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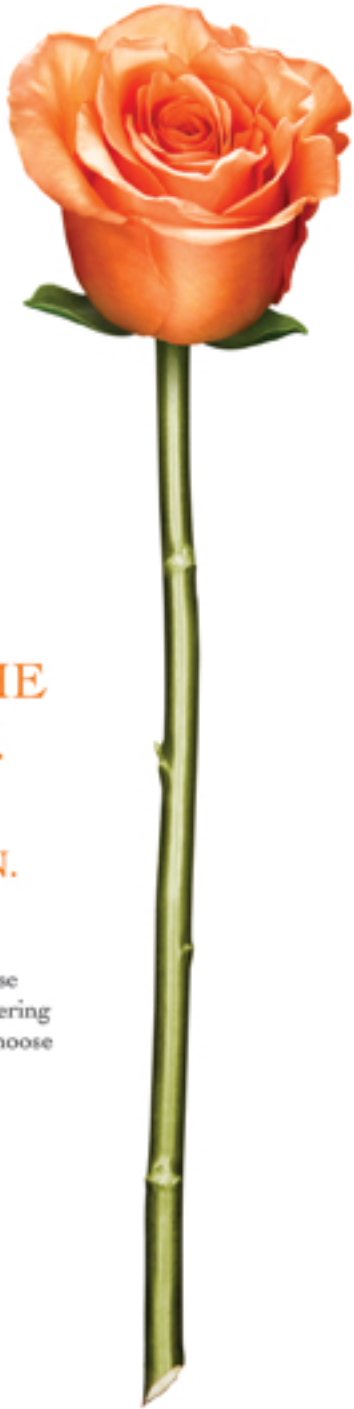

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PUBLICATION SCHEDULE 2014-2015:

2014	
September 2014	**14-1**
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2015	
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April 2015	**15-1**
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Epidemiology of ocular trauma hospital presentations in Sydney, Australia: insights for management and prevention

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Abstract

Aim: *To facilitate care delivery and injury prevention by investigating the nature and outcomes of ocular trauma presentations to a tertiary care center serving an estimated 1.3 million people.*

Patients and methods: *This is an observational case series, retrospectively analyzed, of all patients that presented to the tertiary care center for management of ocular trauma between 01/01/2006-31/12/2006. Data collected included: patient's clinical findings, major diagnoses, initial and final visual acuity, whether the injury was work related, whether protective eyewear was worn, and whether the patient required surgery or admission to hospital. A final BCVA < 6/12 was defined as significant visual deficit.*

Eligible patients were identified prospectively by researchers. Patients underwent standardized clinical assessment. De-identified clinical data was entered into a Microsoft Access database retrospectively and analyzed by separate, blinded researchers. Descriptive statistical analysis was then performed in Microsoft Excel. Analysis based on an ordinal regression model and risk factor analysis was performed in SAS.

Results: *There were 214 cases of ocular trauma in 197 individuals (17 bilateral injuries). Patients were mostly male (83%) with average age 35. The majority of cases were closed globe injuries (92.1%) with no significant final visual deficit (88.3%). Open globe injuries (7.9%) were more likely to have visual deficit (i.e., 47% with final BCVA < 6/12) ($p < 0.01$). In total, 13.1% required surgery and 12.1% required admission to hospital. Eye protection was worn in 7.9% of all cases, and 19.1% of work related cases. Nearly one quarter of cases (22.4%) were work related. Open globe injuries were more likely to occur at work. Open globe injuries at work were caused by a metal projectile in 85.7% of cases. Thirty percent of workers suffered a burn, with final BCVA < 6/12 in 10% of burns.*

Conclusions: *While the vast majority of ocular trauma is superficial with low morbidity, trauma persists as a significant cause of visual impairment. Most vision impairing injuries occur at work, where metal projectiles and burns are common, preventable causes of significant vision loss, which could be targeted in prevention efforts.*

Key words: *Ocular, trauma, epidemiology*

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Introduction

Eye injury is a significant cause of morbidity and economic burden to the community.[1] A 1995 study by Fong conservatively estimated the annual cost in Australia at $155 million.[2] Twenty percent of the population were found to have suffered eye injury in their lifetime according to McCarty *et al*.,[3] slightly higher than a lifetime prevalence of ocular injury in the United States of 14.4%-19.8%.[4,5] Annual incidence of eye injury has been estimated at 11.4 per 1000 of population.[2,6] The incidence of hospitalized eye injuries was found to be 15.3 per 100,000.[7]

The purpose of this study is to investigate the etiology, clinical features, and resulting visual impairment related to ocular trauma in South West Sydney, in order to inform delivery of care and injury prevention efforts. Region specific studies of ocular trauma are important since socioeconomic and demographic variables are significantly correlated with injury frequency and severity.[6,7] Additionally, the study region is significant due to its size, covering a catchment area of 1.35 million people, or 6.5% of the Australian population.[8,9]

Patients and methods

The study is an observational case series of all patients presenting to Liverpool Hospital, including those directly referred to the Liverpool Ophthalmology Department clinic, with ocular trauma during 2006. Participants were referred into the study by treating clinicians in the Emergency Department and Ophthalmology Clinic, and the Emergency triage database was periodically reviewed to identify potentially missed cases. All patients presenting to the care of tertiary hospital ophthalmology department in this manner between 01/01/2006 and 31/12/2006 were considered to meet the inclusion criteria of the study. The exclusion criteria were absence of ocular trauma during the study period, or death prior to ophthalmic assessment, for example due to multi-system trauma.

Patients underwent standardized assessment of ocular trauma, as per the training guidelines of the Royal Australian and New Zealand College of Ophthalmology (RANZCO). This comprised of history taking and an examination including external examination, orbital and full ocular examination for all patients, with subsequent further examination and investigations , including imaging, tailored to clinical findings and suspicion, in keeping with RANZCO training guidelines. Management was also appropriate to diagnosis as per RANZCO training guidelines.

All ocular examination findings were recorded, including initial best corrected visual acuity (BCVA), and final BCVA. For the purposes of statistical analysis, a final BCVA < 6/12 was defined as a significant deficit in BCVA. Other variables recorded were: patient demographics, diagnosis, open globe injury etiology, whether the injury was work related, whether protective eyewear was worn, and finally whether the patient required surgery or admission to hospital (under the care of an ophthalmologist).

De-identified clinical data was entered into a Microsoft Access database retrospectively and analyzed, by separate, blinded researchers. The ocular trauma was

categorized according to Kuhn's classification of ocular trauma into either open globe or closed globe injuries, with further sub-classification by clinical diagnosis (10). Descriptive statistical analysis was then performed in Microsoft Excel. Analysis based on an ordinal regression model and risk factor analysis was performed in SAS (version 9.2).

This study was conducted with the approval of the Human Research Ethics Committee, Liverpool Hospital. The study was conducted as per the tenets of the Helsinki Declaration.

Results

General overview

One hundred ninety-seven individuals presented to Liverpool Hospital with ocular trauma to 214 eyes (17 bilateral injuries). For the purposes of this study, each eye injured was considered a single 'case', with bilateral eye injury counted as two cases.

Age and sex

The average patient age was 35.4 (± 17.1) years. Patients were predominantly male (83%). The average patient age was lower in females (32.9 years) than males (35.8 years).

Nature of Injuries

The majority of injuries were closed globe (197 eyes or 92.1%). The relative frequency of ocular examination findings are listed in Table 1. Occasionally, a single eye had multiple clinical findings. Thus, in total there were 250 clinical findings in 214 injured eyes in 197 patients. Table 1 lists the number of eyes with each clinical finding, as well as the proportion of all 250 findings this represented.

Orbital trauma was the most common finding, recorded in a fifth of all cases. The vast majority of these were orbital wall fractures (47 of 50 orbit trauma cases). Lacerations, to the conjunctiva, cornea or sclera comprised 17% of findings. Iris trauma (12%) was relatively common. Retinal trauma was observed in 10.0%, and lenticular trauma in 4.4%. Vitreous hemorrhages were rarer, observed in 2.8%. Optic nerve trauma and uveal trauma each comprised of 1.6% of cases respectively.

Surgery and hospitalization

Of all cases, 13.1% required surgery, and 12.1% required admission to hospital.

Eye protection

Seventeen (7.9%) patients reported wearing eye protection at the time of trauma. Of those injured at work, eight (19.1%) wore eye protection.

Visual outcomes

Table 2 lists final best corrected visual acuity (BCVA) findings in three categories: (1) all eyes; (2) closed globe eyes; and (3) open globe eyes. Analyzing all eyes, 84.1% had no significant deficit in BCVA at final examination (defined as final BCVA ≥ 6/12).

Table 1. Ocular examination finding frequency is listed by number of cases with each clinical finding. There were 250 findings in 214 eyes. Percentages reflect the proportion of total findings found in each category.

Findings	Number of cases (%)
Orbit trauma	50 (20.0)
- orbital wall fractures	47 (18.8)
- other orbital trauma	3 (1.2)
Lacerations	43 (17.2)
- corneal laceration	16 (6.4)
- scleral laceration	14 (5.6)
- conjunctival laceration	13 (5.2)
Hyphema	39 (15.6)
Iris trauma	30 (12.0)
- traumatic mydriasis	17 (6.8)
- iris prolapse	6 (2.4)
- sphincter tear	3 (1.2)
- other iris trauma	4 (1.6)
Retinal trauma	25 (10.0)
- commotio retinae	13 (5.2)
- retinal hemorrhage	4 (1.6)
- retinal detachment	2 (0.8)
- other retinal trauma	6 (2.4)
Lid trauma	20 (8.0)
Raised intra ocular pressure	16 (6.4)
Lens trauma	11 (4.4)
Vitreous haemorrhage	7 (2.8)
Uvea trauma	4 (1.6)
- uveal prolapse	3(1.2)
- choroidal rupture	1(0.4)
Optic nerve trauma	4 (1.6)

Table 2. Final best corrected visual acuity (VA) of: all 214 eyes; 197 closed globe eyes; and 17 open globe eyes. Percentages, in parenthesis, describe the proportion of each group with a particular visual outcome. For the difference in final VA between closed globe and open globe cases, p-value < 0.001.

Visual Outcomes: Final VA	All Injured Eyes (%)	Closed Globe Eyes (%)	Open Globe Eyes (%)
VA ≥6/12	180 (84.1)	174 (88.3)	6 (35.3)
VA <6/12	8 (3.7)	7 (3.5)	1 (5.9)
VA < 6/60	5 (2.3)	2 (1.0)	3 (17.6)
NPL*	7 (3.3)	3 (1.5)	4 (23.5)
Incomplete data	14 (6.5)	11 (5.6)	3 (17.6)

*** NPL = no perception of light**

Closed globe injuries

There were 197 eyes (92.1%) with closed globe injuries with an average patient age of 35.7 (± 17.1) years, and male preponderance (87.8%).

There were 224 closed globe diagnoses in 197 eyes, as detailed in Table 3, according to Kuhn's diagnostic categories of closed globe injuries. The most common findings were contusion (34.3%), superficial foreign body (31.3%), and burns (17.4%).

Table 3: Closed globe ocular diagnosis frequency is listed by number of eyes with each clinical finding. There were 224 findings in 197 eyes. Percentages, in parenthesis, reflect the proportion of total diagnoses found in each category. Lamellar laceration includes corneal abrasion and conjunctival abrasion.

Findings	Number of eyes (% of total findings)
Contusion	77 (34.3)
Superficial Foreign Body	70 (31.3)
Burns	39 (17.4)
Lamellar laceration	38 (17.0)
- Corneal abrasion	36 (16.1)
- Conjunctival abrasion	2 (0.9)

There were 39 eyes with burns in 28 individuals. Most burns were alkali (61.5%), then acid (15.3%), ultraviolet (12.8%), and thermal (10.2%).

Visual outcomes for the closed globe group are shown in column three of Table 2. Most eyes (88.3%) had no significant deficit of visual acuity. However, twelve (6%) did have significant deficit, including three (1.5%) with no perception of light (NPL) secondary to traumatic optic neuropathy.

Table 4 summarizes visual outcomes for the various diagnostic categories of

closed globe injury. Corneal abrasions and foreign bodies while common were rarely associated with visual deficit. Burns, however, were high morbidity with a significant visual deficit in 10.2% of cases.

Table 4: Final best corrected visual acuity (VA) for various categories of closed globe eye injuries. Numbers of eyes in each category are listed. Percentages, in parenthesis, reflect the proportion of injured eyes in each diagnostic category that have a given visual outcome.

Visual Outcomes (Final VA)	Contusions	Foreign body	Burn	Lamellar laceration	Corneal abrasion	Conjunctival abrasion
VA ≥ 6/12	65 (84.4)	66 (94.3)	34 (87.2)	35 (92.1)	34 (94.4)	0
VA <6/12	2 (2.6)	2 (2.9)	2 (5.1)	3 (7.9)	1 (2.8)	2 (100)
VA < 6/60	1 (1.3)	1 (1.4)	2 (5.1)	0	0	0
NPL	3 (3.9)	0	0	0	0	0
Incomplete data	6 (7.8)	1 (1.4)	1 (2.6)	0	1 (2.8)	0

Open globe injuries

There were a total of seventeen patients with open globe injuries representing 7.9% of the total number of injured eyes. Penetrating globe injuries were observed in nine eyes (52.9%) of which three also had an associated intraocular foreign body. There were five ruptured globes (29.4%), and three full thickness lacerations (17.7%).

The majority (80%) of open globe injuries were in males (14 eyes). Four patients (23.5%) were age 18 or below.

No patient wearing eye protection suffered an open globe injury, and while the findings were suggestive of an association with eye protection use and a reduced risk of open globe injury ($p = 0.30$), the sample size was not large enough to demonstrate statistical significance.

Amongst open globe cases, injury by a metal projectile was involved in seven of seventeen injuries (41.1%), making it the most common mechanism. Six of these seven cases were work-related. The next most common mechanism was assault, with three cases (18%). The other causes were varied including one motor vehicle accident (6%), and one explosion.

In Table 2, column four summarizes the visual outcomes for the open globe cases. As expected, visual outcomes were worse for the open globe cases than the closed globe cases (p value < 0.001). Six eyes (35.3%) had final BCVA ≥ 6/12, the remaining eight eyes (47%) had final BCVA < 6/12 including four eyes (23.5%) with NPL.

Table 5 shows final BCVA for the various types of open globe injuries. The five ruptured globes (29.4% of the open globe eyes) all had poor visual outcomes, four with NPL and one with final BCVA of < 6/60. All three eyes with full thickness laceration had final BCVA ≥ 6/12.

Table 5: Final best corrected visual acuity (VA) for various diagnostic categories of open globe eye injuries. Numbers of eyes in each category are listed along with the percentage, in parenthesis, of total open globe cases that they represent.

Visual Outcomes (Final VA)	Penetrating globe injury	Ruptured globe injury	Perforating globe injury
VA ≥ 6/12	3 (17.0)	0	3 (17.3)
VA <6/12	1 (5.9)	0	0
VA < 6/60	2 (11.8)	1 (5.9)	0
NPL	0	4 (23.5)	0
Incomplete data	3 (17.6)	0	0

Work-related injuries

There were forty-nine work-related (WR) eye injuries, which represented 22.4% of all ocular trauma cases. This included two females and four bilateral injuries.

Forty-two (85.7%) of the work-related injuries were closed globe. These were mainly superficial injuries. Superficial foreign body (SFB) was the most common finding, observed in twenty-three cases (46.9%). Burns were the next most common with thirteen cases (30%). Ten of the burns were alkali (77%) and three (23%) were ultraviolet. Work related alkali burns constituted 50% of total presentations with alkali burns. There were also eight contusions (16.3%), and five lamellar lacerations (10.2%).

There were seven open globe work-related injuries (41.4% of all open globe injuries). Five (71.4%) were penetrating eye injuries and two ruptured globes (28.5%). All but one of the work-related open globe cases involved a metal projectile. In no case of open globe injury eye protection had been worn.

Risk factor analysis suggests open globe injuries are more commonly work-related, albeit not quite reaching statistical significance (p value < 0.06). Eight of the work-related cases (19.1%) wore eye protection, and all of these had good visual outcomes (final BCVA ^{3} 6/12).

In 92.3% of work-related closed globe cases there was no significant deficit of final BCVA. The final visual outcomes for open globe work related cases reflected the recognized poor visual prognosis associated with open globe injuries, with two thirds of the patients suffering significant visual deficit, and nearly one third of patients with NPL.

Discussion

This study provides insights into ocular trauma in Australia. It contributes information about frequency of different types of injury and their associated visual outcomes, injury etiology, use of eye protection and features of work place injury. These insights are useful clinically, logistically, and for injury prevention.

Regional ocular trauma studies are important due to the lack of a national ocular trauma database, and significant local variations in ocular trauma epidemiology.[11] This study was performed in South-West Sydney, Australia, a region that warrants attention due to its size, and high risk demographic features. The 2006 population of South-West Sydney was approximately 1,350,000 (8), or 6.5% of the Australian population.[9] The area is serviced by the South-Western Sydney Local Health District and Liverpool Hospital is the district's only tertiary ophthalmology referral center. The catchment region includes five of the ten most disadvantaged local government areas of Sydney.[12] Employment in the region includes industrial, manufacturing and service sectors. These work types and socioeconomic disadvantage are associated with higher risk of ocular trauma.[13,14]

This study's demographics findings are similar to other studies of its kind, both in Australia and abroad. Males constituted 83% of the cohort; in a similar range to previous studies (70-85%). This is traditionally attributed to higher risk taking and occupational exposure.[13,15] Average age of patients in the low thirties is also consistent with previous studies.[6] Children are well known to have high rates of ocular trauma. Previous studies have found that children account for 20 to 50% of all ocular injury.[16-18] In this study, 23% of the open globe injuries occurred in children.

The study demonstrates that ocular trauma commonly presents to tertiary hospital emergency departments whether the injury is low (84.1%) or high morbidity (15.9%). This is partly due to the pain associated with even superficial injury. Ophthalmologists are rarely the first to see an ocular trauma due to the referral system. Thus, GPs, ED staff and optometrists play an important role in emergency management of cases, which can be critical to visual outcomes. They also play an essential role in appropriately triaging which patients need to see an ophthalmologist urgently. Thus, it is vital that generalists are well-trained in ocular trauma emergency management including identification of urgent referrals.

The ratio of open globe to closed injuries was comparable with other studies in developed countries. Open globe injuries comprised 7.9% of cases, compared to 5% in a recent Singaporean study.[15]

This study demonstrates the heavy burden of disease associated with open globe injury. The visual outcomes were worse for the open globe cases than the closed globe cases (p value < 0.001). Roughly a quarter of the open globe cases had NPL.

In this study, 22.4% of cases were work-related injuries. This is less than reported by McCarty in 1999, which was the most recent study of this kind. That study found 60% to be work related, but included a rural population.[3] Another rural study found that eye injuries accounted for 12% of all injuries to the regional hospital and one third of these were work-related.[19] While the discrepancies may represent

demographic differences in the study populations, recall bias, or differences in reporting eye work-related injury, it is possible that this finding represents a true decrease in the proportion of work-related injuries. To some extent, a reduction should to be anticipated. The prevalence of worker eye injury has been on a steady decline in the western world, due to eye protection and safety standards, and a shift of many high-risk manufacturing jobs to the developing world.[15]

In this study, workers were more likely to sustain an open globe injury than those not injured at work, albeit with a p value < 0.06. Open globe injuries are associated with the poorest visual outcomes and therefore the greatest morbidity and associated costs.

It has been estimated in the ocular trauma literature that 90% of ocular trauma is preventable.[17] The prevention of eye injury amongst workers and in the general community is influenced by awareness of risk, and subsequent steps to prevent injury. One important protective measure is the use of protective eyewear. In Australia, eye protection use is governed by various standards and pieces of legislation, both at the state and national level, and is primarily focused on encouragement of eye protection use in the workplace. In Sydney, the main government bodies affecting use of eye protection by workers are Work Cover NSW and Safe Work Australia. Important legislation at the state level includes the New South Wales Occupational Health and Safety Act of 2000 and New South Wales Occupational Health and Safety Regulation of 2001. Section 8 of the Act specifies that employers must provide safe working conditions, and section 15 of the Regulations specifies that employers must provide adequate personal protective equipment, including eye protection, should a modifiable risk to employees exist. It advises that personal protective equipment should meet standards specified by Standards Australia. Key standards that apply to eye protection include AS1067, 1336, 1337, 1338, 2211, and 2397. Government bodies also provide worker education. For example, WorkCover NSW offers educational workshops for businesses, which include discussion of eye protection. An employee who does not wear available eye protection provided can be reported to WorkCover NSW for failure to cooperate, as can an employer who fails to appropriately provide eye protection.

The findings in this study suggest that people working with metal may be a worthwhile target for injury prevention campaigns. Of workers who suffered an open globe injury, 85.7% were hit by some form of metal projectile. None of these patients wore eye protection. Thompson *et al*. also found in their study in rural NSW that penetrating eye injuries were most commonly caused by metal projectiles, including fencing wire.[6] The study by McCarty et a found that overall 30.7% of cases were caused by metal.[3]

The findings in this study suggest that people working with alkalis are also worthwhile targets for injury prevention efforts. Burns were a leading cause of vision loss amongst workers. Burns comprised 30% of work-related injuries, and nearly 80% of those were alkaline. Burns patients had significant visual deficit in at least 10.2% of closed globe cases. It is possible that alkali burns are becoming more common. Of all cases in this study, 11.2% suffered alkali burns, compared to 4.7%

of the study population in McCarty's 1999 study.[3] However, McCarty's study was a self-reported population-based cross-sectional study, with associated risk of recall bias. Regardless, the risk of an alkali burn, from the likes of cleaning products and cement, could be effectively reduced through more prominent warning labels and consumer education to encourage use of eye protection.

In this study, eye protection was worn in 7.9% of cases in this study, and 19.1% of work-related cases, compared to 3.2 % of non-work-related cases. This study found 7.9% of the total trauma cases wore eye protection, less than the 13% reported in McCarty's 1999 study.[3] Since 1999, extensive ocular trauma prevention strategies have been implemented, including the aforementioned legislation (*e.g.*, *New South Wales Occupational Health and Safety Act of 2000*) and work safety standards by Work Safe NSW and Safe Work Australia. This study is not designed to assess prevalence or effectiveness of eye protection. It primarily identifies patients who did not wear eye protection, or for whom eye protection failed, at least partially. However, future research into the effectiveness of these regulations would be valuable.

A strength of this study is that the data was collected prospectively from a single catchment area within a finite time and is therefore likely to be representative of true community presentation patterns to tertiary care.

A possible weakness of the study is that some patients may not have been captured in the database. It is possible, for example, that some minor cases of ocular trauma seen in the emergency department were not registered in the study. While this study contributes to the epidemiology knowledge base, individual studies at individual centers are prone to bias. Also, data is incomplete, with respect to final BCVA in 6.5% of eyes.

This study provides useful clinical and public health insights into ocular trauma injury patterns in metropolitan Australia by contributing information about injury relative frequency, causation, visual outcomes, burden of disease, use of eye protection and features of work place injury. There is a significant loss of vision related to open globe injury from metal projectiles and closed globe injuries from burns, especially alkali burns. Given the morbidity and relative frequency of these injuries, they are worthy of consideration for targeted prevention efforts.

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References: 1. Xalatan® (latanoprost) Prescription Information, Pfizer Corporation HK Ltd, version date: Oct, 2012. 2. Xalacom® (latanoprost /timolol maleate) Prescription Information, Pfizer Corporation HK Ltd, version date: Jun 2009. 3. Parrish RK et al. *Am J Ophthalmol* 2003;135(5):688–703. 4. Drug Office, Dept of Health, HKSAR – Search Drug Database http://www.drugoffice.gov.hk/eps/do/en/pharmaceutical_trade/search_drug_ database.html

XALATAN® ABBREVIATED PACKAGE INSERT. TRADE NAME: Xalatan® 0.005% w/v eye drops solution. **PRESENTATION:** Each bottle contains 2.5mL eye drops solution; 100 ml eye drops solution contains 0.005g latanoprost. **INDICATIONS:** Reduction of elevated intraocular pressure in patients with open angle glaucoma, chronic angle closure glaucoma and ocular hypertension. Reduction of elevated intraocular pressure in paediatric patients with elevated intraocular pressure and paediatric glaucoma. **DOSAGE:** Instill 1 drop into the affected eye(s) once daily. Optimal effect is obtained when administered in the evening. Xalatan® eye drops may be used in paediatric patients at the same posology as in adults. **CONTRAINDICATIONS:** Known hypersensitivity to any component in Xalatan®. **WARNINGS & PRECAUTIONS:** May gradually change the eye color by increasing the amount of brown pigment in the iris. Patients should be monitored regularly and if the clinical situation warrants, Xalatan® treatment may be discontinued. Xalatan® should be used with caution in peri-operative period of cataract surgery patients, patients with a history of herpetic keratitis, aphakic patients, in pseudophakic patients with torn posterior lens capsule or anterior chamber lenses, or in patients with known risk factors for cystoid macular oedema, asthmatic patients. Experience to date shows that periorbital skin discolouration is not permanent. Latanoprost may gradually change eyelashes and vellus hair in the treated eye and surrounding areas. Xalatan® contains benzalkonium chloride. Contact lenses may absorb benzalkonium chloride and these should be removed before applying Xalatan® but may be reinserted after 15 minutes. Efficacy and safety data in the age group < 1 year are very limited. **INTERACTIONS:** There have been reports of paradoxical elevations in intraocular pressure following the concomitant ophthalmic administration of two prostaglandin analogues. **FERTILITY, PREGNANCY AND LACTATION:** Latanoprost has not been found to have any effect on male or female fertility in animal studies. The safety of this medicinal product for use in human pregnancy has not been established. Latanoprost and its metabolites may pass into breast milk and Xalatan® should therefore not be used in nursing women or breast feeding should be stopped. **SIDE EFFECTS:** Increased iris pigmentation; mild to moderate conjunctival hyperaemia eye irritation; eyelash and vellus hair changes; transient punctate epithelial erosions; blepharitis; eye pain; eyelid oedema: dry eye; keratitus; vision blurred; conjunctivitis; iritis/uveitis; macular oedema; symptomatic corneal oedema and erosions; periorbital oedema; misdirected eyelashes sometimes resulting in eye irritation; extra row of cilia at the aperture of the meibomian glands. **REFERENCE:** HK PI (version date/LPD date) Oct 2012 **DATE OF PREPARATION:** Sep 2014 **IDENTIFIER NUMBER:** XALT0914

XALACOM® ABBREVIATED PACKAGE INSERT. TRADE NAME: Xalacom® eye drops, solution 2.5mL. **PRESENTATION:** Each ml of Xalacom® contains 50mcg latanoprost and 5mg timolol. **INDICATIONS:** Reduction of intraocular pressure in patients with open angle glaucoma and ocular hypertension who are insufficiently responsive to topic beta-blockers or prostaglandin analogues. **DOSAGE:** Instill 1 drop into the affected eye(s) once daily. **CONTRAINDICATIONS:** Hypersensitivity to any component in Xalacom®. Reactive airway disease including bronchial asthma or a history of bronchial asthma, severe chronic obstructive pulmonary disease. Sinus bradycardia, 2nd and 3rd degree atrioventricular block, overt cardiac failure, cardiogenic shock. **WARNINGS & PRECAUTIONS:** History of severe cardiac disease. Respiratory reactions and cardiac reactions, including death due to bronchospasm in patients with asthma and rarely death in association with cardiac failures, have been reported following administration of timolol maleate. Caution in patients subject to spontaneous hypoglycemia or labile insulin-dependent diabetes. May mask signs of hyperthyroidism and worsen Prinzmetal angina, severe peripheral and central circulatory disorders and hypotension. Patients who are aphakic, pseudophakic with a torn posterior lens capsule or with known risk factors for macular oedema. May cause change in eye colour. Contact lenses should be removed before administration and maybe reinserted after 15 minutes **INTERACTIONS:** The use of two local beta-blockers or two local prostaglandins is not recommended. Epinephrine, oral calcium channel blockers, guanethidine or beta-blocking agents, antiarrhythmics, digitalis glycosides or parasympathomimetics, clonidine, antidiabetic agents **PREGNANCY AND LACTATION:** Should not be used during pregnancy since the potential risk for humans is unknown. Active substance and its metabolites may pass into breast milk and should not be used in women who are breast-feeding. **COMMON SIDE EFFECTS:** Increased iris pigmentation; Thickening and lengthening of eye lashes; Mild conjunctival hyperaemia; Transient punctuate epithelial erosions; Macular oedema, including cystoid macular oedema; Iritis/ uveitis; Corneal oedema and erosions; Eye irritation (including stinging, burning and itching) and eye pain. **REFERENCE:** HK PI (version date/LPD date) Jun 2009 **DATE OF PREPARATION:** July 2012 **IDENTIFIER NUMBER:** XALC0712

FULL PRESCRIBING INFORMATION IS AVAILABLE UPON REQUEST.

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