

Kunde:	Export / Pharmaforte	Lackierung:	/
Produkt:	PB ALLERGOCROM 10 ML MAL/SGP	Lackaussparung:	☐ /
Art.-Nr.:	32.1039	Pharmacode:	1410
Format:	148 x 210 mm (Plano)	Zusatzspezifikation:	/
Blindenschrift (FS):	JA / NEIN	Sonstiges:	/
Material:	Offset 60 g (UPM Fine, Fa. Nordland)		
Kleber (ET):	/	Farbtoleranz vorhanden:	JA / NEIN Nr.: FTK_UPH_
Farbe 1:	☒ Schwarz (1/1-farbig)	Farbtoleranz fertigen:	JA / NEIN Nr.: FTK_UPH_
Farbe 2:	☐ /	(6-fache Ausfertigung)	
Farbe 3:	☐ /		
Farbe 4:	☐ /	Korrekturabzug Nr.:	2 (Mockup)
Farbe 5:	☐ /	Erstellt:	01.02.2019 A. Winter
Farbe 6:	☐ /	Freigabe Kunde:	
Farbe 7:	☐ /	Endfreigabe/Gut zum Druck:	

ALLERGOCROM® EYE DROPS

Sodium Cromoglycate 20 mg/ml

Mast cell stabiliser

PRODUCT DESCRIPTION

ALLERGOCROM® eye drops (20 mg/ml sodium cromoglycate) is a clear, colourless to slightly yellow solution available in plastic bottles with dropping inserts and caps containing 10 ml of the eye drops.

PHARMACOLOGY

Pharmacodynamics

Antiallergic eye drops. Cromolyn sodium stabilizes membranes of mast cells after they have been exposed to antigens and thus prevents degranulation and with this the release of various chemical mediators. The mediators are biologically active molecules. They are either preformed and stored in the mast cells (i.e. histamine, kinins), and mediate Type I immediate allergic reactions through their release, or they are synthesized after provocative stimulation (i.e. prostaglandins, leukotrienes) and mediate late type IV inflammatory reactions. Beside other mechanisms of action cromolyn possesses calcium antagonist features. Cromolyn blocks the IgE-receptor linked calcium channel, and therefore blocks the flow of calcium into the cell normally occurring after IgE-binding. As a result, mast cell degranulation is suppressed and histamine release is avoided. Cromolyn sodium is effective in prophylaxis and therapy of an allergic reaction of the eye.

Pharmacokinetics

After single topical eye application to rabbits cromolyn sodium was shown to be present in aqueous humor for at least 7 hours; 24 hours after application no remaining drug was found in the eye. Due to its very low lipid solubility cromolyn sodium has almost no systemic absorption (in humans approximately 0.03%, in rabbits approximately 0.02%). This explains the lack of systemic side effects.

INDICATIONS AND CLINICAL USE

ALLERGOCROM® is indicated for the prophylaxis and treatment of allergic conditions of the eye including acute and chronic conjunctivitis, hay fever conjunctivitis, vernal keratoconjunctivitis.

DOSAGE AND ADMINISTRATION

Instill 1 drop 4 times daily into the conjunctival sac. Children and adults apply the same dosage.

Unscrew the cap covering the nozzle, with a finger retract the lower eye lid until the inner red, moist surface is exposed. Tilt your head back, invert the bottle and gently squeeze out the prescribed number of drops onto the exposed surface of the lower lid avoiding any contact of the bottle with eye or skin. The exact duration of ALLERGOCROM® therapy should be based on the physician's judgement. The treatment with ALLERGOCROM® should not be stopped after symptoms improve. Rather, its use should be continued until the patient is no longer in contact with the allergen (pollen, house dust, mold etc.).

MODE OF ADMINISTRATION

For ophthalmic use only

CONTRAINDICATIONS

In hypersensitivity against one of the ingredients.

WARNINGS AND PRECAUTIONS

Users of soft (hydrophilic) contact lens should refrain from wearing lenses while under treatment with this drug. Wear can be reinserted within a few hours after discontinuation of the drug. A direct contact between contact lens and eye drops should be avoided.

Safety and effectiveness in children below the age of 4 has not been established.

Immediately after applying ALLERGOCROM®, vision will be impaired for a short time. During this time you will not be able to react rapidly and purposefully in the case of unexpected and suddenly occurring events.

Do not drive any vehicle or operate machines during this time.

DRUG INTERACTIONS

Not known.

PREGNANCY AND LACTATION

Although there is no indication of teratogenic effect, ALLERGOCROM® is not recommended for use during the first three months of pregnancy.

ADVERSE REACTIONS

Hypersensitivity and allergic reaction to benzalkonium chloride may occur.

In rare cases the sensation of temporary burning, foreign body sensation and chemosis have been reported.

OVERDOSAGE

Overdosing or intoxications are not to be expected when ALLERGOCROM® is used properly. Due to its very low lipid solubility, cromolyn sodium has almost no systemic absorption (in humans approximately 0.03%, in rabbits approximately 0.02%). This explains the lack of systemic side effects.

STORAGE CONDITIONS

Do not store above 30°C.

AVAILABILITY OF DOSAGE FORMS

10 mL

AVAILABLE PACK SIZE

1 x 10 mL

MANUFACTURER

URSAPHARM Arzneimittel GmbH
66129 Saarbrücken/Germany

DATE OF REVISION

February 2019

