

PF-723/01/081118/03

PRODUCT DATASHEET

Prefilled Syringe, 10ml

Brand : CURAS®
Category : Urology
Range : Catheters

Product Group : Support Products REF : 20350, 20351



PRODUCT DESCRIPTION

Sterile, disposable prefilled syringe. Available in two options,10ml sterile water and 10% aqueous glycerine solution.

INTENDED USE

The prefilled syringe provides a convenient way to inflate the balloon of Foley catheters. The prefilled syringe is beneficial in ensuring the right volume is used to inflate and that an aseptic procedure is carried out. For single-use and balloon inflation only.

FEATURES & BENEFITS

- Sterile, single-use syringe allows for an aseptic procedure and reduces the risk of infection.
- Pre-measured volume ensures accurate and consistent application of fluid.
- The prefilled solution reduces cost and preparatory work and simplifies balloon inflation.
- The diffusion rate of fill volume in the catheter balloon is sustainably reduced when using a 10% aqueous glycerine solution, thus reducing the need for regular checks and re-inflation.
- Green plunger provides clear visualization that syringe is not for intramuscular and intravenous injections.
- Ready-to-use sterile pack provides a high level of patient safety and convenience.
- Latex-free syringe.

PRODUCT SPECIFICATIONS

REF	Contents	Volume	Colour	Packing	
20350	Sterile water + 10% glycerine	10ml	Clear Barrel, Green Plunger	Sterile Peel Pouch	
20351	Sterile water	10ml	Clear Barrel, Green Plunger	Sterile Peel Pouch	

Composition

- Sterile water + 10% glycerine (REF 20350)
- 10ml sterile water (REF 20351)
- Barrel and plunger made of PP homopolymer
- Protective cap made of TPE (styrene block copolymer)
- DEHP-free

Country of Origin

China



PF-723/01/081118/03

Sterilization

Gamma radiation

Shelf Life

3 years

Selected Standards & Guidelines

- MDD 93/42/EEC
- EN ISO 13485
- ISO 9001
- EN ISO 14971
- EN ISO 15223-1
- EN 1041 +A1
- EN ISO 7886-1
- EN ISO 10993-5
- EN ISO 10993-10
- EN ISO 11137-1
- EN ISO 14644
- EN ISO 11607-1
- EN ISO 11607-2
- ASTM F88
- ASTM F1929
- EN ISO 11737-1
- EN ISO 11737-2
- EN 62366 +A1
- MEDDEV 2.12-1
- ASTM F1980
- ASTM F1929
- EN ISO 10993-1

Recommended Storage Condition

- Store at dry, clean, and well-ventilated area at temperatures between 5° to 30°C (41°-86°F).
- Do not expose the product to radiation, sunlight, UV light, and elevated temperature as it will change the properties of the product.

Proposed Disposal Method

 Dispose of the used syringe into a clinical waste bag or according to the clinical waste protocol, e.g., incineration.

Product Symbols























PACKAGING INFO

REF	EAN-13 Barcode	Inner Box	Carton	Gross Weight	
20350	5051400203503	25 pcs / box	200 pcs / carton	~6 kg	
20351	5051400203510	25 pcs / box	200 pcs / carton	~6 kg	

Components / Material Properties			Recommendations on Waste Handling			
Packaging	Material	Contains PVC	Incinerate	Landfill	Recycle	Reuse
Peel Pouch	Paper + PE		√	(√)		
Inner Box	Cardboard		(√)	(√)	√	
Outer Carton	Corrugated Carton		(√)	(√)	√	
Transport Pallet	Wood				(√)	√

 $[\]sqrt{\ }$ = Highly recommended

 $(\sqrt{})$ = Recommended



PF-723/01/081118/03

ADDITIONAL INFO

- HS Code: 9018319000
- Documentation available upon request. Kindly contact: info@curas.com