

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Minims Rose Bengal

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1% w/v solution of rose bengal

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Single-use, sterile eye drops solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As a diagnostic stain.

Rose bengal solution stains degenerated conjunctival and corneal epithelial cells. It is particularly useful in demonstrating these changes in Sjögren's syndrome, where lack of tears has caused damage.

4.2 Posology and method of administration

Adults (including the elderly) and Children:

One or two drops, as required.

4.3 Contraindications

Rose bengal can produce severe stinging in dry eyes, where it should be used with care.

4.4 Special warnings and special precautions for use

Rose bengal should not be instilled into the eye when the patient is wearing contact lenses.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

The use of rose bengal over the last 15 years has not shown any adverse effects. In the absence of any teratology studies, however, rose bengal is not recommended in pregnancy unless the therapeutic benefit exceeds the potential risk.

4.7 Effects on ability to drive and use machines

May cause transient blurring of vision on instillation. Warn patients not to drive or operate hazardous machinery until vision is clear.

4.8 Undesirable effects

Rose bengal may discolour the eye lids and/or conjunctiva.

4.9 Overdose

As Minims are single-dose units, overdose is unlikely to occur.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Not applicable.

5.2 Pharmacokinetic properties

Rose bengal stains degenerated conjunctival and corneal epithelial cells. It will resist penetration through a normal cornea as it is virtually unable to pass through the membrane of live cells. Therefore, the majority of solution will be carried with the tear film away from the conjunctiva and lost via the naso-lacrimal ducts. In rabbits, this has been demonstrated to occur within a few minutes, but in humans with a normal function, this would seem to occur within 15 - 30 minutes. Rose bengal remains in the stained structure and does not diffuse further nor penetrate into the aqueous humour from a mucosal defect. Thus, the stain will remain in the damaged corneal cells and be removed together with these cells. Therefore, the concentration of rose bengal absorbed systemically is likely to be negligible.

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
Purified water

6.2 Incompatibilities

Not applicable

6.3 Shelf Life

15 months

6.4 Special precautions for storage

Store below 25°C. Do not freeze. Store in the original container.

6.5 Nature and contents of container

A sealed conical shaped container fitted with a twist and pull off cap made from Ph. Eur. grade polypropylene for containers and closures for parenteral and ophthalmic preparations. Overwrapped in an individual polypropylene/paper pouch. Each container holds approximately 0.5 ml of solution. 20 units are packed into a suitable carton.

6.6 Instructions for use and handling

Each Minims unit should be discarded after a single use.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

PA 118/18/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 1st April 2003

10 DATE OF REVISION OF THE TEXT

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