

Instruction For Use

IGEL

MULTIPURPOSE DISINFECTING SOLUTIONS

1	IGEL PLUS MULTIPURPOSE SOLUTION
2	IGEL CLEAR, MOIST & REFRESHING MULTIPURPOSE DISINFECTING SOLUTION
3	IGEL CONDITIONING & CLEANING MULTIPURPOSE DISINFECTING SOLUTION

PATIENT PRODUCT INSTRUCTIONS FOR USE & SAFETY INFORMATION

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

DECLARATION

1	IGEL PLUS MULTIPURPOSE SOLUTION 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 CLEAR, MOIST & REFRESHING MULTIPURPOSE DISINFECTING SOLUTION is manufactured in an ISO 13485 certified facility. This medical device is manufactured under strict GMP conditions and guarantees our customers total quality.
3	IGEL CONDITIONING & CLEANING MULTIPURPOSE DISINFECTING SOLUTION 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

1	IGEL PLUS MULTIPURPOSE SOLUTION is a sterile, aqueous, isotonic solution containing Sodium & Potassium Chloride, Disodium Edetate & Power Packed Combination of 4 ingredients which combines Polyhexanide, Poloxamer, Hypromellose & Sodium Phosphate Buffer.
2	IGEL CLEAR, MOIST & REFRESHING MULTIPURPOSE DISINFECTING SOLUTION is a sterile, aqueous, isotonic solution containing Sodium & Potassium Chloride, Disodium Edentate, Polyhexanide, Poloxamer, HPMC, Sodium Hyaluronate and Sodium Phosphate Buffer.
3	IGEL CONDITIONING & CLEANING MULTIPURPOSE DISINFECTING SOLUTION contain Hypromellose, Disodium Edetate, Sodium Chloride, Potassium Chloride, Poloxamer, Polyhexanide, Boric Acid, Borax and Chlorhexidine Gluconate.

ACTIONS

1	IGEL PLUS MULTIPURPOSE SOLUTION is a combination of special agents, that cleans your lenses better, removes protein more effectively, makes your lenses germ free and keeps them moist & well lubricated so that they are more comfortable on your eyes, pH & isotonicity are adjusted to lacrimal fluid.
2	IGEL CLEAR, MOIST & REFRESHING MULTIPURPOSE DISINFECTING SOLUTION is a combination of special agents, that cleans your lenses better, removes protein more effectively, makes your lenses germ free and keeps them double moist so that they are more comfortable on your eyes, pH & isotonicity are adjusted to lacrimal fluid.
3	IGEL CONDITIONING & CLEANING MULTIPURPOSE SOLUTION is a combination of special agents that cleans your lenses better, removes protein more effectively, makes your lenses germ free and keeps them moist & well lubricated 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.
CHLORHEXIDINE GLUCONATE
A disinfectant and preservative with powerful biocidal efficacy.
POLOXAMER
A gentle surfactant and cleaning agent. Removes protein, dirt and debris.
SODIUM PHOSPHATE BUFFER
Keeps solution pH balanced and enhances performance of added electrolytes (sodium and potassium chloride) for more natural lens wear.

INDICATIONS

When use as directed, **IGEL CLEAR, MOIST & REFRESHING MULTIPURPOSE DISINFECTING SOLUTION / IGEL PLUS MULTIPURPOSE SOLUTION** cleans, rinses, disinfects, lubricates, moisturizes, removes protein and stores contact lenses. The solution is indicated for **all soft contact lenses under Daily Wear and Frequent Replacement**. The packaging includes a lens case for storage of contact lenses during chemical disinfection.

When use as directed, **IGEL CONDITIONING & CLEANING MULTIPURPOSE DISINFECTING SOLUTION** cleans, rinses, disinfects, lubricates, moisturizes, removes protein and stores contact lenses. The solution is **only indicated for rigid gas permeable and hard contact lenses** and strictly not to be used on soft contact lenses. The packaging includes a lens case for storage of contact lenses during chemical disinfection.

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.

PROPER LENS CARE PRACTICES

To ensure proper disinfection of the contact lenses, you must follow the instructions completely. Do not skip any steps. Always wash, rinse and dry your hands before handling your lenses. This will help prevent eye infections by removing dirt and oils that could get on the lenses. Clean, rinse and disinfect your lenses each time you remove them. Always handle the same lens, the right or the left, first in order to avoid mix-ups. After use, always empty and rinse the lens case with fresh **IGEL** multi-purpose solution, and allow to air dry. Replace your lens case monthly.

INSTRUCTIONS FOR USE

1	Always wash your hands and dry them with a clean towel before handling your lenses.
2	Always start with the same lens – either right or left side of the eye to avoid confusion.
3	Apply at least 3 drops of the IGEL solution to each lens surface.
4	Gently rub the lens using a backward and forward motion for 20 seconds per side.
5	Rinse both side of the lens surfaces thoroughly with the IGEL solution.
6	Place the lens in the lens case and fill the well with the IGEL solution.
7	Make sure the IGEL solution covers the lens fully.
8	Replace the cap and screw tight. Repeat the procedure with the other eye's lens.
9	Allow the contact lenses to soak in IGEL solution for at least 4 hours.
10	Remember always to use fresh IGEL solution – never reuse any solution.

WARNINGS: PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD RESULT IN SERIOUS INJURY TO THE EYE

It is essential that you follow your eye care professional’s directions and all labeling instructions for proper use and care of your lenses and lens care products, including the lens case. Eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision. Daily wear lenses are not indicated for overnight wear and should not be worn while sleeping. Clinical studies have shown the risk of serious adverse reactions is increased when these lenses are worn overnight. Extended wear lenses should be regularly removed for cleaning and disinfection or for disposal and replacement on the schedule prescribed by your eye care professional. Clinical studies have shown that there is an increased incidence of serious adverse reactions in extended wear contact lens users as compared to daily wear contact lens users. Studies have also shown that the risk of serious adverse reactions increases the longer extended wear lenses are worn before removal for cleaning and disinfection or for disposal and replacement. Studies have also shown that smokers have a higher incidence of adverse reactions. If you experience eye discomfort, excessive tearing, vision changes, redness of the eye, immediately remove your lenses and promptly contact your eye care professional. It is recommended that contact lens wearers see their eye care professional twice each year, or if directed, more frequently.

You should fill your lens case with fresh **IGEL** solution every time you store your lenses, and never “top-off” or re-use solution. You should discard your solution immediately after your lenses have been removed from the lens case. You should not expose or store your lenses in or rinse your lens case with any water, such as tap, bottled or distilled, or with any non-sterile solution. Empty, then clean and rinse your lens case with fresh **IGEL** multi-purpose solution. Air dry your lens case each time you remove your lenses. In order to permit excess solution to drain, you can flip over your lens case while air drying. Replace your lens case monthly. Failure to discard solution from lens case after each use or use of water to care for your lenses may lead to contamination resulting in eye injury and potential loss of vision.

IMPORTANT SAFETY INFORMATION

1	Always follow the product directions for use. Failure to follow product directions may lead to vision loss.
2	Visit your eye care practitioner regularly.
3	Always wash and dry hands before handling lenses.
4	Do not use tap water, bottled water or saliva with lenses or lens case.
5	Only use fresh IGEL solution to clean and disinfect contact lenses.
6	Always discard any remaining solution in your lens case after each disinfection cycle.
7	Saline or rewetting drops will not disinfect your lenses.
8	Always replace your solutions, lenses and lens case as directed.
9	To avoid contamination, do not touch tip of container to any surface. Replace cap after using.
10	Not for use with heat (thermal) disinfection.

PRECAUTIONS

1	Always discard solution from lens case after each use
2	Keep the bottle tightly closed when not in use
3	Use before expiration date marked on the carton and bottle
4	Discard remaining solution within 90 days after opening
5	Keep out of reach of children
6	Store at room temperature

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 Plus Multipurpose Solution is available in sterile 500 ml and 60 ml plastic bottles packed in carton with a lens case. Bottles and cartons are marked with lot number and expiry date.

IGEL Clear, Moist & Refreshing Multipurpose Disinfecting Solution is available in sterile 360 ml and 60 ml plastic bottles packed in carton with a lens case. Bottles and cartons are marked with lot number and expiry date.

IGEL Conditioning & Cleaning Multipurpose Disinfecting Solution is available in sterile 120 ml plastic bottles packed in carton with a lens case. 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.

PRODUCT OWNER	
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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.