 0.5%
- 5ml \$112.84

Dorzolamide

- Trusopt
- 10ml \$25.65
- Cosopt
- 10ml \$30.45

Simbrinza

- 1% brinzolamide
- 0.2% brimonidine
- \$104.96

Glaucoma

- Yearly costs of glaucoma meds:
 - \$150.81 vs. \$203.47 generic to branded timolol
 - \$352.89 vs \$529.34 (bid/tid) generic brimonidine
 - \$559.08 vs \$873.98 (bid/tid) Alphagan P
 - \$427.69 Travatan Z
 - \$577.62 Lumigan

Rylander NR, Vold SD. Cost analysis of glaucoma medications. Am J Ophthalmol. 2008. Jan;145 (1): 106-13.


New Study - Singh 2014

- 20 new start patients were all placed on generic latanoprost for 30 days
- They were all subsequently switched to branded
- Costs between the 2 drops were compared
 - After cost comparison 13 remained on branded (Dr recommended) drug
- Branded choosers showed a \$35 difference between the drugs
- Generic choosers showed \$65 difference between the 2 drugs

Conjunctivitis Time: 15 minutes

SO... this study showed that

- If Drs advocate for the recommended drops the majority will choose those
- Drs need to educate pxs on the difference between branded vs generic drops
- It may be beneficial to point out the actual difference in cost between the 2 drops
- There is a price point difference that will sway pxs to choose generic product despite what the Dr says
- We (the doctors) have to place value on the meds we Rx



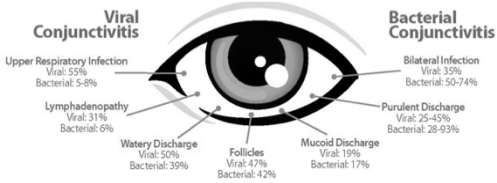
Conjunctivitis

"Is that a pink eye?"

Conjunctivitis Factoids

- The annual cost of treating patients with bacterial conjunctivitis in the US-\$589 million
- Need to treat bacteria rapidly to decrease transmission and shorten symptom duration and minimize resistance
- 1:8 US kids develop bacterial conjunctivitis
- 1.4% of all family doctor appointment

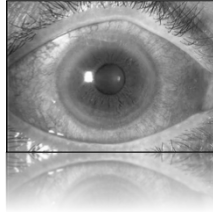
Need to differentiate



Viral Conjunctivitis		Bacterial Conjunctivitis	
Upper Respiratory Infection	Viral: 55% Bacterial: 5-8%	Bilateral Infection	Viral: 35% Bacterial: 50-74%
Lymphadenopathy	Viral: 31% Bacterial: 6%	Purulent Discharge	Viral: 25-45% Bacterial: 28-93%
Watery Discharge	Viral: 50% Bacterial: 39%	Follicles	Viral: 47% Bacterial: 4.2%
Mucoid Discharge	Viral: 19% Bacterial: 17%		

Conjunctivitis

- Finding diagnostic indicators provides optimal results
- Study found viral conjunctivitis has a stronger tendency to recur
- Itch indicates allergic source
- Mild bacterial conjunctivitis will have particulates in the tear film



Conjunctivitis

- Meta-analysis indicates bacterial conjunctivitis is frequently self-limiting
- Clinical remission occurred in 2-5 days in 64% of those treated with placebo
- Treatment with antibiotics had significantly better rates of remission

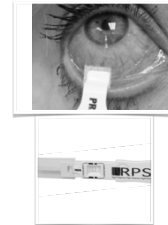
Delayed Approach to Treatment

- Give Rx, filled in 2-3 days after diagnosis (at patients discretion)
- Promote supportive care
 - Eye cleansing
 - Change CL solutions
 - Warm compresses (Bruder Mask)
 - Hand and eye cleanser
 - Palliative tears
- No improvement start delayed approach



RPS AdenoPlus

- RPS Adeno detector
- 10 tests \$135
- CPT 78090W CLIA
- CMS \$17.52



Medications For the Infection

Fourth Gen' Quinolones

- Zymaxid
- Moxeza
- Besivance



Third Gen Quinolones

- * Ciprofloxacin (Ciloxan)
- * Ofloxacin (Ocuflox)



3G's

- * Ciprofloxacin (Ciloxan)
- * Branded- 5ml \$51.00
- * Generic- \$12.87
- * Ofloxacin (Ocuflox)
- * Branded- 5ml \$47.00
- * Generic-\$9.90



Tobramycin

- * Tobramycin
- * Pregnancy Category B
- * \$4.00



Gentamicin

- * Garamycin 0.3%
- * 5ml \$4.00
- * Pregnancy Category C




Resistance

- * Staph aureus is the most common pathogen in bacterial conjunctivitis
- * High levels of resistance: tetracycline, erythromycin and Septra/Bactrim (trimethoprim/sulfamethoxazole)

Relative Cost Study

- * "Sulfacetamide covers 84% of susceptible isolates and an average cost of \$13.11 is the most cost-effective for bacterial conjunctivitis"
- * Sulfa works by competitive inhibition of PABA, and thus are bacterial static
- * "Despite a reputation for broad spectrum activity, sulfa-based med's are often ineffective since many organisms have developed resistance to sulfa drugs"

Blepharitis Time: 10 minutes





Blepharitis..
"ew"

Orcea
\$472.16 Good Rx
\$601 cash price
40mg 30 capsules




Doxycycline Hyclate

- \$93.75 Good Rx
- \$162.00 cash price
- 50 mg 60 tabs

Azasite

- azythromycin ophthalmic solution 1%
- 2.5 ml
- Good Rx—\$133.00
- Akorn

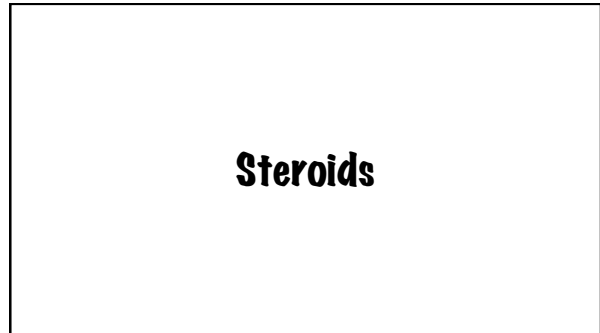



Allergy Topicals
Стом помуря глаза!

Topicals

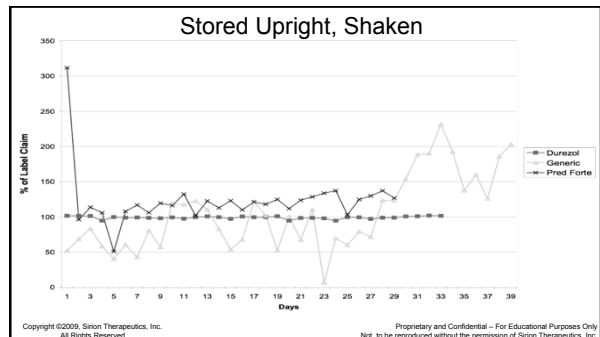
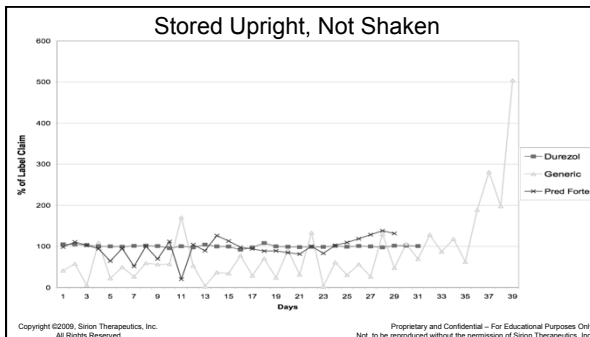
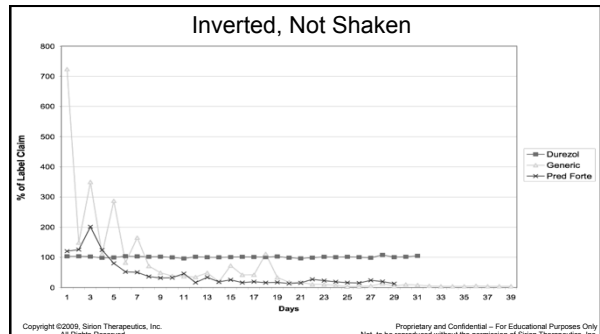
- Cromolyn
- Levocabastine (Livostine)
- Nedocromil (Alocril)
- Olopatadine (Patanol)
- Epinastine (Elestat)
- Ketotifen fumarate (Zaditor)
- Azelastine (Optivar)
- Pemirolast (Alamasat)
- Loteprednol

Steroids Time: 5 minutes



Prednisolone acetate 1%

- * Is there really a difference?
- * In price?
- * In efficacy?



Thank you.....