

INSTRUCTIONS FOR USE

ULTRASTOP ANTIFOG AGENT

15 ml spray

25 ml bottle with dropper pipette

PROPERTIES

ULTRASTOP Antifog Agent is a clear, colourless solution containing a combination of surface-active substances in an alcohol-aqueous matrix (ethanol, purified water, < 5% surface-active substances).

The medical device is available in two commercial forms:

- ULTRASTOP Antifog Agent 15 ml spray
- ULTRASTOP Antifog Agent 25 ml bottle with dropper pipette

INTENDED USE

ULTRASTOP is an anti-fogging agent for medical optics.

Surface-active substances in a special combination form a clear and transparent layer on the treated surfaces. This very thin film has the effect of preventing droplet formation and, in this way, prevents the surface from fogging up with condensed water vapour.

ULTRASTOP can also be used to reduce optical glasses or medical goggles from fogging up during medical examinations or surgical procedures.

AREAS OF APPLICATION

ULTRASTOP is an anti-fogging agent for medical examination mirrors and medical optical devices that do not require strict aseptic handling. The application time is usually less than 60 minutes.

ULTRASTOP Antifog Agent is suitable for:

- medical examination mirrors (e.g. laryngeal and epipharyngeal mirrors, dental mirrors) and endoscope lenses (especially in ENT medicine, for colonoscopy),
- optical glasses and medical goggles,
- lenses and mirrors in microscopes and other medical optics.

NOTES FOR APPLICATION

ULTRASTOP Antifog Agent is intended for use by healthcare professionals.

• Applying the solution

Apply a small amount of ULTRASTOP Antifog Agent either directly or using a non-fibrous cloth moistened with ULTRASTOP to the dry, clean surface and spread evenly. Allow it to act for a short time and, after evaporation, if necessary, polish gently with a dry, clean, non-fibrous cloth.

ULTRASTOP Antifog Agent does not smear when applied correctly, but if it's applied too thickly, the surface may appear somewhat cloudy. In this case, we recommend that you clean the surface with distilled water and to treat it again as described above.

• Adhesion time and application rate

The adhesion time can vary greatly depending on the equipment used, the body cavity treated and any contamination of the lens. The application can be repeated as often as necessary during the procedure/examination, considering the application instructions given above.

PRECAUTIONS FOR SAFE USE

- ULTRASTOP is suitable for use on glass and plastics. If these materials are already coated or if there is any doubt about the resistance of a material, contact the respective manufacturer or distributor of the object to be treated.

- ULTRASTOP contains high-percentage alcohol (ethanol). Keep open bottles or cloths soaked with ULTRASTOP away from heat sources to avoid ignition of the solution.
- The sucker of the pipette set (25 ml bottle with dropper pipette) is made of natural rubber, which may cause allergic reactions in sensitive persons.

REPORTING SERIOUS INCIDENTS

You should report any serious incident that occurs in connection with the ULTRASTOP Antifog Agent to the manufacturer (e-mail: pms@mono.co.at) and to your competent authority:

Ireland – Health Products Regulatory Authority

Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2 – IE

E-mail: devicesafety@hpra.ie, website: <http://www.hpra.ie/>

Malta – Malta Medicines Authority - Medical Devices Unit Medicines Authority

Sir Temi Żammit Buildings, Malta Life Sciences Park San Ġwann SGN 3000 – MT

Tel : +356 2343 9000, e-mail: devices.medicinesauthority@gov.mt

Website: <http://www.medicinesauthority.gov.mt/medicaldevices>

STORAGE INSTRUCTIONS

- Do not store above 25 °C.
- Keep away from light.

SHELF LIFE

ULTRASTOP is stable until the expiry date stated on the folding carton and label if stored correctly. The expiry date refers to the last day of the month indicated.

Shelf life after first use:

The solution must be used within 8 weeks after first use.

OTHER IMPORTANT INFORMATION

Explanation of the symbols on folding box and label:



Manufacturer



Distributor



Medical device



Article code



Batch No.



Use by date



Do not store above 25 °C



Keep away from light



Consult instructions for use!



Caution: see "Precautions for safe use".

Scan the QR code on the folding box for the instructions for use in

bg/cs/da/de/el/en/es/et/fi/fr/hr/hu/it/lt/lv/nl/pl/pt/ro/sk/sl/sv.

Manufacturer: MoNo chem-pharm Produkte GmbH, Leystraße 129, 1200 Vienna – AT

e-mail: pms@mono.co.at

Distributor: SIGMAPHARM Arzneimittel GmbH, Leystraße 129, 1200 Vienna – AT

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