INSTRUCTION FOR USE FOR TURUSOL

TURUSOL (sorbitol/mannitol)
Sterile Solution for Irrigation

Qualitative composition
Sorbitol 27 g.
Mannitol 5,4g
Water for injection Q.S. 100 ml.

Classification of the product
Medical device – sterilized and pyrogen-free- Class IIa.

Package
1000 ml pre-filled disposable plastic bags which contains TURUSOL Sterile Solution.
3000 ml pre-filled disposable plastic bags which contains TURUSOL Sterile Solution.

Indications
TURUSOL is intended for:
- Irrigation during endoscopic examinations of body cavities;
- Irrigation during urological interventions by endoscopy involving HF current, e.g. TUR (transurethral resections), disintegration of bladder stones, interventions of the ureter, interventions of the renal pelvis etc;
- Irrigation of gynecological interventions by endoscopy involving HF current;
- Irrigation during arthroscopy of the knee, shoulder or other joints involving HF current;
- Postoperative irrigation.

Warnings and special precautions for use
- Do not use if the solution is not transparent and colorless.
- Do not use if the package is opened or damaged.
- The product must be used immediately after opening.
- The product is intended for single use. After use, the unused product is no longer sterile. Do not use product residuals;
- Do not reuse. Once the product has been used for the first time, any residuals of the product are not suitable for the repeated use as the product is no longer sterile.
- Do not resterilize. Repeated sterilization may cause cross-contamination.
- Do not freeze.
- The product must not be administered orally.
- The product contains Phthalates. Do not use with pregnant, lactating women and children.

Special warning
- Do not use TURUSOL Solution in patients with known hypersensitivity to any component of the product.
- Do not use TURUSOL Solution in patients with Oligo-anuria, Fructose-sorbitol intolerance, Methyl alcohol intoxication.
- The irrigation into patient should be performed by a trained medical specialist in specialized premise with appropriate equipment and aseptic conditions.
- Do not inject the solution into blood vessels.
- TURUSOL Solution should be applied with care in Cardiopulmonary diseases, Disturbances of renal function and Disturbances of the acid-base balance.
- Disturbances of the water-electrolyte balance should be corrected in the patient before the use of TURUSOL Solution.
- Excessive volumes of liquids for irrigation that enter into systemic circulation should be considered, if one of the following clinical signals occur: nausea, headache, agitation, drowsiness, confusion, blurred vision or amaurosis during anesthesia local/regional (attesting the systemic leakage of the fluid). When significant volumes of solution are absorbed, there is an additional risk of hemolysis and severe electrolyte imbalance. In the presence of these clinical signals, after blood sampling to evaluate hemostasis, blood sodium and hematocrit, the medical procedure should be immediately stopped and then start with appropriate therapy.

Adverse reactions and side effects
The absorption of large volumes of liquid for irrigation through a perforation or open vessels can lead to circulatory overload, cardiac failure, severe alterations of electrolyte or hemolysis. This can be a problem especially in patients with pre-existing renal disease, or cardiopulmonary.
In the presence of these clinical signals the procedure should be stopped immediately after a blood sample to assess hemostasis, blood sodium and hematocrit and then start with appropriate therapy.
If there is a major absorption of solution, the treatment of excessive hydration is directed to restore the sodium balance and to remove excess of fluid for irrigation. In the majority of patients will occur a spontaneous diuresis. In others it may be useful to use an osmotic diuretic (such as hypertonic glucose or mannitol solution) or administration of a diuretic which will cause the secretion of excess of fluid for irrigation. If symptoms of water intoxication are severe, administration of hypertonic saline solution may be useful to correct the hyper-hydration and the alteration of electrolyte balance.
Turusol Diaco contains sorbitol. If there is undiagnosed hereditary fructose-sorbitol intolerance the administration of solutions containing sorbitol can lead to nausea, hypoglycaemia, elevation of lactate levels, acidosis and acute liver damage, with possible lethal consequences.
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For this reason it is necessary to exclude the possibility of an hereditary fructose intolerance or a fructose-1.6-diphosphatase deficiency before commencement of irrigation. If details on the case history are not available or are not unequivocal a fructose intolerance test must be carried out first. If this is not done there is the possibility of severe complications (including a lethal outcome under certain circumstances).

How to use
- Check package integrity and air tightness before use.
- Check the expiration date indicated on the bag. Do not use after the expiry date.
- Take one of the plastic bag with TURUSOL Solution.
- Turn the cap in the direction of the arrow to break the seal and remove the cap.
- If an irrigation set is used, connect the irrigation set to the bag using an aseptic procedure and the perform the irrigation. The volume required will depend on the extent and duration of the intervention and on the postoperative course.

Shelf life
3 years in an intact package.

How to store
Store at the temperatures from 5 ° to 30 ° C (included), away from direct light and heat, in the adequately closed packaging. The expiry date is applied to the product which is correctly stored in an intact package.

Disposal
The product must be disposed in accordance with applicable laws on medical waste.

<table>
<thead>
<tr>
<th>Symbols used on the packaging</th>
<th>Do not reuse – for single use</th>
<th>Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOT</td>
<td>Batch code</td>
<td>Sterilized using steam or dry heat</td>
</tr>
<tr>
<td>Expire date</td>
<td></td>
<td>Do not resterilize</td>
</tr>
<tr>
<td>Do not use if the package is opened or damaged</td>
<td></td>
<td>Protect from light and heat</td>
</tr>
<tr>
<td>Consult instructions for use</td>
<td></td>
<td>Temperature limit for warehouse storage</td>
</tr>
<tr>
<td>Date of Manufacture</td>
<td></td>
<td>Non - pyrogenic</td>
</tr>
<tr>
<td>Medical device according to Directive 93/42/CEE</td>
<td></td>
<td>Product contains Phtalates</td>
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</tbody>
</table>

Diaco
Biofarmaceutici S.R.L.
Via Flavia 124, 34147
Trieste - Italy

Diaco
1936

Diaco
Medical device according to Directive 93/42/CEE

Diaco
Product contains Phtalates