1. Name of the medicinal product

Xolamol Ophthalmic Solution

2. Qualitative and quantitative composition

Each ml contains: Dorzolamide 20 mg (as Hydrochloride) and Timolol 5 mg (as Maleate)
Excipients: Benzalkonium chloride 0.075 mg/ml
For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Eye drops, solution.
Clear, Colorless, slightly viscous solution and free from particulate matter, filled in 10 mL HDPE opaque bottles with LDPE nozzle and HDPE cap.

4. Clinical particulars

4.1 Therapeutic indications

Indicated in the treatment of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or pseudoexfoliative glaucoma when topical beta-blocker monotherapy is not sufficient.

4.2 Posology and method of administration

Posology

The dose is one drop of Dorzolamide/Timolol Eye Drops Solution in the (conjunctival sac of the) affected eye(s) two times daily.

If another topical ophthalmic agent is being used, Dorzolamide/Timolol Eye Drops Solution and the other agent should be administered at least ten minutes apart.

Method of administration

Please follow these instructions carefully when using Dorzolamide/Timolol Eye Drops Solution eye drops solution. It is recommended that you wash your hands before putting in your eye drops.

1. You must not use the bottle if the tamper-proof seal on the bottle neck is broken before you first use it.
2. To open the bottle unscrews the cap by turning it until the tamper-proof seal breaks.

3. Tilt your head back and pull your lower eyelid down slightly to form a pocket between your eyelid and your eye .
4. Invert the bottle and press gently until a single drop as instructed by your doctor is dispensed into your eye. DO NOT TOUCH YOUR EYE OR EYELID WITH THE TIP OF THE CONTAINER.
5. Repeat steps 3 and 4 with the other eye if instructed to do so by your doctor.
6. Reclose the bottle by turning the cap firmly immediately after use and return the bottle to the original outer carton.
7. The dispenser tip is designed to provide a pre-measured drop; therefore, do not enlarge the hole of the dispenser tip.

Paediatric population

Efficacy in paediatric patients has not been established.

Safety in paediatric patients below the age of 2 years has not been established. (For information regarding safety in paediatric patients ≥ 2 and < 6 years of age, see section 5.1).

4.3 Contraindications

Dorzolamide/Timolol Eye Drops Solution is contraindicated in patients with:

- Reactive airway disease, including bronchial asthma or a history of bronchial asthma, or severe chronic obstructive pulmonary disease
- Hypersensitivity to the active substance s or to any of these excipients
- Sinus bradycardia, sick sinus syndrome, sino-atrial block, second or third degree atrioventricular block not controlled with pacemaker, overt cardiac failure, cardiogenic shock
- Severe renal impairment (CrCl < 30 ml/min) or hyperchloraemic acidosis
- Hypersensitivity to one or both active substances or to any of the excipients listed in section 6.1.

The above are based on the components and are not unique to the combination.

4.4 Special warnings and precautions for use

Cardiovascular/Respiratory Reactions

Like other topically applied ophthalmic agents Timolol is absorbed systemically. Due to beta-adrenergic component, Timolol, the same types of cardiovascular, pulmonary and other adverse reactions seen with systemic beta-adrenergic blocking agents may occur. Incidence of systemic ADRs after topical ophthalmic administration is lower than for systemic administration. To reduce the systemic absorption, see section 4.2.

Cardiac Disorders:

In patients with cardiovascular diseases (e.g. coronary heart disease, Prinzmetal's angina and cardiac failure) and hypotension therapy with beta-blockers should be critically assessed and the therapy with other active substances should be considered. Patients with cardiovascular diseases should be watched for signs of deterioration of these diseases and of adverse reactions.

Due to its negative effect on conduction time, beta-blockers should only be given with caution to patients with first degree heart block.

Vascular Disorders:

Patients with severe peripheral circulatory disturbance/disorders (i.e. severe forms of Raynaud's disease or Raynaud's syndrome) should be treated with caution.

Respiratory Disorders:

Respiratory reactions, including death due to bronchospasm in patients with asthma have been reported following administration of some ophthalmic beta-blockers.

Dorzolamide/Timolol Eye Drops Solution should be used with caution, in patients with mild/moderate chronic obstructive pulmonary disease (COPD) and only if the potential benefit outweighs the potential risk.

Hepatic Impairment

This medicinal product has not been studied in patients with hepatic impairment and should therefore be used with caution in such patients.

Immunology and Hypersensitivity

As with other topically-applied ophthalmic agents, this medicinal product may be absorbed systemically. Dorzolamide contains a sulfonamido group, which also occurs in sulphonamides. Therefore, the same types of adverse reactions found with systemic administration of sulfonamides may occur with topical administration, including severe reactions such as Stevens-Johnson syndrome and toxic epidermal necrolysis. If signs of serious reactions or hypersensitivity occur, discontinue use of this preparation.

Local ocular adverse effects, similar to those observed with Dorzolamide hydrochloride eye drops, have been seen with this medicinal product. If such reactions occur, discontinuation of this medicinal product should be considered.

While taking beta-blockers, patients with a history of atopy or a history of severe anaphylactic reaction to a variety of allergens may be more reactive to repeated challenge with such allergens and may be unresponsive to the usual dose of adrenaline used to treat anaphylactic reactions.

Concomitant Therapy

The effect on intra-ocular pressure or the known effects of systemic beta-blockade may be potentiated when Timolol is given to the patients already receiving a systemic beta-blocking agent. The response of these patients should be closely observed. The use of two topical beta-adrenergic blocking agents is not recommended (see section 4.5).

The use of Dorzolamide and oral carbonic anhydrase inhibitors is not recommended.

Withdrawal of Therapy

As with systemic beta-blockers, if discontinuation of ophthalmic timolol is needed in patients with coronary heart disease, therapy should be withdrawn gradually.

Additional Effects of Beta-Blockade

Hypoglycaemia/diabetes:

Beta-blockers should be administered with caution in patients subject to spontaneous hypoglycaemia or to patients with labile diabetes, as beta-blockers may mask the signs and symptoms of acute hypoglycaemia.

Beta-blockers may also mask the signs of hyperthyroidism. Abrupt withdrawal of beta-blocker therapy may precipitate a worsening of symptoms.

Corneal diseases:

Ophthalmic beta-blockers may induce dryness of eyes. Patients with corneal diseases should be treated with caution.

Surgical anaesthesia:

Beta-blocking ophthalmological preparations may block systemic beta-agonist effects e.g. of adrenaline. The anaesthesiologist should be informed when the patient is receiving Timolol.

Therapy with beta-blockers may aggravate symptoms of myasthenia gravis.

Additional Effects of Carbonic Anhydrase Inhibition

Therapy with oral carbonic anhydrase inhibitors has been associated with urolithiasis as a result of acid-base disturbances, especially in patients with a prior history of renal calculi. Although no acid-base disturbances have been observed with this medicinal product, urolithiasis has been reported infrequently. Because Dorzolamide/Timolol Eye Drops Solution contains a topical carbonic anhydrase inhibitor that is absorbed systemically, patients with a prior history of renal calculi may be at increased risk of urolithiasis while using this medicinal product.

Other

The management of patients with acute angle-closure glaucoma requires therapeutic interventions in addition to ocular hypotensive agents. This medicinal product has not been studied in patients with acute angle-closure glaucoma.

Corneal oedema and irreversible corneal decompensation have been reported in patients with pre-existing chronic corneal defects and/or a history of intraocular surgery while using dorzolamide. There is an increased potential for developing corneal oedema in patients with low endothelial cell counts. Precautions should be used when prescribing Dorzolamide/Timolol Eye Drops Solution to these groups of patients.

Choroidal detachment has been reported with administration of aqueous suppressant therapies (e.g. timolol, acetazolamide) after filtration procedures.

As with the use of other antiglaucoma medicines, diminished responsiveness to ophthalmic timolol maleate after prolonged therapy has been reported in some patients. However, in clinical studies in which 164 patients have been followed for at least three years, no significant difference in mean intraocular pressure has been observed after initial stabilisation.

Contact Lens Use

This medicinal product contains the preservative Benzalkonium chloride, which may cause eye irritation. Remove contact lenses prior to application and wait at least 15 minutes before reinsertion. Benzalkonium chloride is known to discolour soft contact lenses.

Paediatric population

See section 5.1.

4.5 Interaction with other medicinal products and other forms of interaction

Specific medicine interaction studies have not been performed with the fixed combination of Dorzolamide and Timolol.

In clinical studies, this medicinal product was used concomitantly with the following systemic medications without evidence of adverse interactions: ACE-inhibitors, calcium channel blockers, diuretics, non-steroidal anti-inflammatory medicines including aspirin, and hormones (*e.g.* oestrogen, insulin, thyroxine).

There is a potential for additive effects resulting in hypotension and/or marked bradycardia when ophthalmic beta-blockers solution is administered concomitantly with oral calcium channel blockers, catecholamine-depleting medicines or beta-adrenergic blocking agents, antiarrhythmics (including amiodarone), digitalis glycosides, parasympathomimetics, guanethidine, narcotics, and monoamine oxidase (MAO) inhibitors.

Potentiated systemic beta-blockade (e.g., decreased heart rate, depression) has been reported during combined treatment with CYP2D6 inhibitors (*e.g.* quinidine, fluoxetine, paroxetine) and Timolol.

Although fixed combination of Dorzolamide and Timolol alone has little or no effect on pupil size, mydriasis resulting from concomitant use of ophthalmic beta-blockers and adrenaline (epinephrine) has been reported occasionally.

Beta-blockers may increase the hypoglycaemic effect of antidiabetic agents.

Oral beta-adrenergic blocking agents may exacerbate the rebound hypertension which can follow the withdrawal of clonidine.

4.6 Fertility, pregnancy and lactation

Pregnancy

Dorzolamide/Timolol Eye drop solution should not be used during pregnancy.

Dorzolamide

No adequate clinical data in exposed pregnancies are available. In rabbits, Dorzolamide produced teratogenic effect at maternotoxic doses (see section 5.3).

Timolol

There are no adequate data for the use of Timolol in pregnant women. Timolol should not be used during pregnancy unless clearly necessary. To reduce the systemic absorption, see section 4.2.

Epidemiological studies have not revealed malformative effects but show a risk for intra uterine growth retardation when beta-blockers are administered by the oral route. In addition, signs and symptoms of beta-blockade (e.g. bradycardia, hypotension, respiratory distress and hypoglycaemia) have been observed in the neonate when beta-blockers have been administered until delivery. If this medicinal product is administered until delivery, the neonate should be carefully monitored during the first days of life.

Breast-feeding

It is not known whether Dorzolamide is excreted in human milk. In lactating rats receiving Dorzolamide, decreases in the body weight gain of offspring were observed. Beta-blockers are excreted in breast milk. However, at therapeutic doses of Timolol in eye drops it is not likely that sufficient amounts would be present in breast milk to produce clinical symptoms of beta-blockade in the infant. To reduce the systemic absorption, see section 4.2.

If treatment with the fixed combination of Dorzolamide and Timolol is required, then lactation is not recommended.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed. Possible side effects such as blurred vision may affect some patients' ability to drive and/or operate machinery.

4.8 Undesirable effects

In clinical studies for the fixed combination of Dorzolamide and Timolol the observed adverse reactions have been consistent with those that were reported previously with Dorzolamide hydrochloride and/or Timolol Maleate.

During clinical studies, 1035 patients were treated with the fixed combination of Dorzolamide and Timolol. Approximately 2.4% of all patients discontinued therapy with this medicinal product because of local ocular adverse reactions, approximately 1.2% of all patients discontinued because of local adverse reactions suggestive of allergy or hypersensitivity (such as lid inflammation and conjunctivitis).

Like other topically applied ophthalmic medicines, Timolol is absorbed into the systemic circulation. This may cause similar undesirable effects as seen with systemic beta-blocking agents. Incidence of systemic ADRs after topical ophthalmic administration is lower than for systemic administration.

The following adverse reactions have been reported with the fixed combination of Dorzolamide and Timolol or one of its components either during clinical trials or during post-marketing experience:

[Very Common: (≥ 1/10), Common: (≥ 1/100 to <1/10), Uncommon: ≥ 1/1000 to <1/100), and Rare: (≥ 1/10,000 to <1/1000), Not known (cannot be estimated from the available data)]

System Organ Class (MedDRA)	**Formulation**	**Very Common**	**Common**	**Uncommon**	**Rare**	**Not Known****
Immune system disorders	Fixed combination of Dorzolamide and Timolol Eye drops Solution				signs and symptoms of systemic allergic reactions, including angioedema, urticaria, pruritus, rash, anaphylaxis	
	Timolol maleate eye drops, solution				signs and symptoms of allergic reactions including angioedema,	pruritus

					urticaria, localised and generalised rash, anaphylaxis	
Metabolism and nutrition disorders	Timolol maleate eye drops, solution					hypoglycaemia
Psychiatric disorders	Timolol maleate eye drops, solution			depression*	insomnia*, nightmares*, memory loss	
Nervous system disorders	Dorzolamide hydrochloride eye drops, solution		headache*		dizziness*, paraesthesia*	
	Timolol maleate eye drops, solution		headache*	dizziness*, syncope*	paraesthesia*, increase in signs and symptoms of myasthenia gravis, decreased libido*, cerebrovascular accident*, cerebral ischaemia	
Eye disorders	Fixed combination of Dorzolamide and Timolol Eye drops Solution	burning and stinging	conjunctival injection, blurred vision, corneal erosion, ocular itching, tearing			
	Dorzolamide hydrochloride eye drops, solution		eyelid inflammation*, eyelid irritation*	iridocyclitis*	irritation including redness*, pain*, eyelid crusting*, transient myopia (which resolved upon	

					discontinuation of therapy), corneal oedema*, ocular hypotony*, choroidal detachment (following filtration surgery)*	
	Timolol maleate eye drops, solution		signs and symptoms of ocular irritation including blepharitis*, keratitis*, decreased corneal sensitivity, and dry eyes*	visual disturbances including refractive changes (due to withdrawal of miotic therapy in some cases)*	ptosis, diplopia, choroidal detachment following filtration surgery* (see Special warning and precautions for use 4.4)	itching, tearing, redness, blurred vision, corneal erosion
Ear and labyrinth disorders	Timolol maleate eye drops, solution				tinnitus*	
Cardiac disorders	Timolol maleate eye drops, solution			bradycardia*	chest pain*, palpitation*, oedema*, arrhythmia*, congestive heart failure*, cardiac arrest*, heart block	atrioventricular block, cardiac failure
Vascular disorders	Timolol maleate eye drops, solution				hypotension*, claudication, Raynaud's phenomenon*, cold hands and feet*	
Respiratory, thoracic, and mediastinal	Fixed combination of Dorzolamide		sinusitis		shortness of breath, respiratory failure, rhinitis,	

disorders	and Timolol Eye drops Solution				rarely bronchospasm	
	Dorzolamide hydrochloride eye drops, solution				epistaxis*	
	Timolol maleate eye drops, solution			dyspnoea*	bronchospasm (predominantly in patients with pre-existing bronchospastic disease)*, respiratory failure, cough*	

Gastrointestinal disorders	Fixed combination of Dorzolamide and Timolol Eye drops Solution	dysgeusia				
	Dorzolamide hydrochloride eye drops, solution		nausea*		throat irritation, dry mouth*	
	Timolol maleate eye drops, solution			nausea*, dyspepsia*	diarrhoea, dry mouth*	dysgeusia, abdominal pain, vomiting
Skin and subcutaneous tissue disorders	Fixed combination of Dorzolamide and Timolol Eye drops Solution				contact dermatitis, Stevens-Johnson syndrome, toxic epidermal necrolysis	
	Dorzolamide hydrochloride eye drops,				rash*	

	solution					
	Timolol maleate eye drops, solution				alopecia*, psoriasiform rash or exacerbation of psoriasis*	skin rash
Musculoskeletal and connective tissue disorders	Timolol maleate eye drops, solution				systemic lupus erythematosus,	myalgia
Renal and urinary disorders	Fixed combination of Dorzolamide and Timolol Eye drops Solution			urolithiasis		
Reproductive system and breast disorders	Timolol Maleate eye drops, solution				Peyronie's disease*, decreased libido	sexual dysfunction
General disorders and administration site conditions	Dorzolamide hydrochloride eye drops, solution		asthenia/ fatigue*			
	Timolol Maleate eye drops, solution			asthenia/ fatigue*		

*These adverse reactions were also observed with the fixed combination of Dorzolamide and Timolol Eye drops Solution during post-marketing experience.

**Additional adverse reactions have been seen with ophthalmic beta-blockers and may potentially occur with the fixed combination of Dorzolamide and Timolol Eye drops Solution.

4.9 Overdose

No data are available in humans in regard to overdose by accidental or deliberate ingestion of fixed combination of Dorzolamide and Timolol Eye drops Solution

Symptoms

There have been reports of inadvertent overdoses with Timolol Maleate ophthalmic solution resulting in systemic effects similar to those seen with systemic beta-adrenergic blocking agents such as dizziness, headache, shortness of breath, bradycardia, bronchospasm, and cardiac arrest. The most common signs and symptoms to be expected with overdoses of dorzolamide are electrolyte imbalance, development of an acidotic state, and possibly central nervous system effects.

Only limited information is available with regard to human overdose by accidental or deliberate ingestion of dorzolamide hydrochloride. With oral ingestion, somnolence has been reported. With topical application the following have been reported: nausea, dizziness, headache, fatigue, abnormal dreams, and dysphagia.

Treatment

Treatment should be symptomatic and supportive. Serum electrolyte levels (particularly potassium) and blood pH levels should be monitored. Studies have shown that Timolol does not dialyse readily.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antiglaucoma preparations and miotics, Beta blocking agents, Timolol, combinations, ATC code: S01ED51

Mechanism of action

Dorzolamide/Timolol Eye Drops Solution is comprised of two components: Dorzolamide hydrochloride and Timolol Maleate. Each of these two components decreases elevated intraocular pressure by reducing aqueous humor secretion, but does so by a different mechanism of action.

Dorzolamide hydrochloride is a potent inhibitor of human carbonic anhydrase II. Inhibition of carbonic anhydrase in the ciliary processes of the eye decreases aqueous humor secretion, presumably by slowing the formation of bicarbonate ions with subsequent reduction in sodium and fluid transport. Timolol Maleate is a non-selective beta-adrenergic receptor blocking agent. The precise mechanism of action of Timolol Maleate in lowering intraocular pressure is not clearly established at this time, although a fluorescein study and tonography studies indicate that the predominant action may be related to reduced aqueous formation. However, in some studies a slight increase in outflow facility was also observed. The combined effect of these two agents results in additional intraocular pressure reduction (IOP) compared to either component administered alone.

Following topical administration, this medicinal product reduces elevated intraocular pressure, whether or not associated with glaucoma. Elevated intraocular pressure is a major risk factor in the pathogenesis of optic nerve damage and glaucomatous visual field loss. This medicinal product reduces intra-ocular pressure without the common side effects of miotics such as night blindness, accommodative spasm and pupillary constriction.

Pharmacodynamic effects

Clinical effects

Clinical studies of up to 15 months duration were conducted to compare the IOP-lowering effect of fixed combination of Dorzolamide and Timolol *b.i.d.* (dosed morning and bedtime) to individually- and concomitantly-administered 0.5% Timolol and 2.0% Dorzolamide in patients with glaucoma or ocular hypertension for whom concomitant therapy was considered appropriate in the trials. This included both untreated patients and patients inadequately controlled with Timolol monotherapy. The majority of patients were treated with topical beta-blocker monotherapy prior to study enrollment. In an analysis of the combined studies, the IOP-lowering effect of fixed combination of Dorzolamide and Timolol *b.i.d.* was greater than that of monotherapy with either 2% Dorzolamide

t.i.d. or 0.5% Timolol *b.i.d.* The IOP-lowering effect of fixed combination of Dorzolamide and Timolol *b.i.d.* was equivalent to that of concomitant therapy with Dorzolamide b.i.d. and Timolol b.i.d. The IOP-lowering effect of fixed combination of Dorzolamide and Timolol b.i.d. was demonstrated when measured at various time points throughout the day and this effect was maintained during long-term administration.

Paediatric population

A 3-month controlled study, with the primary objective of documenting the safety of 2% dorzolamide hydrochloride ophthalmic solution in children under the age of 6 years has been conducted. In this study, 30 patients under 6 and greater than or equal to 2 years of age whose IOP was not adequately controlled with monotherapy by dorzolamide or timolol received fixed combination of Dorzolamide and Timolol in an open label phase. Efficacy in those patients has not been established. In this small group of patients, twice daily administration of the fixed combination of Dorzolamide and Timolol was generally well tolerated with 19 patients completing the treatment period and 11 patients discontinuing for surgery, a change in medication, or other reasons.

5.2 Pharmacokinetic properties

Dorzolamide hydrochloride

Unlike oral carbonic anhydrase inhibitors, topical administration of dorzolamide hydrochloride allows for the active substance to exert its effects directly in the eye at substantially lower doses and therefore with less systemic exposure. In clinical trials, this resulted in a reduction in IOP without the acid-base disturbances or alterations in electrolytes characteristic of oral carbonic anhydrase inhibitors.

When topically applied, Dorzolamide reaches the systemic circulation. To assess the potential for systemic carbonic anhydrase inhibition following topical administration, active substance and metabolite concentrations in red blood cells (RBCs) and plasma and carbonic anhydrase inhibition in RBCs were measured. Dorzolamide accumulates in RBCs during chronic dosing as a result of selective binding to CA-II while extremely low concentrations of free active substance in plasma are maintained. The parent active substance forms a single N-desethyl metabolite that inhibits CA-II less potently than the parent active substance but also inhibits a less active isoenzyme (CA-I). The metabolite also accumulates in RBCs where it binds primarily to CA-I. Dorzolamide binds moderately to plasma proteins (approximately 33%). Dorzolamide is primarily excreted unchanged

in the urine; the metabolite is also excreted in urine. After dosing ends, dorzolamide washes out of RBCs non-linearly, resulting in a rapid decline of active substance concentration initially, followed by a slower elimination phase with a half-life of about four months.

When Dorzolamide was given orally to simulate the maximum systemic exposure after long term topical ocular administration, steady state was reached within 13 weeks. At steady state, there was virtually no free active substance or metabolite in plasma; CA inhibition in RBCs was less than that anticipated to be necessary for a pharmacological effect on renal function or respiration. Similar pharmacokinetic results were observed after chronic, topical administration of Dorzolamide hydrochloride. However, some elderly patients with renal impairment (estimated CrCl 30-60 ml/min) had higher metabolite concentrations in RBCs, but no meaningful differences in carbonic anhydrase inhibition and no clinically significant systemic side effects were directly attributable to this finding.

Timolol Maleate

In a study of plasma active substance concentration in six subjects, the systemic exposure to Timolol was determined following twice daily topical administration of Timolol Maleate ophthalmic solution 0.5%. The mean peak plasma concentration following morning dosing was 0.46 ng/ml and following afternoon dosing was 0.35 ng/ml.

5.3 Preclinical safety data

The ocular and systemic safety profile of the individual components is well established.

Dorzolamide

In rabbits given maternotoxic doses of dorzolamide associated with metabolic acidosis, malformations of the vertebral bodies were observed.

Timolol

Animal studies have not shown teratogenic effect.

Furthermore, no adverse ocular effects were seen in animals treated topically with Dorzolamide hydrochloride and Timolol Maleate ophthalmic solution or with concomitantly-administered Dorzolamide hydrochloride and Timolol Maleate. *In vitro* and *in vivo* studies with each of the components did not reveal a mutagenic potential. Therefore, no significant risk for human safety is expected with therapeutic doses of the fixed combination of Dorzolamide and Timolol.

6. Pharmaceutical particulars

6.1 List of excipients

Benzalkonium Chloride

Sodium Citrate

Mannitol

Hydroxyethyl Cellulose
Sodium Hydroxide 1 N and/or Hydrochloric Acid (for pH adjustment)

Water for injections

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Before Opening:

2 years

After Opening:

The Bottle should be discarded after 30 days from opening.

6.4 Special precautions for storage

Storage condition Before and After opening the bottle

Do not store above 30˚C
Keep out of the reach and sight of children.

6.5 Nature and contents of container

5ml of Xolamol Ophthalmic Solution filled in 10ml of HDPE (High Density Polyethylene) opaque bottles with LDPE nozzle and HDPE cap.

6.6 Special precautions for disposal and other handling

No special requirements.

7. Marketing authorisation holder

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Website: www.jamjoompharma.com

8. Marketing authorisation number(s)

-

9. Date of first authorisation/renewal of the authorisation

-

10. Date of revision of the text

-