

PRODUCT DATASHEET

Prefilled Syringe

Brand	: CURAS [®]
Category	: Urology
Range	: Support Product
Product REF	: 20350
Product Description	: Prefilled Syringe w/10% Aqueous Glycerine, 10ml, Sterile



PRODUCT DESCRIPTION

Curas sterile disposable prefilled syringes are available with 10% aqueous glycerine solution. It is packed individually in peel pouch for easy and hygienic dispensing at the ward level.

INTENDED USE

The prefilled syringe provides a convenient way to inflate the balloon of 100% silicone Foley catheters. This ready-to-use sterile product provides high level patient safety and convenience. The product is beneficial in ensuring the accurate amount of volume is used to inflate the balloon of Foley catheter, whilst ensuring that an aseptic procedure is carried out. This is for single-use and Foley balloon inflation only.

FEATURES & BENEFITS

- The sterile, single-use syringe allows for an aseptic procedure and reduces risks of cross-contamination and Hospital-Acquired Infections (HAI).
- The pre-measured volume ensures accurate and consistent application of fluid into the 100% Silicone Foley balloon.
- The prefilled solution reduces preparatory work for the nursing staff, saves cost due to less nursing time and also simplifies Foley balloon inflation procedure during catheterisation.
- 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.
- The green plunger provides a clear visualization that this syringe is not meant to be used for intramuscular and intravenous injections. It also differentiates the syringe from the version with pure Sterile water.
- The syringe is designed with rounded wings to avoid pressure and damage on package during assembling and delivery.
- The bigger plunger bottom allows comfortable and easy operation by the end-user.
- The prefilled syringe with 10% glycerine is suitable to be used with the silicone Foley catheter.
- Graduation mark is printed on the syringe to provide clear volume indication.
- The safety warning indicated on the syringe helps to avoid misuse of the product.

- The high quality protective cap of the product prevents leakage and contamination.
- The product is DEHP and latex free.
- These prefilled syringes are packed in individual sterile peel pouches to maintain hygiene and sterility.
- The product is packed in the user-friendly inner box to protect the prefilled syringe from dust and contamination before reaching its point of use. It also allows easy dispensing, placement, stacking and storage at the ward level.

PRODUCT SPECIFICATIONS

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

Composition

- Sterile water + 10% glycerine.
- Barrel and plunger made of polypropylene homopolymer.
- Protective cap made of TPE (styrene block copolymer)
- Latex-Free and DEHP-Free

Country of Origin

- China

Sterilization

- Gamma radiation

Shelf Life

- 3 years

Selected Standards & Guidelines

- ISO 9001:2015
- MDD 93/42/EEC (Class 1s), amended by Directive 2007/47/EC
- EN ISO 13485:2016

Recommended Storage Condition

- Store at dry, clean, and well-ventilated area at room temperatures between 15° to 25°C (59°-77°F).
- Avoid exposure to extreme temperatures. Keep away from moisture, heat and sources of ignition.
- Do not expose the product to radiation, sunlight and UV light, as it will change the properties of the product.

Proposed Disposal Method




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

Product Symbols



PACKAGING INFO

REF	GTIN	Peel Pouch	Inner box	Carton	Gross Weight (Carton)
20350	05051400203503	1 pc / pouch	25 pcs / box	200 pcs / carton	~6 kg

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

√ = Highly recommended (√) = Recommended

ADDITIONAL INFO

- HS Code: 9018310000
- Documentation available upon request. Kindly contact: info@curas.com