

RE: FOI 24/231 Re NHS Eye Drops

Informationservices <Informationservices@mhra.gov.uk>

Thu 28/03/2024 11:39

To [REDACTED]
Dear [REDACTED]

Thank you for your enquiry to the MHRA.

According to our records the following eye drops are approved as mydriatics, for example to dilate the eye for diagnostic or therapeutic procedures.

Pharm Form Type	Authorisation Number	Licensed Product Name	Authorisation Holder Company
EYE DROPS	PL 03468/0068	MINIMS ATROPINE SULPHATE 1%	BAUSCH & LOMB (UK) LIMITED
EYE DROPS	PL 03468/0076	MINIMS PHENYLEPHRINE HYDROCHLORIDE 2.5%W/V	BAUSCH & LOMB (UK) LIMITED
EYE DROPS	PL 03468/0077	MINIMS PHENYLEPHRINE HYDROCHLORIDE 10% W/V	BAUSCH & LOMB (UK) LIMITED
EYE DROPS	PL 03468/0084	MINIMS TROPICAMIDE 0.5% W/V	BAUSCH & LOMB (UK) LIMITED
EYE DROPS	PL 03468/0085	MINIMS TROPICAMIDE 1%W/V	BAUSCH & LOMB (UK) LIMITED
EYE DROPS	PL 17509/0007	CYCLOPENTOLATE HYDROCHLORIDE 0.5% W/V EYE DROPS, SOLUTION	ESTEVE PHARMACEUTICALS
EYE DROPS	PL 17509/0007	MYDRILATE 0.5% EYE DROPS	ESTEVE PHARMACEUTICALS
EYE DROPS	PL 17509/0008	CYCLOPENTOLATE HYDROCHLORIDE 1.0% W/V EYE DROPS, SOLUTION	ESTEVE PHARMACEUTICALS
EYE DROPS	PL 17509/0008	MYDRILATE 1.0% EYE DROPS	ESTEVE PHARMACEUTICALS
EYE DROPS, SOLUTION	PL 35533/0162	ATROPINE 1% W/V EYE DROPS, SOLUTION	ASPIRE PHARMA LIMITED
EYE DROPS, SOLUTION	PL 41809/0003	MYDRIACYL 1% W/V EYE DROPS, SOLUTION	ALCON EYE CARE UK LIMITED
EYE DROPS	PL 03468/0070	MINIMS CYCLOPENTOLATE HYDROCHLORIDE 0.5%W/V	BAUSCH & LOMB (UK) LIMITED
EYE DROPS	PL 03468/0071	MINIMS CYCLOPENTOLATE HYDROCHLORIDE 1.0%W/V	BAUSCH & LOMB (UK) LIMITED

The ingredients are as follows:

Minims Atropine Sulphate 1%

Atropine Sulphate PhEur 1% w/v.

List of excipients

Hydrochloric acid
Purified water

Minims Phenylephrine Hydrochloride 2.5%w/v

Phenylephrine Hydrochloride Ph. Eur. 2.5% w/v.

List of excipients

Sodium metabisulphite
Disodium edetate
Purified water

Minims Phenylephrine Hydrochloride 10%w/v

Phenylephrine Hydrochloride Ph. Eur. 10% w/v.

List of excipients
Purified water.
Sodium metabisulphite
Disodium edetate

Minims Tropicamide 0.5 %.

Tropicamide Ph.Eur 0.5 % w/v.

List of excipients

Sodium hydroxide
Hydrochloric acid
Purified water

Minims Tropicamide 1%.

Tropicamide Ph.Eur 1 % w/v.

List of excipients

Sodium hydroxide
Hydrochloric acid
Purified water

**Mydrilate 0.5% Eye Drops
Cyclopentolate Hydrochloride 0.5% w/v Eye Drops, Solution**

Cyclopentolate Hydrochloride BP 0.5 % w/v

List of Excipients

Boric acid
Potassium chloride
Benzalkonium chloride solution
Purified water

**Mydrilate 1.0% Eye Drops
Cyclopentolate Hydrochloride 1.0% w/v Eye Drops, Solution**

Cyclopentolate Hydrochloride BP 1.0 % w/v

List of Excipients

Boric acid
Potassium chloride
Benzalkonium chloride solution
Purified water.

Atropine 1% w/v eye drops, solution

1 ml of solution contains 10 mg atropine sulfate.

List of excipients

Benzalkonium chloride
Boric Acid
Hypromellose
Hydrochloric acid and/or Sodium hydroxide (for pH adjustment)
Water for injections

MYDRIACYL 1% w/v eye drops, solution

Tropicamide 1.0% w/v

List of excipients

Benzalkonium chloride, Disodium edetate, Sodium chloride, Sodium Hydroxide and/or Hydrochloric acid and Purified water.

Minims Cyclopentolate Hydrochloride 1.0%.

Cyclopentolate hydrochloride BP 1.0% w/v.

List of excipients

Hydrochloric acid
Purified water

Minims Cyclopentolate Hydrochloride 0.5%.

Cyclopentolate hydrochloride BP 0.5% w/v.

List of excipients

Hydrochloric acid
Purified water

From: [REDACTED]
Sent: Tuesday, March 5, 2024 4:01 PM
To: MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Subject: FOI 24/231 Re NHS Eye Drops

MHRA,
I wish to make a FOIR- please fulfill within 21 days as per FOI framework.
"What are the full ingredients of the eye drops used in NHS hospital ophthalmologist eye clinics?
(the drops used to dilate the eyes to be able to examine them with specialist eye machinery)
if there are more than one class of eye drops used, please state ingredients of all eye drops used."
Thanks
[REDACTED]

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