Generic vs Branded: Is There Really a Difference?

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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

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.”

More generic Information

Yes,... the active ingredients are regulated and they do do have to show bioequivalence
BUT... the inactive ingredients (Buffers, preservatives, viscosity agents)
Are NOT regulated... you ignorant...!#&%!*!

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 < 19% of all Rx’s in US
Today 54% of all Rx’s in US

Generics can be Scary...

• 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.

When to consider a Generic

- Not an extended release medication
- When you can identify the consistency of the manufacturer
- When there are few manufacturers of the product
- Avoid Generic Suspensions
- When you gain clinical proof that there is equivalence
- When it is better than not getting any drop at all!

So What Does That Mean...???

- Bottles are different
- Bottle tips are different
- Drop size is different
- pH is different
- Preservatives are different
- The ONLY thing that has to be the same is the concentration of the active ingredient!

Glaucoma meds are uniquely affected by the inactive ingredient differences

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 95% of an ophthalmic drug can be the inactive ingredient

Beta-blockers

- The one anti-glaucoma class of drugs that has shown that the generics are as equivalent as branded
Xalatan vs Latanoprost

They both are 0.0005% latanoprost but that's where the similarity ends.
- BAK concentration is different (even between the generics)
- Bottles are different
- Head-to-head study
- Anecdotal data

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 Travaprost
- Also compared safety profiles of the 3 drugs
- Conclusions: All 3 drugs were comparable in their ability to lower IOP at all time periods.
  - Xalatan exhibited greater ocular tolerability

Is there a generic Lumigan?

There will be soon
... it will be OLD Lumigan (0.03%)

What about generic Travatan?

It exists but it is Travatan without Sofzia
When is the last time you chose Travatan w/BAK over Travatan Z?

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 4.1mm Hg (19%) (17.9mm Hg) at 12 weeks

Switch Study #2

• Switch Resulted in reduction of >15% in peak IOP in 73%
• 43.9% had reduction of IOP between 15-30%
• 29.6% had IOP reduced >30%

Switch Study #2

Hot Off The Presses
Effect of Switching From Latanoprost to Bimatoprost...
Renato et al. J Glaucoma 2016;25(4)

Conclusion:
Pxs who exhibited IOP rise while on latanoprost achieve further IOP-lowering when switched to bimatoprost

Brimonidine

• Alphagan P 0.1%
• Generics are 0.15% or 0.2%
• Generics are drastically different from branded

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>
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<tr>
<td>pH</td>
<td>7.7</td>
<td>7.2</td>
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<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>
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**Mean Change From Baseline at Month 12**

- Baseline IOP
  - 8 AM: ALPHAGAN® 24.7 mm Hg; ALPHAGAN® P 0.1% 24.7 mm Hg, P = .94
  - 10 AM: ALPHAGAN® 23.3 mm Hg; ALPHAGAN® P 0.1% 23.4 mm Hg, P = .6
  - 4 PM: ALPHAGAN® 22.1 mm Hg; ALPHAGAN® P 0.1% 22.6 mm Hg, P = .20

**In regards to Brimonidine:**
- There is a huge difference between generic and branded
- Both in side effects and desired effects
- THERE IS NO GENERIC ALPHAGAN P 0.1%!!!

**Adverse Events Typically Associated With Brimonidine 0.2%* Are Lower With Brimonidine-PURITE® 0.15%**

- **Percentage of patients**
  - Allergic Conjunctivitis
  - Oral Dryness
  - Conjunctival Hyperemia
  - Eye Discharge
  - Somnolence

  - Brimonidine-PURITE® 0.15% (n = 381)
  - Brimonidine 0.2%* (n = 383)

  *Original ALPHAGAN

  Katz. J Glau

**Carbonic Anhydrase Inhibitors**

- Differences between generics and branded?
- Differences between Co索pt and Trusopt?

**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
  - Remember branded Alphagan is preserved with Purite, Generic (either 0.15 or 0.2) is preserved with BAK

  *Katz. J Glau

**Recent Study – Singh 2014**

- 20 new start pxs 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 a $65 difference between the 2 drugs
SO... this study showed that

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

Steroids

Prednisolone acetate
1%
Is there really a difference?
In price?
In efficacy?
Are there differences between the branded and generic antihistamines?

I Mean Really???

Efficacy differences
Brandeds are dual acting – antihistamine and mast cell stabilizer
That combo yields quicker more effective therapy
More convenient dosing – better compliance
Longer duration of action
Stronger binding at H1 receptor site

Side effect differences
The 3 branded antihistamines all showed less drying as a side effect
They tend to have higher affinities for the H1 receptor (greater effectivity and less drying)

SAC pxs often show symptoms of both allergy and dryness

Approx. 40% of AC pxs report clinically significant dryness symptoms
~50% of pxs reporting itching also reported clinically significant dry eye