

Manufacturer: TECHNOVENT LIMITED Unit 5, York Park, Bridgend Industrial Estate Bridgend, CF31 3TB, UK Tel: +44 (0) 1656 768566 www.technovent.com



INSTRUCTIONS FOR USE

Opsil Artificial Eye Lubricant

PRODUCT DESCRIPTION:

Material for the lubrication of artificial eyes.

INTENDED USE:

Opsil fluid is a silicone-based preparation used as a lubricant for artificial eyes. The specific lubricating characteristic of Opsil makes it extremely effective at relieving irritation and discomfort which can occur when wearing artificial eyes.

INTENDED USERS:

Opsil is intended for use by patients with artificial eyes.

INTENDED PATIENT GROUP:

Opsil is intended to be used on patients with artificial eyes due to the loss of the eye due to tumour surgery or trauma of the craniofacial region.

INDICATIONS OF USE:

Opsil Artificial Eye Lubricant is useable in most situations – see Intended Use (above) for conditions indicating the use of the device.

CONTRAINDICATIONS/LIMITATIONS OF USE:

If any skin irritation occurs stop using immediately.

PRODUCT RANGE:

| M901 | Opsil – Standard (15ml) |
|------|-------------------------|
| M902 | Opsil – Thick (15ml) |

DETAILED DESCRIPTION:

A common cause of discomfort, irritation and dryness experienced from time to time by artificial eye prosthesis wearers is excessive protein accumulation upon the surface of the prosthesis. Protein is present within the tears to feed the natural eye. If the natural eye is absent the protein is no longer absorbed and can build up upon the surface of the prosthesis causing irritation and dryness, hindering eyelid closure and affecting the cosmetic appearance of the prosthesis.

Contact lens cleaning solutions can be used to help remove accumulations of protein. Manufacturers and your Ocularists instructions should be followed.

The tears also contain natural oils. If the oil concentration is low, natural lubrication is lessened and may require supplementation. Opsil will help.

User Instructions:

Silicone oil is a highly effective lubricant. Only minimal application is necessary. Initially one drop, three to four times a day should suffice but can be increased to two drops three to four times a day if necessary. Over application may leave the eyelids and the surface of the prosthesis greasy.

If symptoms persist contact your Ocularist, General Practitioner or Ophthalmologist.

Do not remove your artificial eye prosthesis and leave out for too long, socket contracture can occur very quickly.

In order to keep the tip of the dropper bottle clean, it is recommended that you try to avoid contact between the dropper tip and the surface of the artificial eye or surrounding skin.

STORAGE:

Opsil is supplied in plastic dropper bottles and it is recommended that it is stored in its original container. Replace the cap securely after use. It is recommended that it is stored at ambient temperature (between 15 and 30 degrees Celsius) and out of direct sunlight. Do not use if the packaging is open or has been damaged and do not use after the labelled expiry date. Keep out of the sight and reach of children.

PRECAUTIONS / RESIDUAL RISKS / SIDE EFFECTS:

- Opsil is designed for external use only. Avoid use on broken skin.
- In the unlikely event of a localized allergic reaction to the material, stop using immediately and seek advice from Technovent.

DISPOSAL:

Disposal of the materials should follow local regulations and environmental requirements taking different contamination levels into account.

| HARMONISED SYMBOLS: | |
|---|---|
| Consult Instructions for Use | LOT Lot Number |
| Manufacturer | REF Product Code/Ref |
| Manufacturing Date | Do Not Store in Direct Sunlight |
| Expiry Date | Do Not Use if Packaging is Open/Damaged |
| ^{15℃} J ^{30℃} Store Between 15-30 Degrees Celsius | MD Medical Device |
| EC REP Authorised Representative in the European Community | |

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