Generic or Brandname
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- President of MRB Eye Consultants
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- Board Member of OSSO
- No Financial Interest

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.”

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 bloodstream from a generic medication, compared to the original
- 1984 < 18% of all Rx’s in US
- Today 54% of all Rx’s in US
Generic Information

- Many different generics and not all the same
- 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 Marc, the active ingredients are regulated and they do have to show bioequivalence
- BUT... the inactive ingredients
  - (Buffers, preservatives, viscosity agents)
  - Are NOT regulated... you ignorant...!#&%!*!

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 fail 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%)
- Generics 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

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**
- 0.04%
- Travoprost
- Prostaglandin analog
- Travatan Z
- 5ml  $14.78

**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?

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**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

<table>
<thead>
<tr>
<th></th>
<th>ALPHAGAN® P</th>
<th>ALPHAGAN®</th>
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</thead>
<tbody>
<tr>
<td>Concentration of Brimonidine</td>
<td>0.1%</td>
<td>0.15%</td>
</tr>
<tr>
<td>pH</td>
<td>7.7</td>
<td>7.2</td>
</tr>
<tr>
<td>Preservative</td>
<td>PURITE®</td>
<td>BAK</td>
</tr>
<tr>
<td>Viscosity agent</td>
<td>Carboxymethylcellulose</td>
<td>Polyvinyl alcohol</td>
</tr>
<tr>
<td>Electrolytes</td>
<td>Potassium chloride, calcium chloride dihydrate, magnesium chloride hexahydrate</td>
<td>—</td>
</tr>
</tbody>
</table>

Mean Change From Baseline at Month 12

ALPHAGAN® P 0.1% demonstrates IOP-lowering efficacy equivalent to ALPHAGAN® 0.2% over 12 months.
Adverse Events Typically Associated With Brimonidine 0.2%* Are Lower With Brimonidine-PURITE® 0.15%†


**Combigan**
- Brimonidine 0.2%/timolol 0.5%
- 5ml $112.04

**Dorzolamide**
- Trusopt
  - 10ml $25.65
  - Cosopt
  - 10ml $30.45

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

Simbrinza

- 1% brinzolamide
- 0.2% brimonidine
- $104.96

Yearly costs of glaucoma meds:

- $150.81 vs $203.47 generic to branded timolol
- $352.00 vs $529.34 (bid/tid) generic brimonidine
- $559.00 vs $873.98 (bid/tid) Alphagan P
- $427.89 Travatan Z
- $577.62 Lumigan


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 15 remained on branded (or recommended) drug
- Branded choosers showed a $35 difference between the drops
- Generic choosers showed a $65 difference between the 2 drops

SO... this study showed that

- If Drs advocate for the recommended drops the majority will choose those
- Drs need to educate pts 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 pts 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 appointments

Need to differentiate

- Viral Conjunctivitis
  - Upper Respiratory Infection
  - Sympathetic coryza
  - Ciliary follicles
  - Heavy discharge: viral 50%, bacterial 30%
  - Proptosis: viral 10%, bacterial 5%

- Bacterial Conjunctivitis
  - Bacterial 80%

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 84% 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 7809QW 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

Staph aureus is the most common pathogen in bacterial conjunctivitis.

High levels of resistance: tetracycline, erythromycin and Septra/Bactrim (trimethaprim/sulfamethoxazole)

Resistance

Relative Cost Study

"Sulfacetamide covers 84% of susceptible isolates and an average cost of $13.11 is the most cost-effective for bacterial conjunctivitis"

Sulf works by competitive inhibition of PABA, and thus are bacterial static

"Despite a reputation for broad spectrum activity, sulf-based med's are often ineffective since many organisms have developed resistance to sulf drugs"

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

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

Azasite
- Azithromycin ophthalmic solution
  1x
- 2.5 ml
- Good Rx-$133.00
- Akorn

Allergy Topicals
Слон позирует глаза!
### Topicals
- Cromolyn
- Levocabastine (Livostine)
- Nedocromil (Alocril)
- Olopatadine (Patanol)
- Epinastine (Elestat)
- Ketotifen fumarate (Zaditor)

### Non-sedating antihistamines

<table>
<thead>
<tr>
<th>Brand</th>
<th>Image</th>
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<tbody>
<tr>
<td>Claritin</td>
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</tr>
<tr>
<td>Zyrtec</td>
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### Steroids
- Prednisolone acetate 1%
  - Is there really a difference?
  - In price?
  - In efficacy?