

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1 NAME OF THE MEDICINAL PRODUCT**

Minims Tropicamide 0.5 %.

### **2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

Clear, colourless, sterile eye drops containing tropicamide Ph.Eur 0.5 % w/v.

### **3 PHARMACEUTICAL FORM**

Single-use, sterile eye drops.

### **4 CLINICAL PARTICULARS**

#### **4.1 Therapeutic indications**

As a topical mydriatic and cycloplegic.

#### **4.2 Posology and method of administration**

*Adults (including the elderly):*

1 drop followed by a second drop after an interval of 5 minutes. A further 1 drop may be instilled after 30 minutes, if required.

*Children:*

At the discretion of the physician.

#### **4.3 Contraindications**

Do not use in patients with a known hypersensitivity to tropicamide.

Tropicamide is contraindicated in narrow angle glaucoma and in eyes where the filtration angle is narrow, as an acute attack of angle closure glaucoma may be precipitated.

#### **4.4 Special warnings and precautions for use**

Use with caution in an inflamed eye, as hyperaemia greatly increases the rate of systemic absorption through the conjunctiva.

Care should be exercised in small children.

Systemic absorption may be reduced by compressing the lacrimal sac at the medial canthus for a minute during and following the instillation of the drops. (This blocks the passage of drops via the naso-lacrimal duct to the wide absorptive area of the nasal and pharyngeal mucosa. It is especially advisable in children.)

Tropicamide may cause increased intraocular pressure. The possibility of undiagnosed glaucoma should be considered in some patients, such as elderly patients. Determine the intraocular pressure and an estimation of the depth of the angle of the anterior chamber prior to initiation of therapy.

#### **4.5 Interaction with other medicinal products and other forms of interaction**

None known.

#### **4.6 Fertility, Pregnancy and lactation**

There is no evidence as to the drug's safety in human pregnancy, nor is there evidence from animal work that it is free from hazard. This product should only be used in pregnancy if considered essential by the physician.

#### **4.7 Effects on ability to drive and use machines**

Patient warning: Patients who receive a mydriatic may suffer from photophobia and this may impair their ability to drive under certain circumstances.

#### **4.8 Undesirable effects**

Transient stinging, dry mouth and blurred vision may occur following the use of this product.

#### **4.9 Overdose**

Systemic effects from Minims Tropicamide are not expected. Should an overdose occur causing local effects, e.g. sustained mydriasis, pilocarpine or 0.25% w/v physostigmine should be applied.

## **5 PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

Tropicamide is a parasympatholytic agent, which acts by blocking the action of the parasympathetic nervous system. As acetylcholine is the neuro-humoral transmitter at the receptor site of the parasympathetic nervous system, tropicamide competes with acetylcholine for uptake at the receptor sites, thereby blocking its action. The results are mydriasis, due to unopposed action of the dilator pupillae, and cycloplegia.

### **5.2 Pharmacokinetic properties**

No data on the pharmacokinetics of topical tropicamide are available.

### **5.3 Preclinical safety data**

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Sodium hydroxide  
Hydrochloric acid  
Purified water

### **6.2 Incompatibilities**

None known.

### **6.3 Shelf life**

15 months.

**6.4 Special precautions for storage**

Store below 25°C. Do not freeze. Protect from light.

**6.5 Nature and contents of container**

A sealed, conical shaped container fitted with a twist and pull-off cap. Each Minims unit is overwrapped in an individual polypropylene/paper pouch. Each container holds approximately 0.5ml of solution.

**6.6 Special precautions for disposal**

Each Minims unit should be discarded after a single use.

**7 MARKETING AUTHORISATION HOLDER**

Bausch & Lomb UK Limited

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**8 MARKETING AUTHORISATION NUMBER(S)**

PL 03468/0084

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

29/01/2011

**10 DATE OF REVISION OF THE TEXT**

13/09/2016