



R&D Bausch + Lomb		ULOTKA PIL		BAUSCH + LOMB	
Nazwa produktu Product Name	Minims Dexamethasone sodium phosphate 0.1% w/v DRP		Kolor nadruku Colours		
			Black		
Kraj Country (ISO)	United Kingdom (UK)		Nr wykrojnika Spec No	5538 rev. F	
Opracowane przez Designed by	5536		Kod Wytwórcy Manufacturer code	77463	
Nr korekty Proof No	1	Data Date	07.05.2024	Kod farmaceutyczny Pharmacode	-
Kod wersji Internal version code	P1UK07		Inny kod Other code	77463 (Data Matrix)	
Rozmiar czcionki Font size	minimum 8,6 pt		Wymiar ulotki PIL size	160 x 240 mm	
Krój czcionki Font used	Frutiger Neue LT W1G Condensed Frutiger Neue LT W1G Condensed Bold		Gramatura papieru Paper weight	60 g/m ²	
Komentarze Comments (Reason for the change)					
Safety updates to leaflet - see attached tracked change version PMR_BNL-24-0181-A Packing Site: Laboratoire Chauvin, Aubenas, France					
Akceptacja Techniczna Technical Approval					
Akceptacja Działu ds. Rejestracji Regulatory Affairs Dept. Approval					

BAUSCH + LOMB

Minims® Dexamethasone Sodium Phosphate 0.1% w/v Eye Drops, solution

Dexamethasone sodium phosphate

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Minims® Dexamethasone Sodium Phosphate eye drops are and what they are used for
2. What you need to know before you use your eye drops
3. How to use your eye drops
4. Possible side effects
5. How to store your eye drops
6. Contents of the pack and other information

1. What Minims® Dexamethasone Sodium Phosphate eye drops are and what they are used for

Minims® Dexamethasone Sodium Phosphate contains a corticosteroid. It is used to treat inflamed eyes (red and painful). The part of the eye affected will vary depending on the cause of the inflammation.

Your doctor may sometimes prescribe other drugs at the same time to make sure that the inflammation is treated effectively. This medicine is indicated for children, adults and the elderly.

2. What you need to know before you use your eye drops

Do not use these drops if:

- you are allergic to the active substance (dexamethasone sodium phosphate) or any of the other ingredients in this medicine (listed in section 6).
- you currently have conditions affecting your cornea (the clear part at the front of your eye) such as damage to the cornea, or an ulcer (open sore/inflammation) on the cornea.
- you have any type of eye infection which you are not currently having treatment for, unless your doctor prescribed other medicines to treat the infection at the same time.
- it is intended for long term continuous treatment in children.

Warning and precautions

Talk to your doctor if you or your family have or have had a history of glaucoma (an increased pressure in your eye(s)). Talk to your doctor if you experience swelling and weight gain around the trunk and in the face as these are usually the first manifestations of a syndrome called Cushing's syndrome (a disorder that occurs when your body makes too much of the hormone cortisol over a long period of time). Suppression of the adrenal gland function may develop after stopping a long-term or intensive treatment with Minims® Dexamethasone Sodium Phosphate. Talk to your doctor before stopping the treatment by yourself. These risks are especially important in children and patients treated with a drug called ritonavir or cobicistat.

Contact your doctor if you experience blurred vision or other visual disturbances.

If you have pre-existing eye infection you can receive Minims® Dexamethasone Sodium Phosphate eye drops only while using specific medicines to treat infection at the same time.

You should avoid treatment with Minims® Dexamethasone Sodium Phosphate for longer than 10 days except under medical supervision. Long-term treatment with dexamethasone may increase the risk of Cushing's syndrome, fungal infection and glaucoma development.

Children

In children, continuous, long term use of these eye drops should be avoided. Check with your doctor if your child has been using this medicine for a long time. The doctor or eye specialist may decide to prescribe an alternative.

Other medicines and your eye drops

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. If you use more than one type of eye medicine, take them at least 5 minutes apart. Eye ointments should be used last.

Minims® Dexamethasone Sodium Phosphate used together with anticholinergics used for pupil dilatation during eye examinations (such as atropine) may increase the risk of increased pressure in your eye(s).

Use of Minims® Dexamethasone Sodium Phosphate together with topical anti-inflammatory medicines (NSAIDs) may increase the potential for corneal healing problems.

Minims® Dexamethasone Sodium Phosphate may be less effective if you are taking:

- medicine used to treat epilepsy (phenytoin, phenobarbitone)
- medicine used to make breathing easier by widening the airways during cold or flu (ephedrine)
- medicine used to treat tuberculosis (a serious illness that mainly affects the lungs) (rifampicin).

Minims® Dexamethasone Sodium Phosphate can decrease the effects of medicines similar to aspirin called salicylates (indicated for inflammation, pain, fever and blood thinning).

Tell your doctor if you are using ritonavir or cobicistat (which are used to treat HIV/AIDS), as this may increase the amount of dexamethasone in the blood.

Pregnancy, breast-feeding and fertility

Tell your doctor or eye specialist, he/she may decide to use these drops or to prescribe you an alternative.

Contact lenses

Your doctor will ask you to remove your contact lenses prior to the use of the drops. There is no information on the effect of this product on contact lenses. Therefore, do not wear contact lenses until the effects of the drops have completely worn off as contact lenses may increase the risk of eye infection.

Driving and using machines

As with all eye drops, your vision may be blurred and you may have other visual disturbances after putting the drops in. Wait until your vision is clear before driving or using machines.

Minims® Dexamethasone Sodium Phosphate contains sodium dihydrogen phosphate dihydrate and disodium phosphate

This medicine contains 0.16mg phosphates in each drop which is the equivalent of 3.95mg/ml. If you suffer from severe damage to the clear layer at the front (the cornea), phosphates may cause in very rare cases cloudy patches on the cornea due to calcium build-up during treatment.

R&D Bausch + Lomb		ULOTKA PIL		BAUSCH + LOMB	
Nazwa produktu Product Name	Minims Dexamethasone sodium phosphate 0.1% w/v DRP		Kolor nadruku Colours		
			Black		
Kraj Country (ISO)	United Kingdom (UK)		Nr wykrojnika Spec No	5538 rev. F	
Opracowane przez Designed by	5536		Kod Wytwórcy Manufacturer code	77463	
Nr korekty Proof No	1	Data Date	07.05.2024	Kod farmaceutyczny Pharmacode	-
Kod wersji Internal version code	P1UK07		Inny kod Other code	77463 (Data Matrix)	
Rozmiar czcionki Font size	minimum 8,6 pt		Wymiar ulotki PIL size	160 x 240 mm	
Krój czcionki Font used	Frutiger Neue LT W1G Condensed Frutiger Neue LT W1G Condensed Bold		Gramatura papieru Paper weight	60 g/m ²	
Komentarze Comments (Reason for the change)					
Safety updates to leaflet - see attached tracked change version PMR_BNL-24-0181-A Packing Site: Laboratoire Chauvin, Aubenas, France					
Akceptacja Techniczna Technical Approval					
Akceptacja Działu ds. Rejestracji Regulatory Affairs Dept. Approval					

Art.77463 P1UK07

3. How to use your drops

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The drops are for single use only and provided in single use Minims units, to treat both eyes if necessary. Once opened, use immediately. The eye drops are intended only for use in the eye. Discard any unused portion

Dosage

- The normal adult dose is 1 to 2 drops in one or both eyes as often as directed by your doctor.
- The dose for children will be decided by the doctor or eye specialist.

Method of administration

If you are putting the eye drops in yourself, then follow these instructions carefully:

- Wash your hands.
- Use a mirror, this will help you to see what you are doing.
- Carefully dry your eyes using a tissue. Twist and pull cap to separate from the Minims body (Diagram 1).
- Pull your lower eyelid down gently, and then carefully place 1 or 2 drops inside your lower eyelid. Make sure the dropper does not touch any parts of your eye.
- Close your eye and blink a few times to make sure your eye is covered by the liquid.
- Close the eyelids. It is advisable to press gently on the inner corner of your eyelid for a minute. This will help stop the solution draining into your nose and throat. This is especially advisable in children, the elderly and population at risk.
- Repeat steps 4, 5 and 6 for the other eye if necessary, then throw away the Minims unit, even if some solution remains.

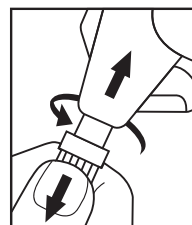


Diagram 1

If your eyes get worse or are not better after a few weeks of using the eye drops, see your doctor or eye specialist or pharmacist.

This medicine should not be used for long term and frequent use without talking to your doctor or pharmacist.

If you use more Minims® Dexamethasone Sodium Phosphate than you should, an overdose is very unlikely to occur. If you suddenly feel unwell after using the drops, tell your doctor or eye specialist or contact the nearest emergency department immediately.

If you forget to use Minims® Dexamethasone Sodium Phosphate, you should take the missed dose as soon as you remember, unless it is nearly time for the next dose, but you should not take a double dose to make up for a missed dose. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Most people who are treated with these eye drops do not suffer from any side effects. The following side effects may occur after taking Minims® Dexamethasone Sodium Phosphate:

- Clouding of the lens of the eye (subcapsular cataract)
- Increased flow of tears
- Eye redness
- Eye stinging and burning may occur
- Infections may be masked
- Secondary infections (caused by long term use of corticosteroids)
- Hypersensitivity. The symptoms of hypersensitivity include difficulty breathing or swallowing, swelling of the face,

lips, throat or tongue and severe skin rash.

- Hormone problems: growth of extra body hair (particularly in women), muscle weakness and wasting, purple stretch marks on body skin, increased blood pressure, irregular or missing periods, changes in the levels of protein and calcium in your body, stunted growth in children and teenagers and swelling and weight gain of the body and face (called 'Cushing's syndrome') (see section 2, "Warnings and precautions").
- Clouding of the lens in the eye (cataract with long-term use)
- Eye irritation
- Drooping of the eyelid (ptosis)
- Eye pain
- Inflammation of the cornea (keratitis)
- Pupil dilation (mydriasis)
- Disease of the cornea leading to inflammation, blurred vision and reduced clarity of vision (ulcerative keratitis)
- An increase of the pressure inside the eye (caused by long term use of corticosteroids)
- An increase of blood sugar levels if you are diabetic
- Impaired healing
- Eye wall wound
- Optic nerve injury

Consult your doctor or pharmacist if you notice any changes to your eyesight.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

Yellow Card Scheme - Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store your eye drops

Keep this medicine out of the sight and reach of children. Do not use this medicine after the expiry date which is stated on the overwrap of each unit and on the carton after the letters "EXP". The expiry date refers to the last day of that month. Do not store above 25°C. Do not freeze. Store in original package in order to protect from light.

The drops are for single use only and provided in single use Minims units, to treat both eyes if necessary. Once opened, use immediately. Discard any unused portion.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What do your eye drops contain

- The active substance is dexamethasone sodium phosphate. Each Minims unit contains approximately 0.5 ml eye drops solution of dexamethasone sodium phosphate 0.1% w/v (0.5 mg).
- The other ingredients are disodium edetate, sodium dihydrogen phosphate dihydrate, anhydrous disodium hydrogen phosphate and purified water.

This medicine does not contain a preservative as it is a sterile single use unit.

What your eye drops look like and contents of the pack

Your eye drops are a colourless solution. Each carton contains 20 units.

Marketing Authorisation Holder:

Bausch & Lomb UK Ltd.
106 London Road - Kingston-upon-Thames - KT2 6TN – UK

Manufacturer:

Laboratoire Chauvin - Z.I.Ripotier - 07200 Aubenas - France

This leaflet was last revised in: April 2024.