INSTRUCTIONS FOR USE ULTRASTOP pro med. Solution Antifog Agent

PROPERTIES

ULTRASTOP pro med. is a sterile anti-fogging agent for medical optics.

ULTRASTOP pro med. reliably prevents fogging of the surfaces of 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.

COMPONENTS

ULTRASTOP pro med. contains a combination of surface-active substances in an alcohol-aqueous matrix (ethanol, purified water, < 5 % surface-active substances).

AREAS OF APPLICATION

ULTRASTOP pro med. is a sterile anti-fogging agent for medical optics. ULTRASTOP pro med. is particularly suitable for:

- use in **strictly aseptic endoscopy**, which has to be carried out with sterile equipment in hollow organs and body cavities (e.g., laparoscopies, thoracoscopies, arthroscopies, etc.) and for
- medical inspection mirrors and optics (e.g., laryngeal and epipharyngeal mirrors, stroboscopes, dental mirrors, colonoscopes, etc.).

NOTES FOR APPLICATION

ULTRASTOP pro med. is intended to be used by medical professionals.

• Strictly aseptic use

Do not use the contents of the vial if the protective ring around the rubber stopper is damaged before the first withdrawal, as in this case the sterility of the solution may no longer be guaranteed!

Withdrawal of the solution

Disinfect the aluminium cap and rubber stopper (latex-free) with an alcohol-based disinfectant before and after each use. Use only sterile syringes for withdrawal. Do not leave the needle stuck in the rubber stopper! After sterile withdrawal, the contents must be used up within 4 weeks. Observe the storage instructions!

Alternatively, you can remove the solution by opening the rubber stopper. To do this, remove the protective aluminium ring around the rubber stopper. Care must be taken when opening and removing the aluminium cap to avoid the risk of cuts to the hand!

If ULTRASTOP pro med. has been taken out of the vial in this way, use the solution immediately and discard any leftover solution that has not been taken out.

Applying the solution

Apply a small amount of ULTRASTOP pro med. either directly or using a sterile gauze moistened with ULTRASTOP pro med. to the disinfected or sterilised and dry surface and spread evenly. Allow to act for a short time and, if necessary, gently polish with sterile, non-linting gauze after evaporation.

ULTRASTOP pro med. does not smear when applied correctly, but if applied too thickly, the surface may appear somewhat cloudy. In this case, cleaning the surface with distilled water or sterile gauze and re-treatment as indicated above is recommended.

• Duration of action and application rate

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

PRECAUTIONS FOR SAFE USE

ULTRASTOP pro med. is suitable for use on glass and plastics. If these materials are already coated or if there are doubts about the resistance of a material, please contact the respective manufacturer or dealer of the object to be treated.

WARNINGS

- Do not inject! Highly flammable!
- Keep out of reach of children!

STORAGE INSTRUCTIONS

- Do not store above 25°C.
- Keep protected from light.
- Store vial upright.

SHELF LIFE

ULTRASTOP pro med. 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 that month.

Shelf life after opening:

After sterile removal, the contents of the vial must be used within 4 weeks. Observe storage instructions! If the rubber stopper has been opened, the solution must be used immediately, and any residual solution not removed must be discarded.

COMMERCIAL FORMATS

ULTRASTOP pro med. Solution, 30 ml pierceable cap vial

ULTRASTOP pro med. Solution Monodose: 30 x 5ml ULTRASTOP pro med. Solution Monodose (Clinic)

OTHER IMPORTANT INFORMATION

Explanation of the symbols on folding box and label:

644	Manufacturer	REF	Article code
LOT	Batch No.	$\mathbf{\Sigma}$	Use-by Date
Ĩ	Consult instructions for use!		Caution: Do not inject! Highly flammable!
9	Do not use when package is damaged	STERILEA	Sterilised using aseptic processing techniques
25	Do not store above 25 °C	米	Keep away from light
Manufad	Consult instructions for use! Image: Caution: Do not inject! Highly flammable! Do not use when package is damaged Sterilised using aseptic processing techniques		

Manufacturer: MoNo chem-pharm Produkte GmbH, Leystraße 129, 1200 Vienna – AT Distribution: SIGMAPHARM Arzneimittel GmbH. 1200 Vienna – AT

Status of information: September 2021