Ocular lubricants: analysis of utilisation

Drug utilisation sub-committee (DUSC)

## June 2014

### Abstract

#### Purpose

To review utilisation of ocular lubricants.

#### Data Source / methodology

Data for all ocular lubricants listed on the PBS were extracted from the DUSC database for the 10 years from 2003 to 2013.

#### Key Findings

* The total number of prescriptions for ocular lubricants has been fairly steady over the last ten years from 2003, increasing gradually to a peak of 2.53 million in 2009, and then slowly decreasing to 2.46 million in 2012.
* Expenditure across the whole group of ocular lubricants has been fairly stable over the last ten years, gradually rising from a low of $19.7 million in 2006. Expenditure in 2012 was $26.2 million.
* Almost all prescriptions for ocular lubricants are over the patient co-payment (97%).
* Concessional prescriptions compile the bulk of prescriptions for ocular lubricants, with 85% of prescriptions in 2012.
* Multi-dose products account for the majority of PBS prescriptions for ocular lubricants supplied. In 2013 (until end September), 85% of prescriptions were for multi-dose products.
* Prescribing of single dose unit products is gradually increasing. Single dose unit products comprised 1.3% of prescriptions supplied in 1994, 6.7% in 2003, 14% in 2012 and 15% in 2013 (to end September). This is likely to explain the small gradual increase in expenditure on ocular lubricants despite stable prescription numbers.
* The most common prescribers of ocular lubricants are GPs, followed by ophthalmologists. In 2013 (to end September), approximately 72% of prescriptions supplied were prescribed by GPs and 19% by ophthalmologists. Optometrists accounted for approximately 1% of prescriptions supplied.

## Purpose of analysis

At its February 2014 meeting the DUSC noted the high number of ocular lubricant available on the PBS. The DUSC requested an overview of the utilisation of ocular lubricants including the use and expenditure, and who is prescribing ocular lubricants. The DUSC was also interested in the utilisation of single dose unit products in comparison to multi-dose ocular lubricants, considering the higher price of the single dose unit products.

## Background

### Pharmacology

Ocular lubricants lubricate the surface of the eye and are often referred to as artificial tears.

### Therapeutic Goods Administration (TGA) approved indications

Ocular lubricants are registered with the TGA as class III medical devices.

### Dosage and administration

Ocular lubricant eye drops are used every 1 to 12 hours on an as required basis. Eye ointments are used at night as required.

The current Product Informations (PI) and Consumer Medicine Informations (CMI) are available through [the TGA website product information access page](http://tga.gov.au/hp/information-medicines-pi.htm) and [the TGA website consumer medicines information access page](http://www.tga.gov.au/consumers/information-medicines-cmi.htm).

### Clinical situation

Ocular lubricants are used to relieve the symptoms associated with dry eye syndrome.[[1]](#footnote-1) The definition and classification sub-committee of the International Dry Eye Workshop (2007) defined dry-eye disease as: ‘A multifactorial disease of the tears and ocular surface that results in symptoms of discomfort, visual disturbances and tear-film instability with potential damage to the ocular surface. It is accompanied by increased osmolarity of the tear film and inflammation of the ocular surface.’ Symptoms of dry eye include dryness, stinging, burning, foreign-body sensation, gritty feeling, itching, and the eyes feeling heavy and tired. Dry eye can be exacerbated by environmental conditions such as wind, air conditioning and air pollution.[[2]](#footnote-2)

Dry eye syndrome can be secondary to a number of causes including Sjögren's syndrome, rheumatoid arthritis, contact lenses, surgery, meibomian gland dysfunction and adverse drug effects.1

There are two distinct classes of dry-eye disease: tear-deficient dry eye (keratoconjunctivitis sicca) and evaporative dry eye. Tear-deficient dry eye can result from Sjögren's syndrome. This is a systemic autoimmune disease in which immune cells attack and destroy the exocrine glands that produce tears and saliva.2

The Blue Mountains Eye Study (BMES) examined 3654 residents aged 49 years or older who were identified in a door-to-door census of two postcode areas (2780, 2782), west of Sydney during 1992–1994. The extension cohort of the BMES, conducted during 1999 to 2001, included a dry eye questionnaire that was not administered to the initial cohort. Participants of the Extension Blue Mountains Eye Study (mean age 60.8 years, n=1174) completed a comprehensive eye examination and dry eye questionnaire. At least one dry eye symptom was reported by 57.5% of participants, with 16.6% reporting moderate to severe symptoms. Three or more symptoms were reported by 15.3% of participants. No age-related trends or significant ocular associations were observed. After adjusting for age and sex, systemic factors significantly associated with dry eye syndrome included a history of arthritis, asthma, gout, use of corticosteroids, antidepressants and hormone replacement therapy.[[3]](#footnote-3)

Multi-dose ocular lubricants may contain a preservative or be preservative free. Single dose units are preservative free. Preservatives may irritate the corneal and conjunctival epithelium, particularly if it is already inflamed. Normally tears quickly dilute and remove preservatives; however in dry eye syndrome (particularly when severe) reduced tear secretion may result in increased sensitivity to preservatives.1

Many ocular lubricants are available at low cost over the counter at pharmacies. These supplies are not captured in this report.

### PBS listing details (as at 1 April 2014)

There are numerous ocular lubricant products listed on the PBS. For details of the current PBS listings refer to [the PBS website](http://www.pbs.gov.au/pbs/home).

### Relevant aspects of PBAC consideration

Ocular lubricant products have been considered by the PBAC as minor submissions and recommended on a cost minimisation basis.

### Previous reviews by DUSC

The DUSC has not considered the utilisation of ocular lubricants in the past ten years. The DUSC has noted that during this time a large number of ocular lubricant products, both multi-dose and single dose unit presentations, have been added to the PBS.

## Methods

De-identified data for the number of prescriptions supplied and government expenditure for all ocular lubricants PBS listed under the anatomical, therapeutic, chemical classification (ATC) S01XA, Sensory Organs, Other Ophthalmologicals, were extracted from the DUSC database for the ten years from 2003 to 2013. For full calendar year data, the data for 2003 to 2012 inclusive was used. For quarterly data, the most recent data to end September 2013 was used. The DUSC database combines data on PBS prescriptions submitted to the Department of Human Services (DHS) for payment of a PBS/RPBS subsidy by the Government, with an estimate of under general copayment prescriptions based on dispensing data from a sample of pharmacies to the end of August 2012, replaced by actual under copayment data from 1 April 2012. The DUSC database includes an estimate of private prescriptions based on dispensing data from a sample of pharmacies to the end of August 2012.

The majority of the multi-dose ocular lubricants are under the general patient copayment, however the majority of single dose unit products are priced above the general copayment.

The drug data was further categorised by multiple dose and single dose preparations to compare the utilisation of the more expensive single use preparations to the use of multi-dose use preparations.

Data on the major specialty of prescribers was also extracted from the DUSC database.

Patients initiating and prevalent patients were counted for the twelve months from September 2012 to August 2013. Initiators were defined as patients who did not have a PBS prescription supplied for at least the twelve months prior, i.e. since September 2011.

## Results

### Analysis of drug utilisation

#### Overall utilisation

The total number of prescriptions for the ATC group of S01XA, Sensory Organs, Other Ophthalmologicals, has been fairly steady over the last ten years, with 2.19 million in the calendar year 2003 gradually rising to a peak of 2.53 million in 2009, and then slowly decreasing to 2.46 million in 2012.

The total number of prescriptions for ocular lubricants for the calendar years 2003 through to end 2012 is shown in Figure 1.

**Figure 1: Total number of prescriptions for ocular lubricants by calendar year 2003 to 2012.**

Figure 2 shows the number of prescriptions for ocular lubricants by drug for the calendar years 2003 to end 2012.

 **Figure 2: Number of prescriptions of ocular lubricants by drug, calendar years 2003 to 2012.**

At the beginning of the time period (2003) hypromellose multi-dose preparations dominated the market with the highest number of prescriptions supplied per year, and their utilisation has gradually declined over the last ten years. Carmellose sodium preparations were the second most commonly supplied items at the beginning of the time period with prescription numbers steadily increasing to 2008, after which they overtook hypromellose preparations, with utilisation approximately plateauing to 2012. The third most commonly supplied ocular lubricants in the last decade were polyethylene glycol 400 with propylene glycol preparations, for which utilisation has steadily increased over the last ten years. These three ocular lubricants made up the majority of prescriptions supplied in the last ten years.

#### Patient count

For the twelve months from September 2012 to August 2013, 167,816 patients initiated an ocular lubricant and there were 464,132 prevalent patients.

#### Utilisation of ocular lubricants by patient category

Almost all of the prescriptions for ocular lubricants supplied in the last ten years were over the patient co-payment, with the under patient co-payment proportion and private prescriptions making up very small components of the market. Figure 3 shows the prescription numbers by year for PBS/RPBS, under co-payment and private market categories. Table 1 displays the same categories by percentages for the most recent three years of data through to the end of September 2013. Approximately 97% of prescriptions are PBS/RPBS, approximately 2% under co-payment and less than 1% are private prescriptions.

**Figure 3: Number of prescriptions by patient category, years 2003-2012.**

**Table 1: Prescriptions by patient category for 2010 Q4 to 2013 Q3**

| **Patient category** | **Sum of prescriptions****2010 Q4 – 2011 Q3** | **Percentage** | **Sum of prescriptions****2011 Q4 – 2012 Q3** | **Percentage** | **Sum of prescriptions****2012 Q4 – 2013 Q3** | **Percentage** |
| --- | --- | --- | --- | --- | --- | --- |
| PBS/RPBS | 2,411,115 | 97.27 | 2,385,447 | 97.13 | 2,349,712 | 97.26 |
| Under co-payment Medicare | Not available | Not available | 31,447\* | 1.28\* | 66,085 | 2.74 |
| Under co-payment estimate | 54,455 | 2.2 | 27,211\* | 1.11\* | Not available | N/A |
| Private estimate | 13,167 | 0.53 | 11,774\* | 0.48\* | Not available | N/A |
| **Total** | 2,478,737 | 100 | 2,455,879 | 100 | 2,415,797 | 100 |

\* Incomplete data: Under co-payment Medicare data is from April 2012. Under co-payment estimate and private estimate ceased at the end of August 2012.

Concessional prescriptions compiled the bulk of prescriptions for ocular lubricants, with 2.09 of 2.46 million (85%) prescriptions in 2012, as illustrated in Figure 4. RPBS account for approximately one tenth of the market with 263,402 prescriptions (10.1%) in 2012, with general prescriptions at about 1.5%.

The under co-payment proportion in 2012 (2.5%) was slightly higher than in previous years, however the data for under co-payment prescriptions for 2012 was a composite of the DUSC database under co-payment estimate (to the end of August 2012) and actual under co-payment data collected by the Department of Human Services, Medicare from April 2012. This indicates that the DUSC database under co-payment estimate may have been a small underestimate.

The proportion of utilisation of ocular lubricants by patient category has been fairly stable over the last ten years. The proportion of concessional patients in the last six years to 2012 has been almost identical.

Figure 4 shows the number of prescriptions per year by patient category, for 2003 to 2012.

**Figure 4: Number of prescriptions per year by patient category with concessional and general breakdown, years 2003-2012.**

#### Utilisation of ocular lubricants by form – multi-dose and single dose unit

The DUSC had noted that a considerable number of single dose unit ocular lubricant products had been listed on the PBS in recent years. To investigate the utilisation of multi-dose ocular lubricants in comparison to single dose unit products, prescription data was grouped by single dose unit and multi-dose forms. Figure 5 shows multi-dose and single dose unit products as a percentage of total prescriptions. Data is shown for the last twenty years, as there has been a gradual upward trend in the use of single dose unit products over this time. Multi-dose products still account for the majority of PBS prescriptions for ocular lubricants supplied.

In 2013 (until end September), 85% of prescriptions were for multi-dose products, which is a very small decrease compared to 2012 (the most recent full calendar year data) at 86%. This compares to 93.3% ten years ago in 2003, and 98.7% in 1994.

**Figure 5: Multi-dose and single dose unit products grouped as a percentage of total prescriptions, 1994-2013 (end September)**

#### Prescribers of ocular lubricants

The last three years (end September 2011 to end September 2013) of prescription data for ocular lubricants was investigated by major specialty prescriber code, including optometrists. Figure 6 shows the sum of prescriptions supplied for ocular lubricants by prescriber type. Figure 6 was truncated to the top ten prescriber types as three prescriber groups constituted the bulk of prescribing of ocular lubricants. The majority of prescriptions supplied were prescribed by general practitioners (specialty codes vocationally registered GP, and fellow of the College of GPs). Ophthalmologists were the next most common prescribers. In 2013 (to end September), 72% of prescriptions supplied were prescribed by GPs (under the two specialty codes noted above) and 19% by ophthalmologists. Optometrists accounted for approximately 1% of prescriptions supplied.

A breakdown of prescribing into multi-dose and single dose unit products for the top three prescriber groups is presented in Figure 7. 13% of prescriptions written by vocationally registered GPs and Fellows of the College of GPs for ocular lubricants were for single dose unit products. For ophthalmologists, 23% of prescriptions were written for single dose unit preparations, which may be explained by the specialised nature of their practice. The proportion of prescribing of single dose unit ocular lubricants by optometrists was the same as GPs at 13%.

**Figure 6: Sum of prescriptions by top 10 prescribers by major specialty codes.**

**Figure 7: Sum of prescriptions for the top three prescribers groups by major specialty code by form (multi-dose and single dose unit products)**

***Expenditure***

The total expenditure for the ATC group of S01XA, Sensory Organs, Other Ophthalmologicals, which covers all the ocular lubricants, was $26.2 million in 2012. The expenditure across the whole group of ocular lubricants has been fairly stable over the last ten years with $21.2 million in 2003, gradually increasing per year from a low of $19.7 million in 2006.

Figure 8 shows the total PBS benefits per calendar year on ocular lubricants for the ten years of 2003 to 2012.

**Figure 8: Total PBS benefits per calendar year, 2003-2012**

Figure 9 shows the expenditure per calendar year per drug for the ten years 2003-2012.

**Figure 9: Expenditure by drug per calendar year, 2003-2012**

Hypromellose products, which are available on the PBS as multi-dose products only, were the market leaders at the beginning of the time period in 2003, with $7.6 million in expenditure for the 2003 calendar year. From 2004, the expenditure for hypromellose products decreased steadily to $3.3 million in 2012. Hypromellose use was largely replaced over the last ten years by carmellose sodium multi-dose and single dose unit preparations, with $4.3 million expenditure in 2003 increasing to $8.5 million in 2012. Expenditure on polyethylene glycol 400 with propylene glycol multi-dose and single unit preparations has risen steadily over the last ten years from $41,000 in 2003 to $4.3 million in 2012. Paraffin eye ointments, which accounted for $2.5 million expenditure in 2003, had steady utilisation over the ten years with $2.9 million in expenditure in 2012.

## Discussion

The total number of prescriptions for ocular lubricants has been fairly steady over the last ten years, increasing gradually from 2003 to a peak in 2009, and then slowly decreasing to 2.46 million in 2012. Expenditure across the whole group of ocular lubricants has been fairly stable over the last ten years, gradually rising from a low of $19.7 million in 2006. Expenditure in 2012 was $26.2 million.

Multi-dose products account for the majority of PBS prescriptions for ocular lubricants supplied. In 2013 (until end September), 85% of prescriptions were for multi-dose products. In recent years a considerable number of single dose unit products have been listed on the PBS and this data illustrates that prescribing of single dose unit products is gradually increasing. Single dose unit products comprised 1.3% of prescriptions supplied in 1994, 6.7% in 2003, 14% in 2012 and 15% in 2013 (to end September). The gradual increase in prescribing of the more expensive single dose unit products is likely to explain the small gradual increase in expenditure on ocular lubricants despite stable prescription numbers.

Almost all prescriptions for ocular lubricants are priced over the patient co-payment (97%), with concessional prescriptions compiling the bulk of prescriptions, with 85% of prescriptions in 2012. It is noted that a number of products are available at low cost over-the-counter, which may be more attractive, particularly for general patients, who may not consider regular monitoring of their condition necessary. The DUSC noted that the cost of a number of ocular lubricant products listed on the PBS is higher than the price these products are sold for from pharmacies (without a prescription).

The most common prescribers of ocular lubricants are GPs, followed by ophthalmologists. In 2013 (to end September), approximately 72% of prescriptions supplied were prescribed by GPs and 19% by ophthalmologists. Optometrists accounted for approximately 1% of prescriptions supplied.

## DUSC actions

The DUSC noted that expenditure across the ocular lubricants has been gradually increasing whilst prescription numbers are fairly stable. The DUSC noted that there are currently a large number of ocular lubricant products listed on the PBS with a variety of prices. The DUSC noted that currently prices vary both between ocular lubricants that contain a preservative and the ocular lubricants that are preservative free. The DUSC also noted that a substantial price differential exists between preservative containing products and preservative free products. The DUSC referred these matters to the PBAC to consider if the current pricing is appropriate.

**Context for analysis**

The DUSC is a Sub Committee of the Pharmaceutical Benefits Advisory Committee (PBAC). The DUSC assesses estimates on projected usage and financial cost of medicines.

The DUSC also analyses data on actual use of medicines, including the utilisation of PBS listed medicines, and provides advice to the PBAC on these matters. This may include outlining how the current utilisation of PBS medicines compares with the use as recommended by the PBAC.

The DUSC operates in accordance with the quality use of medicines objective of the National Medicines Policy and considers that the DUSC utilisation analyses will assist consumers and health professionals to better understand the costs, benefits and risks of medicines.

The utilisation analysis report was provided to the pharmaceutical sponsors of each drug and comments on the report were provided to DUSC prior to its consideration of the analysis.

## Sponsors’ comments

AFT Pharmaceuticals Pty Ltd

Alcon Laboratories (Australia) Pty Ltd

Allergan Australia Pty Ltd

AMO Australia Pty Ltd

Aspen Pharma Pty Ltd

Bausch & Lomb (Australia) Pty Ltd

Bio Revive Pty Ltd

Contact Lens Centre Australia Limited

Petrus Pharmaceuticals Pty Ltd

The sponsors have no comment.

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The Department of Health (DoH) has made all reasonable efforts to ensure that information provided in this report is accurate. The information provided in this report was up-to-date when it was considered by the Drug Utilisation Sub-committee of the Pharmaceutical Benefits Advisory Committee. The context for that information may have changed since publication.

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1. Australian Medicines Handbook 2014. Adelaide: Australian Medicines Handbook Pty Ltd; 2014. [↑](#footnote-ref-1)
2. Miller S. Dry eye requires a little TLC – tear layer care. Art & Science 2013;23(9): 30-33. [↑](#footnote-ref-2)
3. Ee-Munn Chia, Paul Mitchell, Elena Rochtchina, Anne J Lee, Rita Maroun and Jie Jin Wang. Clinical and Epidemiology

Prevalence and associations of dry eye syndrome in an older population: the Blue Mountains Eye Study. Clinical and Experimental Ophthalmology 2003; 31: 229–232. [↑](#footnote-ref-3)