

Instruction For Use

IGEL

LENS LUBRICANT EYE DROPS

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| 1 | IGEL REFRESHING DROPS |
| 2 | IGEL COMFORT DROPS |

PATIENT PRODUCT INSTRUCTIONS FOR USE & SAFETY INFORMATION

PLEASE READ THE FOLLOWING INFORMATION CAREFULLY AND KEEP IT FOR REFERENCE.

DECLARATION

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| 1 | IGEL REFRESHING DROPS is manufactured in an ISO 13485 certified facility. This medical device is manufactured under strict GMP conditions and guarantees our customers total quality. |
| 2 | IGEL COMFORT DROPS is manufactured in an ISO 13485 certified facility. This medical device is manufactured under strict GMP conditions and guarantees our customers total quality. |

PRODUCT DESCRIPTION

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| 1 | IGEL REFRESHING DROPS is a sterile, isotonic solution that contains Sodium Hyaluronate (0.3% in w/v), Sodium Chloride, Anhydrous Disodium Hydrogen Phosphate, Sodium Dihydrogen Phosphate Dihydrate & Polyhexanide. |
| 2 | IGEL COMFORT DROPS is a sterile, isotonic solution that contains Hydroxy Propyl Methyl Cellulose (0.3% in w/v), Sodium Chloride, Boric Acid, Potassium Chloride & Sodium Per Borate. |

ACTIONS

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| 1 | IGEL REFRESHING DROPS is a combination of special agents, that moisten and lubricates your lenses, and help to remove particulate material that may cause irritation and/or discomfort so that they are more comfortable on your eyes, pH & isotonicity are adjusted to lacrimal fluid. |
| 2 | IGEL COMFORT DROPS is a combination of special agents, that moisten and lubricates your lenses, and help to remove particulate material that may cause irritation and/or discomfort so that they are more comfortable on your eyes, pH & isotonicity are adjusted to lacrimal fluid. |

FEATURES

SODIUM HYALURONATE

Forms a lubricating shield to keep in moisture for long lasting eye comfort.

HYDROXYPROPYL METHYLCELLULOSE

Forms a lubricating shield to keep in moisture for long lasting eye comfort.

POLYHEXANIDE

A disinfectant and preservative with powerful biocidal efficacy.

SODIUM PHOSPHATE BUFFER

Keeps solution pH balanced and enhances performance of added electrolytes (sodium and potassium chloride) for more natural lens wear.

INDICATIONS

IGEL REFRESHING DROPS helps to lubricate and moisturize your contact lenses while on the eyes, thus soothes and refreshes your eyes for long lasting comfortable lens wear. For contact lens wearers, the extra moisture of the lens can help to alleviate eye dryness or irritation symptoms such as in case of sensation of dryness, burning and ocular fatigue and other minor complaints of no pathological significance induced, for example, by dust, smoke, dry heat, air conditioning, wind, cold, extended computer screen use or contact lens wear (rigid or soft). It is recommended for daily wear & frequent replacement soft contact lenses and gas permeable & hard contact lenses.

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CONTRAINDICATIONS (REASONS NOT TO USE)

There are no known contraindications for use of the products as listed above. If you are allergic to any ingredient in this product, please do not use.

INSTRUCTIONS FOR USE

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| 1 | If minor irritation, discomfort or blurring occur while wearing lenses, you may apply IGEL drops. |
| 2 | Twist the cap to break open the safety ring. |
| 3 | Apply 2 – 3 drops whenever needed. |
| 4 | Blink several times. |
| 5 | Screw the cap tightly after use. |
| 6 | If discomfort persists, remove lenses and see your eyecare practitioner immediately. |

PRECAUTIONS

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| 1 | Always wash and rinse your hands before handling your lenses. |
| 2 | Store at room temperature. |
| 3 | Use before expiration date marked on the carton and bottle. |
| 4 | Keep container tightly closed when not in use. |
| 5 | Keep out of reach of children |

ADVERSE REACTIONS (Problems and what to do)

The following problems may occur: eyes sting, burn or itch (irritation), comfort is less than when lens was first placed on the eye, feeling of something in the eye (foreign body, scratched area), excessive watering (tearing) of the eye, unusual eye secretions, redness of the eye, reduced sharpness of vision (poor visual acuity), blurred vision, rainbows or halos around objects, sensitivity to light (photophobia), or dry eyes.

If you notice any of the above: **IMMEDIATELY REMOVE YOUR LENSES.**

If the discomfort or problem stops, then look closely at the lens.

If the lens is in any way damaged, DO NOT put the lens back on your eye. Place the lens in the storage case and contact your eye care professional.

If the lens has dirt, an eyelash, or other foreign body on it, or the problem stops and the lens appears undamaged, thoroughly clean, rinse and disinfect the lens, then reinsert it.

If the problem continues, IMMEDIATELY remove the lens and consult your eye care professional.

If any of the above symptoms occur, a serious condition such as infection, corneal ulcer, neovascularization or iritis may be present. Seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage.

HOW SUPPLIED

IGEL REFRESHING DROPS is available in sterile 15 ml plastic bottles packed in carton. Bottles and cartons are marked with lot number and expiry date.

IGEL COMFORT DROPS is available in sterile 10 ml plastic bottles packed in carton. Bottles and cartons are marked with lot number and expiry date.






IN CASE OF COMPLAINT

Please contact your eye-care practitioner with details of your concern. Give details of batch references to assist with prompt processing of concerns.

CONTACT LENS PATIENTS SHOULD FOLLOW INSTRUCTIONS GIVEN BY THEIR EYE CARE PRACTITIONER STRICTLY AND DISCARD THEIR CONTACT LENSES AFTER THE WEARING PERIOD (MODALITY) AS PRESCRIBED BY THE EYE CARE PRACTITIONER.

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| PRODUCT OWNER | |
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| EC | REP | MYM STC. SL Avda, De Los Rosales 32, 28935 Mostoles Madrid, Spain |
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|  | Manufacturer Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC. |
|  | Batch Code or Lot Number Indicates the manufacturer's batch code so that the batch or lot can be identified. |
|  | Caution (See product information) Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself |
|  | Sterile Indicates a medical device that has been subjected to a sterilization process. |
|  | Prescription Device Indicates that the product is a medical device as defined in Malaysian Medical Device Act 737 and Medical Device Regulations 2012 restricts this device to sale by or on the order of a licensed eyecare practitioner. |