



AWMSG Secretariat Assessment Report – Limited submission

Ketotifen (Ketofall®) 0.25mg/ml preservative-free eye drops

Company: Scope Ophthalmics Ltd

Licensed indication under consideration: Symptomatic treatment of seasonal allergic conjunctivitis.

The applicant company suggests that use of Ketofall® (preservative-free ketotifen) eye drops should be considered in a subgroup of patients, within its licensed indication, who require a preservative-free preparation for symptomatic treatment of seasonal allergic conjunctivitis.

Marketing authorisation date: 4th October 2017

Comparator(s)

The comparators in the company submission are:

- olopatadine (Opatanol®) eye drops
- ketotifen (Zaditen®) eye drops
- sodium cromoglicate eye drops
- sodium cromoglicate (preservative-free) eye drops

Limited submission details

- Anticipated usage in NHS Wales is considered to be of minimal budgetary impact.

Clinical effectiveness

- Ketotifen is a histamine H1-receptor antagonist and has additional activities of mast cell stabilisation and inhibition of infiltration, activation and degranulation of eosinophils. Marketing authorisation was granted in October 2017.
- The College of Optometrists advise that a variety of topical treatments are available for example: topical mast cell stabilizers (such as sodium cromoglicate), topical antihistamines (such as azelastine, emedastine or epinastine) and dual action topical antihistamine plus mast cell inhibitor (such as olopatadine or ketotifen) but there is insufficient evidence to recommend use of one over another.
- The company submission included a randomised study, comparing preservative-free ketotifen with preservative containing olopatadine eye drops in the treatment of moderate to severe allergic conjunctivitis. A rapid and comparable improvement in the composite end point for seasonal allergic conjunctivitis was achieved after 28 days of treatment with both ketotifen and olopatadine ophthalmic solutions, but ketotifen had a slightly better ocular tolerance. A published meta-analysis was also submitted and supports



ketotifen being as effective as olopatadine in reducing itching in allergic conjunctivitis.

- Ketotifen has established efficacy and was slightly better tolerated than olopatadine in the randomised study submitted by the company.
- AWTTTC sought clinical expert opinion suggests that olopatadine and ketotifen are comparable in terms of treatment for seasonal allergic conjunctivitis and that having a preservative-free form of ketotifen would be advantageous for some patients who already have a compromised ocular surface in allergic eyes.
- The safety and efficacy of ketotifen in children below the age of 3 years has not been established.

Budget impact

- The company estimate that around 4-5 per 1,000 general practice consultations are for allergic conjunctivitis, around half of which are for seasonal allergic conjunctivitis. This equates to approximately 7,062 patients in Wales who see their GP for seasonal allergic conjunctivitis each year.
- Based on clinical expert feedback the company estimated the proportion of these patients requiring a preservative free medicine to be 10%, which equates to 706 patients. Prescribing data shows approximately 2% of treatment currently prescribed for seasonal allergic conjunctivitis is preservative-free.
- The comparators chosen by the company are: ketotifen (Zaditen®); olopatadine (Opatanol®); sodium cromoglicate and sodium cromoglicate preservative-free.
- Estimated uptake rates of Ketofall® are 2% in year 1 rising to 8% in year 5. This leads to an estimated budget impact of £207 in year 1 rising to £522 in year 5.
- The company's model considers acquisition costs only and there is some uncertainty as to the choice and weightings of displaced comparators. However, the total number of patients expected to receive Ketofall® is low and the cost differences between comparators are small; as a result the budget impact is anticipated to be minimal.

Additional information

- AWTTTC is of the opinion that, if recommended, Ketotifen (Ketofall®) may be appropriate for prescribing by all prescribers within NHS Wales for the indication under consideration.

Evidence search

Date of evidence search: 28 November 2019.

Date of range of evidence search: No date limits were applied to database searches.

Further information

This assessment report will be considered for review every three years. References are available on request. Please email AWTTTC at AWTTTC@Wales.nhs.uk for further information.

This report should be cited as: All Wales Therapeutics and Toxicology Centre. AWMSG Secretariat Assessment Report. ketotifen (Ketofall®) 0.25 mg/ml eye drops. Reference number: 3930. February 2020.