

IFU/Οδηγίεςχρήσης

Biourisol Diluted (1+9)

Description: Sterile, endotoxin free, non-toxic, non-hemolytic, non-electrolytic aqueous solution suitable for urologic irrigation.

Composition: 1000ml solution contains:

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|---------------------|--------------|
| Sorbitol | 27.0g |
| Mannitol | 5.4g |
| Water for injection | q.s. 1000 ml |

Indications: Biourisol Diluted (1+9) is used for the mechanical intraoperative and post-operative irrigation of the bladder (debris, tissue fragments, blood removal) and for clearance of the surgical field during urological interventions such as transurethral prostatectomy (TURP), open prostatectomy (suprapubic incision), cystoscopy, lithotripsy.

Intended Use: Biourisol Diluted (1+9) is intended to be used for intraoperative and post-operative irrigation of the urinary bladder (debris, tissue fragments, blood removal) in urological interventions, such as transurethral prostatectomy (TURP), open prostatectomy (suprapubic incision), cystoscopy and lithotripsy. Biourisol Diluted (1+9) is also intended to be used for clearance of the surgical field during endoscopy.

Intended users: Biourisol Diluted (1+9) is intended to be handled by healthcare professionals.

Patient population: Biourisol Diluted (1+9) can be used in all age groups.

Intended clinical

benefits: • Biourisol Diluted (1+9) (2.7% sorbitol – 0.54% mannitol solution) has osmolality and pH similar to tissues, thus it is used to dilate the operating field and to wash away debris and blood without damaging the normal tissue.

- Excellent clarity in solution without altering the refractive index of the irrigant significantly at the concentrations used.
- Non-toxic and non-hemolytic irrigant which is beneficial in the unfortunate case of fluid absorption.
- Less time needed for post operative irrigation of the bladder.
- The osmotic diuretic property of mannitol may maintain the effective osmolality of plasma preventing potential adverse effects such as cerebral edema from excess free water.
- Safer modality to be used in TURP procedures by new surgeons as putative hemolytic incidents with water as an irrigation fluid, for example, can be very serious if you cannot control duration of resection, technique of resection and pressure conditions.

Instructions

for use: Check package integrity before use. The solution should not be used if packaging is damaged.

Check the expiry date indicated on the bag. The solution should not be used after the expiry date. Remove the bag from the packaging just before use. Connect the irrigation set to the Biourisol Diluted (1+9) bag according to the operating instructions of the irrigation set made by its manufacturer. After the Biourisol diluted (1+9) bag has been connected to the irrigation set, hang the bag to the appropriate infusion stand.

The volume required will depend on the extent and duration of the intervention and on the post-operative course.

Contraindications: Biourisol Diluted (1+9) is contraindicated in patients with oligo-anuria, fructose-sorbitol intolerance, methyl alcohol intoxication and fructose-1,6-bisphosphatase deficiency.

Side effects: There is no known side effect.

Warnings –

Precautions: Use only if the solution is clear, free from particles and the package is undamaged.

Do not use for injection or intravenous infusion. The solution must be used immediately after opening.

The solution is intended for single use. After use, the unused product is no longer sterile.

Any unused portion of the solution must be discarded.

Do not use after the expiry date stated on the bag.

Storage: Store between 4°C– 25°C.

Content and

Materials: 3000ml - PVC Bag with transparent overwrap.

Notice: Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the Competent Authority.

Disposal: Dispose according to national and local regulations.

Date of issue: 01/2023

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| Do not re-use | Consult instructions for use | Batch number | Use by date | Date of manufacture | Single sterile barrier system with a protective packaging outside |
|  |  |  |  |  |  |
| Temperature limit | Do not use if packaging is damaged | Sterilized using steam or dry heat | Medical Device | Unique Device Identifier | Manufacturer |



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