

Paediatric glaucoma

Overview of existing PIP Decisions

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Authorisations and PIP Decisions to date

- Timolol and Latanoprost only licensed glaucoma medications
- Public PIP opinions to date
 - Latanoprost – PK, S & E studies – Article 29 proc.
 - Travaprost/Brinzolamide – waiver (sig. benefit)
 - Bimatoprost – PK, safety and efficacy studies
- Other PIPs under consideration

Other glaucoma medications

Betaxolol	not recommended
Levobunolol	not recommended
Metipranolol	“discretion of the physician”
Brinzolamide	not recommended
Dorzolamide	no indication, although study information in section 5.1
Acetazolamide	not licensed
Pilocarpine	Not licensed, but reference made to paediatric administration in SmPC
Carbachol	no license
Brimonidine	“Not recommended below 12, contraindicated below 2”
Travaprost	not recommended

Unanswered questions

- 1) How far can one extrapolate adult efficacy and safety data, taking into account the developmental state of both the eye and the body in general at the various ages?
 - Eye fully developed at 6 years? 12 years?
 - Systemic effects, Sexual maturation.

Unanswered questions

- 2) For the majority, medical products are used as short term adjuncts for surgery. Nonetheless, long term use can be expected in patients with secondary glaucoma, or those not amenable to surgical treatment.

How does the long-term safety profile of the various agents affect patient acceptability? (e.g. latanoprost)

Unanswered questions

- 3) The safety profile of timolol was possibly improved by the introduction of a gel form. Could this be extended to other products to improve their profiles?

Unanswered questions

- 4) The Paediatric Regulation states the new medicinal products or forms must demonstrate a significant therapeutic benefit over existing licensed products.

Where would such a significant benefit lie?

Unanswered questions

5) Ideal trial design:

3-arm, blinded, placebo and comparator controlled trial, poss. with group numbers weighted toward the active arms

2 arm active controlled non-inferiority study

Given the prevalence and incidence of these conditions, can you comment on the feasibility of such trials?

(multicentre – multinational)