General disorders and administration site conditions
Common (>1/100, <1/10): asthenic conditions

Investigations
Common (>1/100, <1/10): LFTs abnormal

Immune system disorders
Uncommon (>1/1000, <1/100): allergic contact dermatitis

Additional Adverse Events:
Additional adverse events that have been seen with one of the components and may potentially occur also with COMBIGAN®:

Brimonidine

Eye disorders: iridocyclitis (anterior uveitis), iritis, miosis

Immune system disorders: hypersensitivity, skin reaction (including erythema, face edema, pruritus, rash), vasodilatation

Psychiatric disorders: insomnia

Cardiac disorders: arrhythmias (including bradycardia and tachycardia)

Vascular disorders: hypotension, syncope

Respiratory, thoracic and mediastinal disorders: upper respiratory symptoms, dyspnoea

Gastrointestinal disorders: Gastrointestinal symptoms

General disorders and administration site conditions: systemic allergic reactions

Timolol

Eye disorders: decreased corneal sensitivity, diplopia, ptosis, choroidal detachment (following filtration surgery), refractive changes (due to withdrawal of miotic therapy in some cases), cystoid macular oedema, keratitis, pseudopemphigoid

Psychiatric disorders: insomnia, nightmares, decreased libido, behavioural changes and psychic disturbances including anxiety, confusion, disorientation, hallucinations, memory loss, nervousness

Nervous system disorders: memory loss, increase in signs and symptoms of myasthenia gravis, paresthaesia, cerebral ischaemia, cerebral vascular accident

Ear and labyrinth disorders: tinnitus

Cardiac disorders: heart block, cardiac arrest, arrhythmia, bradycardia, atrioventricular block, cardiac failure, chest pain, oedema, pulmonary oedema, worsening of angina pectoris

Vascular disorders: hypotension, cerebrovascular accident, claudication, Raynaud's phenomenon, cold hands and feet

Respiratory, thoracic and mediastinal disorders: bronchospasm (predominantly in patients with preexisting bronchospastic disease) dyspnoea, cough, respiratory failure, nasal congestion, upper respiratory infection

Gastrointestinal disorders: nausea, diarrhoea, dyspepsia, abdominal pain, anorexia, vomiting

Skin and subcutaneous tissue disorders: alopecia, psoriasiform rash, exacerbation of psoriasis, skin rash

Musculoskeletal, connective tissue and bone disorders: systemic lupus erythematosus, myalgia

Renal and urinary disorders: Peyronie's disease, decreased libido, retroperitoneal fibrosis, sexual dysfunction

General disorders and administration site conditions: oedema, chest pain

Immune system disorders: systemic allergic reactions including anaphylaxis, angioedema, generalized and localized rash, pruritus, urticaria, systemic lupus erythematosus

Metabolism and nutrition disorders: hypoglycemia (in diabetic patients)

Postmarketing Experience:
The following adverse reactions have been identified during postmarketing use of COMBIGAN® in clinical practice. Because they are reported voluntarily from a population of unknown size, estimates of frequency cannot be made.

Eye disorders: Vision blurred

Vascular disorders: Hypotension

Skin and subcutaneous tissue disorders: Erythema facial

OVERDOSAGE

There is limited data available of overdosage in humans with the use of COMBIGAN®. Bradycardia has been reported in association with use of a higher than recommended dose. If overdosage occurs, treatment should be symptomatic and supportive; a patent airway should be maintained.

Brimonidine
In cases where brimonidine has been used as part of the medical treatment of congenital glaucoma, symptoms of brimonidine overdose such as hypotension, bradycardia, hypothermia and apnoea, coma, hypotonia, lethargy, pallor, respiratory depression, and somnolence have been reported in a few neonates, infants, and children receiving brimonidine.

Oral overdoses of other alpha-2-agonists have been reported to cause symptoms such as hypotension, asthenia, vomiting, lethargy, sedation, bradycardia, arrhythmias, miosis, apnoea, hypotonia, hypothermia, respiratory depression and seizure.

Timolol
There have been reports of inadvertent overdosage with timolol ophthalmic solution resulting in systemic effects similar to those seen with systemic beta-adrenergic blocking agents such as bradycardia, hypotension, bronchospasm, headache, dizziness, shortness of breath and cardiac arrest. An *in vitro* haemodialysis study, using 14C timolol added to human plasma or whole blood showed that timolol was readily dialysed from these fluids; however, a study of patients with renal failure showed that timolol did not dialyse readily.

If overdose occurs treatment should be symptomatic and supportive.

DOSAGE AND ADMINISTRATION

Recommended dosage in adults (including the elderly)
The recommended dose is one drop of COMBIGAN® in the affected eye(s) twice daily, approximately 12 hours apart. If more than one topical ophthalmic product is to be used, the different products should be instilled at least 5 minutes apart. As with any eye drops, to reduce possible systemic absorption, it is recommended that the lachrymal sac be compressed at the medial canthus (punctual occlusion) for one minute. This should be performed immediately following the instillation of each drop. To avoid contamination of the eye or drops do not allow the dropper tip to come into contact with any surface.

HOW SUPPLIED

COMBIGAN® eye drops are supplied sterile in white opaque plastic dropper bottles of 5 mL.

NOTE:
Store below 25°C. On prescription only. Keep out of reach of children. Keep the bottle in the outer carton. Discard unused contents 4 weeks after opening.

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Westport, Ireland
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COMBIGAN® eye drops

brimonidine tartrate 2 mg/mL and timolol 5 mg/mL

DESCRIPTION

Each mL contains: 2.0 mg brimonidine tartrate (equivalent to 1.3 mg of brimonidine) and 5.0 mg timolol (equivalent to 6.8 mg of timolol maleate) with benzalkonium chloride, sodium phosphate monobasic monohydrate, sodium phosphate dibasic heptahydrate , hydrochloric acid or sodium hydroxide to adjust pH, and purified water.

CLINICAL PHARMACOLOGY

Pharmacodynamic properties

Pharmacotherapeutic group:
Ophthalmological –antiglaucoma preparations and miotics -beta blocking agents - timolol, combinations
ATC code: S01ED 51

Mechanism of action:
COMBIGAN® consists of two active substances: brimonidine tartrate and timolol maleate. These two components decrease elevated intraocular pressure (IOP) by complementary mechanisms of action and the combined effect results in additional IOP reduction compared to either compound administered alone.

COMBIGAN® has a rapid onset of action.

Brimonidine tartrate is an alpha-2 adrenergic receptor agonist that is 1000-fold more selective for the alpha-2 adrenoreceptor than the alpha-1 adrenoreceptor. This selectivity results in no mydriasis and the absence of vasoconstriction in microvessels associated with human retinal xenografts.

It is thought that brimonidine tartrate lowers IOP by enhancing uveoscleral outflow and reducing aqueous humour formation. Timolol is a beta$_1$ and beta$_2$ non-selective adrenergic receptor blocking agent that does not have significant intrinsic sympathomimetic, direct myocardial depressant, or local anaesthetic (membrane-stabilising) activity. Timolol lowers IOP by reducing aqueous humour formation. The precise mechanism of action is not clearly established, but inhibition of the increased cyclic AMP synthesis caused by endogenous beta-adrenergic stimulation is probable.

Clinical effects:
In three controlled, double-masked clinical studies, COMBIGAN® (twice daily) produced a clinically meaningful additive decrease in mean diurnal IOP compared with timolol (twice daily) and brimonidine (twice daily or three times a day) when administered as monotherapy.

In a study in patients whose IOP was insufficiently controlled following a minimal 3-week run-in on any monotherapy, additional decreases in mean diurnal IOP of 4.5, 3.3 and 3.5 mmHg were observed during 3 months of treatment for COMBIGAN® (twice daily), timolol (twice daily) and brimonidine (twice daily), respectively. In this study, at trough, a significant additional decrease in IOP could only be demonstrated on comparison with brimonidine but not with timolol, however a positive trend was seen with superiority at all other timepoints. In the pooled data of the other two trials statistical superiority versus timolol was seen throughout.

In addition, the IOP-lowering effect of COMBIGAN® was consistently non-inferior to that achieved by adjunctive therapy of brimonidine and timolol (all twice daily).

The IOP-lowering effect of COMBIGAN® has been shown to be maintained in double-masked studies of up to 12 months.

Pharmacokinetic properties
COMBIGAN®:

Plasma brimonidine and timolol concentrations were determined in a crossover study comparing the monotherapy treatments to COMBIGAN® treatment in healthy subjects. There were no statistically significant differences in brimonidine or timolol AUC between COMBIGAN® and the respective monotherapy treatments. Mean plasma C_{max} values for brimonidine and timolol following dosing with COMBIGAN® were 0.0327 and 0.406 ng/mL respectively.

Brimonidine:
After ocular administration of 0.2% eye drops solution in humans, plasma brimonidine concentrations are low. Brimonidine is not extensively metabolised in the human eye and human plasma protein binding is approximately 29%. The mean apparent half-life in the systemic circulation was approximately 3 hours after topical dosing in man.

Following oral administration to man, brimonidine is well absorbed and rapidly eliminated. The major part of the dose (around 74% of the dose) was excreted as metabolites in urine within five days; no unchanged drug was detected in urine. *In vitro* studies, using animal and human liver, indicate that the metabolism is mediated largely by aldehyde oxidase and cytochrome P450. Hence, the systemic elimination seems to be primarily hepatic metabolism.

Brimonidine binds extensively and reversibly to melanin in ocular tissues without any untoward effects.

Accumulation does not occur in the absence of melanin. Brimonidine is not metabolised to a great extent in human eyes.

Timolol:
After ocular administration of a 0.5% eye drops solution in humans undergoing cataract surgery, peak timolol concentration was 898 ng/mL in the aqueous humour at one hour post-dose. Part of the dose is absorbed systemically where it is extensively metabolised in the liver. The half-life of timolol in plasma is about 7 hours. Timolol is partially metabolised by the liver with timolol and its metabolites excreted by the kidney. Timolol is not extensively bound to plasma protein.

INDICATIONS AND USAGE

Reduction of intraocular pressure (IOP) in patients with chronic open-angle glaucoma or ocular hypertension who are insufficiently responsive to topical beta-blockers.

CONTRAINDICATIONS

- Reactive airway disease including bronchial asthma or a history of bronchial asthma, severe chronic obstructive pulmonary disease
- Sinus bradycardia, sick sinus syndrome, sino-atrial nodal block, second or third degree atrioventricular block, not controlled with a pace-maker, overt cardiac failure, cardiogenic shock
- Use in neonates and infants (children under the age of 2 years; see PAEDIATRIC USE section)
- Patients receiving monoamine oxidase (MAO) inhibitor therapy
- Patients on antidepressants which affect noradrenergic transmission (e.g. tricyclic antidepressants and mianserin)
- Hypersensitivity to the active substances or any of the excipients

WARNINGS AND PRECAUTIONS

Like other topically applied ophthalmic agents, the active substances (brimonidine tartrate and timolol) in COMBIGAN® may be absorbed systemically. No enhancement of the systemic absorption of the individual active substances has been observed. Some patients have

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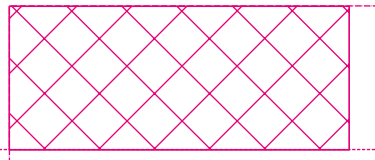

experienced ocular allergic type reactions (allergic conjunctivitis and allergic blepharitis) with COMBIGAN® in clinical trials. Allergic conjunctivitis was seen in 5.2% of patients. Onset was typically between 3 and 9 months resulting in an overall discontinuation rate of 3.1%. Allergic blepharitis was uncommonly reported (<1%). If allergic reactions are observed, treatment with COMBIGAN® should be discontinued.

Due to the beta-adrenergic component, timolol, the same types of cardiovascular and pulmonary adverse reactions as seen with systemic beta-adrenoceptor blocking agents may occur.

Caution should be exercised in treating patients with severe or unstable and uncontrolled cardiovascular disease (e.g., coronary heart disease, Prinzmetal's angina and cardiac failure) and hypotension. Cardiac failure should be adequately controlled before beginning therapy. Patients with a history of severe cardiac diseases should be watched for signs of cardiac failure and have their pulse rates checked. Due to its negative effect on conduction time, beta-blockers should only be given with caution to patients with first degree heart block. Cardiac and respiratory 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.

COMBIGAN® has not been studied in children under the age of 18 years. However, in a 3-month phase 3 study in children (ages 2-7 years) with glaucoma inadequately controlled by beta-blockers, the use of brimonidine tartrate ophthalmic solution 0.2% led to a high incidence and severity of somnolence in children 2 years of age and above, especially those weighing ≤ 20 kg.82,100 (See PAEDIATRIC USE section.)

Delayed ocular hypersensitivity reactions have been reported with brimonidine tartrate ophthalmic solution 0.2%, with some reported to be associated with an increase in IOP.

Ophthalmic beta-blockers may impair compensatory tachycardia and increase risk of hypotension when used in conjunction with anaesthetics. The anaesthetist must be informed if the patient is using COMBIGAN®.

Patients with chronic obstructive pulmonary disease of mild or moderate severity should, in general, not receive products containing beta-blockers, including COMBIGAN®; however, if COMBIGAN® is deemed necessary in such patients, it should be administered with caution.

Beta-blockers may also mask the signs of hyperthyroidism and cause worsening of Prinzmetal angina, severe peripheral and central circulatory disorders and hypotension.

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

Caution should be exercised when used concomitantly with systemic beta-adrenergic blocking agents because of the potential for additive effects on systemic beta-blockade. The response of these patients should be closely observed. The use of two topical beta-adrenergic blocking agents is not recommended. COMBIGAN® must be used with caution in patients with metabolic acidosis and untreated phaeochromocytoma.

Beta-adrenergic blocking agents should be administered with caution in patients subject to spontaneous hypoglycaemia or to uncontrolled diabetic patients (especially those with labile diabetes) as beta-adrenergic blocking agents may mask the signs and symptoms of acute hypoglycaemia. The indicatory signs of acute hypoglycaemia may be masked, in particular tachycardia, palpitations and sweating. COMBIGAN® should be used with caution in patients with depression, cerebral or coronary insufficiency, Raynaud's phenomenon, orthostatic hypotension.

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

As with systemic beta-blockers, if discontinuation of treatment is needed in patients with coronary heart disease, therapy should be withdrawn gradually to avoid rhythm disorders, myocardial infarct or sudden death.

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

The preservative in COMBIGAN®, benzalkonium chloride, may cause eye irritation. Patients wearing soft (hydrophilic) contact lenses should be instructed to remove contact lenses prior to application and wait at least 15 minutes after instilling COMBIGAN® before reinsertion. Benzalkonium chloride is known to be absorbed by and discolour soft contact lenses. Avoid contact with soft contact lenses. Patients should be instructed to avoid allowing the tip of the dispensing container to contact the eye or surrounding structures to avoid eye injury and contamination of eye drops.

COMBIGAN® has not been studied in patients with closed-angle glaucoma.

COMBIGAN® has not been studied in patients with hepatic or renal impairment. Therefore, caution should be used in treating such patients.

DRUG INTERACTIONS

No interaction studies have been performed with COMBIGAN®. Although specific drug interactions studies have not been conducted with COMBIGAN®, the theoretical possibility of an additive or potentiating effect with CNS depressants (alcohol, barbiturates, opiates, sedatives, or anaesthetics) should be considered.

There is potential for additive effects resulting in hypotension, and/or marked bradycardia when beta-blocker eye drops are administered concomitantly with oral calcium channel blockers, guanethidine, beta- blocking agents, anti-arrhythmics (including amiodarone), digitalis glycosides parasympathomimetics, and other anti-hypertensives. After the application of brimonidine, very rare (<1 in 10,000) cases of hypotension have been reported. Caution is therefore advised when using COMBIGAN® with systemic antihypertensives. Although timolol has little or no effect on the size of the pupil, mydriasis has occasionally been reported when timolol has been used with mydriatic agents such as adrenaline. Beta- blockers may increase the hypoglycaemic effect of antidiabetic agents. Beta-blockers can mask the signs and symptoms of hypoglycaemia.

The hypertensive reaction to sudden withdrawal of clonidine can be potentiated when taking beta- blockers.

Potentiated systemic beta-blockade (e.g. decreased heart rate, depression) has been reported during combined treatment with CYP2D6 inhibitors [e.g., quinidine, selective serotonin reuptake inhibitors (SSRIs)] and timolol, possibly because quinidine inhibits the metabolism of timolol via the P450 enzyme, CYP2D6.

Concomitant use of a beta-blocker with anaesthetic drugs may attenuate compensatory tachycardia and increase the risk of hypotension, and therefore the anaesthetist must be informed if the patient is using COMBIGAN®. Caution must be exercised if COMBIGAN® is used concomitantly with iodine contrast products or intravenously administered lidocaine. Cimetidine, hydralazine and alcohol may increase the plasma concentrations of timolol.

Tricyclic antidepressants have been reported to blunt the hypotensive effect of systemic clonidine. It is not known whether the concurrent use of these agents with COMBIGAN® in humans can lead to resulting interference with the IOP lowering effect. No data on the level of circulating catecholamines after COMBIGAN® administration are available. Caution, however, is advised in patients taking tricyclic antidepressants which can affect the metabolism and uptake of circulating amines e.g. chlorpromazine, methylphenidate, reserpine.

Caution is advised when initiating (or changing the dose of) a concomitant systemic agent (irrespective of pharmaceutical form) which may interact with α-adrenergic agonists or interfere with their activity i.e. agonists or antagonists of the adrenergic receptor (e.g. isoprenaline, prazosin).

Although specific drug interactions studies have not been conducted with COMBIGAN®, the theoretical possibility of an additive IOP lowering effect with prostamides, prostaglandins, carbonic anhydrase inhibitors and pilocarpine should be considered. Concomitant administration of MAO inhibitors is contraindicated (see CONTRAINDICATIONS section). Patients who have been receiving MAOI therapy should wait 14 days after discontinuation before commencing treatment with COMBIGAN®.

Patients who are receiving a systemic (e.g., oral or intravenous) beta-adrenergic blocking agent and COMBIGAN® should be observed for potential additive effects of beta-blockade, both systemic and on intraocular pressure.

Preclinical safety data:

The ocular and systemic safety profile of the individual components is well established. Preclinical data reveal no special hazard for humans based on conventional studies of the individual components in safety pharmacology, repeated dose toxicity, genotoxicity and carcinogenicity studies. Additional ocular repeated dose toxicity studies on COMBIGAN® also showed no special hazard for humans.

Brimonidine

Brimonidine tartrate did not cause any teratogenic effects in animals, but caused abortion in rabbits and postnatal growth reduction in rats at systemic exposures approximately 37-times and 134-times those obtained during therapy in humans, respectively.

Timolol

In animal studies, beta-blockers have been shown to produce reduced umbilical blood flow, reduced foetal growth, delayed ossification and increased foetal and postnatal death, but no teratogenicity. With timolol, embryotoxicity (resorption) in rabbit and foetotoxicity (delayed ossification) in rats have been seen at high maternal doses. Teratogenicity studies in mice, rats and rabbits, at oral doses up to 4200 times the human daily dose of COMBIGAN®, showed no evidence of foetal malformation.

PREGNANCY

There are no adequate and well-controlled studies with COMBIGAN® in pregnant women. Because animal reproduction studies are not always predictive of human response, COMBIGAN® should be used during pregnancy only if the potential benefit to the mother justifies the potential risk to the foetus.

Brimonidine tartrate

No adequate clinical data on exposed pregnancies are available. Animal studies have shown reproductive toxicity at high maternotoxic doses.

Timolol

Epidemiological studies have not revealed malformative effects but shown 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 COMBIGAN® is administered until delivery, the neonate should be carefully monitored during the first days of life.

Animal studies with timolol have shown reproductive toxicity at doses significantly higher than would be used in clinical practice. COMBIGAN® should not be used during pregnancy unless clearly necessary.

LACTATION

Timolol is excreted in human milk. It is not known if brimonidine is excreted in human milk but is excreted in the milk of the lactating rat. Therefore, COMBIGAN® should not be used by women breast- feeding infants.

PAEDIATRIC USE

COMBIGAN® should not be used in neonates and children under the age of 2 years old. The safety and effectiveness of COMBIGAN® in children and adolescents have not been established and therefore, its use is not recommended in children or adolescents. There are no adequate and well-controlled studies with COMBIGAN® in children (less than 18 years old). In a 3-month, Phase 3 study in children (ages 2-7 years) with glaucoma inadequately controlled by beta-blockers, a high prevalence of somnolence (55%) was reported with brimonidine tartrate ophthalmic solution 0.2% as adjunctive treatment to topical beta- blockers. This was severe in 8% of the children and led to discontinuation of treatment in 13%. The incidence of somnolence decreased with increasing age, the least being in the 7 year old age group (25%), but was more affected by weight, occurring more frequently in children weighing ≤ 20 kg (63%) compared to those weighing > 20 kg (25%).

During post-marketing surveillance, apnoea, bradycardia, coma, hypotension, hypothermia, hypotonia, lethargy, pallor, respiratory depression, and somnolence have been reported in neonates, infants, and children receiving brimonidine either for congenital glaucoma or by accidental ingestion (see CONTRAINDICATIONS section).

GERIATRIC USE

No overall differences in safety and effectiveness have been observed between elderly and other adult patients.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

COMBIGAN® has minor influence on the ability to drive and use machines. COMBIGAN® may cause transient blurring of vision, visual disturbance, fatigue and/or drowsiness which may impair the ability to drive or operate machines. Patients who engage in activities such as driving and operating machinery should be cautioned of the potential for a decrease in mental alertness. The patient should wait until these symptoms have cleared before driving or using machinery.

ADVERSE EVENTS

Based on 12 month clinical data, the most commonly reported ADRs were conjunctival hyperaemia (approximately 15% of patients) and burning sensation in the eye (approximately 11% of patients). The majority of cases was mild and led to discontinuation rates of only 3.4% and 0.5% respectively.

The following adverse drug reactions were reported during clinical trials with COMBIGAN®:

Eye disorders

Very Common (>1/10): conjunctival hyperaemia, burning sensation in the eye Common (>1/100, <1/10): stinging sensation in the eye, eye pruritus, allergic conjunctivitis, conjunctival folliculosis, visual disturbance, blepharitis, epiphora, corneal erosion, superficial punctate keratitis, erythema eyelid, eye dryness, eye discharge, eye pain, eye irritation, foreign body sensation, eyelid oedema, eyelid pruritus

Uncommon (>1/1000, <1/100): visual acuity worsened, conjunctival oedema, follicular conjunctivitis, allergic blepharitis, conjunctivitis, vitreous floater, asthenopia, photophobia, papillary hypertrophy, eyelid pain, conjunctival blanching, corneal oedema, corneal infiltrates, vitreous detachment

Psychiatric disorders

Common (>1/100, <1/10): depression

Nervous system disorders

Common (>1/100, <1/10): somnolence, headache

Uncommon (>1/1000, <1/100): dizziness, syncope

Cardiac disorders

Uncommon (>1/1000, <1/100): congestive heart failure, palpitations, bradycardia

Vascular disorders

Common (>1/100, <1/10): hypertension Respiratory, thoracic and mediastinal disorders

Uncommon (>1/1000, <1/100): rhinitis, nasal dryness

Gastrointestinal disorders

Common (>1/100, <1/10): oral dryness

Uncommon (>1/1000, <1/100): taste perversion, diarrhoea, nausea

Skin and subcutaneous tissue disorders

Common (>1/100, <1/10): eyelid oedema, eyelid pruritus, eyelid erythema

Uncommon (>1/1000, <1/100): allergic contact dermatitis

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