

Pro-Ophta[®] Eye Dressing S

REF 34227 - 34230

September 2021

1. Composition of the product

Pro-ophta[®] eye dressings S consist of a round and convex transparent disc made of polycarbonate (Makrolon 2458 or Calibre 2061-22) and of cross-elastic fabric made of 70 % viscose and 30 % polyamide, coated on one side with a polyacrylate adhesive.

The adhesive side is covered with a perforated paper, siliconised on one side and printed on the reverse side.

This product data sheet covers the following items:

REF	Product description	Size
34227	Pro-ophta [®] Eye Dressing S	small
34228	Pro-ophta [®] Eye Dressing S	small
34229	Pro-ophta [®] Eye Dressing S	large
34230	Pro-ophta [®] Eye Dressing S	large

2. Packaging, structure and composition

2.1 Unit Container

1 tubular bag made of polypropylene

2.2 Shelf Container

1 cover (container) resp. folding box made of cellulose:

REF	pieces	
34227, 34229	5	1 cover / container
34228, 34230	50	1 folding box

2.3 Transit Container

1 corrugated cardboard box made of cellulose

REF	pieces	
34227	200	40 covers / container
34228, 34230	600	12 folding boxes
34229	120	24 folding boxes

3. **Manufacture**

The Pro-ophta® eye dressing S is produced according to specification in hygienic conditions and packed as described in its relevant packaging specification.

4. **Description**

The Pro-ophta® eye dressings S are non-sterile, individually sealed, light-brown eye dressings with transparent discs in watch glass shape in the product sizes large and small.

5. **Properties**

- transparent, rigid, unbreakable disk
- allows regular checks of the eye
- pharmaceuticals can be administered
- skin-friendly adhesive — suitable for long-term treatment
- quick to apply
- available in 2 disk sizes

6. **Intended purpose**

For eye protection, for protection from ocular drying and after ophthalmologic surgery.

7. **Medical device classification**

The Pro-ophta® eye dressings S is a medical device of class I according to Rule 4 (according to Regulation (EU) 2017/745).

8. **Biological evaluation and biocompatibility (DIN EN ISO 10 993)**

The starting materials used in the manufacture of Pro-ophta® eye dressings S are safe if the product is used appropriately.

The purpose of this documentation and the statements made therein is to show that there is no risk involved in the use of the product 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 used under the conditions and for the purposes intended.

9. **Requirements regarding the safety/harmlessness of the constituents**

Cover paper, siliconised on one side

The cover paper contains a maximum of 0.2 % colophony.

Eye disc made of polycarbonate injection moulding granulate Calibre 2061-22

Disks made of polycarbonate injection molding granules CALIBRE 2061-22 may contain ADM (animal derived material).

The following declaration is available from the manufacturer of the polycarbonate:

“One or more additives used in above mentioned formulation [CALIBRE™ 2061 TRP Polycarbonate Resin, colour TC030003] have been synthesized from animal extracts.

We would like to refer to the attached statement of APME, the Association of Plastic Manufactures in Europe (“APME Statement on the Use of Tallow Derivatives for Food Contact Plastics – January 2002.”)

In view of the severe thermal and chemical treatments that the additives undergo during the successive process steps, it is concluded that these plastic materials do not pose any risk to people`s health in respect of TSE/BSE.”

10. Stability

Stored appropriately (keep dry, protected from dust and light) Pro-ophta® eye dressings S have a shelf life of 5 years from the date of manufacture.

11. Disposal

The user is advised to observe current national legislation, standards, and guidelines regulating the disposal of medical waste.

Packaging materials must also be disposed of in compliance with applicable national requirements.

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signed by

Peter Grillitsch
Director Global Marketing