

✉ **Generic drops can differ from brand drops and it may be necessary to monitor patients more closely after switching**

The Science behind the Tip

In order to be approved for general use, a generic drug has to show the criterion of "essential similarity" when compared to the corresponding brand-name drug. However, unlike the situation with systemic drugs, this concept of bioequivalence is difficult to prove with ophthalmological drops. While bioequivalence is tested on blood samples in individuals on treatment with systemic generics, there is no acknowledged test of this nature for eye drops. Interestingly, no clinical studies are needed for the acceptance of generics in ophthalmology. The problem arises in the fact that, although the active principle is similar in generics and brands (by definition a generic drug is identical to a brand name drug in dosage, strength, route of administration, performance characteristics and intended use) the adjuvants can vary considerably. This may induce change in viscosity, osmolality and pH which can have an impact on tolerability and corneal penetration.

Today little is known about the interchangeability of a generic ophthalmic drug with the corresponding brand. One study has suggested equivalence of efficacy and tolerance of the generic latanoprost formulation with Xalatan¹. However another study has shown less efficacy with the generic latanoprost, compared to brand². Poor stability of the substance, difference in the size and amount of drops in the bottle or the structure of the bottle and the bottle tips were some reasons incriminated for poorer efficacy³. Safety issues with corneal epithelial disorders have also been described with generics, due to an additional stabiliser compound⁴.

Therefore when switching patients from brand drugs to generic drugs the follow-up should be sooner than usual, particularly in respect to endpoints like IOP and visual field.

References

1. Allaire C, Dietrich A, Allmeier H, Grundmane I, Mazur-Piotrowska G, Neshev P, Kahle G. Latanoprost 0.005% test formulation is as effective as Xalatan® in patients with ocular hypertension and primary open-angle glaucoma. *Eur J Ophthalmol.* 2012;22(1):19-27



2. Narayanaswamy A, Neog A, Baskaran M, George R, Lingam V, Desai C, Rajadhyaksha V. A randomized, crossover, open label pilot study to evaluate the efficacy and safety of Xalatan in comparison with generic Latanoprost (Latoпрост) in subjects with primary open angle glaucoma or ocular hypertension. *Indian J Ophthalmol.* 2007;55(2):127-31.
3. Brian S et al, Arvo Abstract 5103/A244, 2012. Lu et al, Arvo Abstract 3162/D617, 2010. Joag M et al, Arvo Abstract 5096/A237, 2012). (Mammo ZN, Flanagan JG, James DF, Trope GE. Generic versus brand-name North. American topical glaucoma drops. *Can J Ophthalmol.* 2012;47(1):55-61
4. Takada Y, Okada Y, Fujita N, Saika S. A patient with corneal epithelial disorder that developed after administration of a latanoprost generic, but not a brand-name drug, eye drop. *Case Rep Ophthalmol Med.* 2012; 2012:536-46.