

2.2 Shelf container

1 case or folding box made of cellulose

REF	pcs.	
34227, 34240	5	1 case / bunch
34228, 34241	50	1 folding box
34229, 34243	5	1 case / bunch
34230, 34244	50	1 folding box

2.3 Transit container

1 corrugated cardboard box made of cellulose

REF	pcs.	
34227, 34240	200	40 cases / bunches
34228, 34241	600	12 folding boxes
34229, 34243	120	24 folding boxes
34230, 34244	600	12 folding boxes

3. Manufacture:

The Pro-Ophta® Eye Dressing S is produced according to specification in hygienic conditions and packed in accordance with applicable packaging specifications.

4. Description

The Pro-Ophta® Eye Dressing S consist of a diagonally elastic fabric and transparent disk made of polycarbonate.

5. Properties

The Pro-Ophta® Eye Dressing S is an elastic, tan-coloured eye dressing with a transparent curved eye disk which is affixed in the centre.

- Transparent, rigid, unbreakable disk
- Allows regular checks on the eye
- pharmaceuticals can be administered
- skin-friendly adhesive – suitable for long term treatment
- quick to apply
- available in 2 disk sizes

Natural rubber latex is not an intentional ingredient in the production of the above mentioned products or its packaging. However, to the best of our knowledge we can't completely exclude any potential contaminations with latex traces from the production or the environment.

6. Intended Purpose

Pro-Ophta® Eye Dressings S are designed to protect eye, for protection from ocular drying and after ophthalmologic surgery. The eye dressing can be used in case of Lagophthalmus, Facial paresis, Sicca syndrome and after Ptosis surgery.

7. Medical device classification

The Pro-Ophta® Eye Dressing S is a medical device of Class I in terms of Rule 4. (Council Directive 93/42/EEG concerning medical devices, Annex IX)

8. Biological evaluation and biocompatibility (DIN EN ISO 10993)

The starting materials used in the manufacture of Pro-Ophta® Eye Dressing S are safe if the product is used appropriately and for the purposes intended.

The purpose of this documentation and the statements made therein is to show that there is no risk involved in the use of the medical device Pro-Ophta® Eye Dressing S and that it is designed, manufactured and packaged in such a way that it will not compromise the clinical condition or the safety of patients, or the safety and health of users and other persons when the product is used under the conditions and for the purposes intended.

9. Stability

Stored appropriately – keep dry, protected from dust and light - the Pro-Ophta® Eye Dressing has a shelf life of 5 years from the date of manufacture.

10. Disposal

The user is advised to observe current national legislation, norms and guidelines, regulating the disposal of medical refuse. Packaging materials must also be disposed of in compliance with applicable national requirements.

Lohmann & Rauscher GmbH & Co. KG
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signed by
Dr. Klemens Schulz
Executive Board/ Chief Portfolio Officer