


MD TECHNICAL DATA SHEET

Sheet nr.	Data	Rev	Type of MD	CND code	Codice GMDN
001	24/06/2019	0	Vaginal douche	U0899 - GYNAECOLOGICAL DEVICES - OTHERS	

Description, intended use and instructions			Image	
<p>The Medical Device is a vaginal douche, divided into single-dose 100 ml bottles, containing a plant extract with filming and emollient properties. The protective action onto vaginal mucosa gives relief from irritation and the associated symptoms such as pain, itching and sensitivity. The MD is intended to come into contact with the patient's vaginal mucosa by directly inserting the washing solution into the vaginal cavity using a special vaginal dispenser combined with a cannula.</p> <p>The Medical Device must be used according to the following general instructions:</p> <ol style="list-style-type: none"> before using the product, it is recommended to carefully clean hands shake well the bottle before use keep the bottle from its neck and rotate the cap until the seal is broken apply the cannula onto the bottle neck using a firm pressure to lock it find a comfortable position, anywhere you like (sitting on the toilet, in the bath tub or under the shower: it's important that position ensures the vaginal douche to be flushed away squeeze the bottle; repeat if necessary to empty the bottle dry yourself externally without rinse the product is for single-use only. Discard the bottle after use <p>Use the vaginal douche preferably before bedtime.</p>				
Risk class 93/42/CEE	Rule of classification	CE marking annex	Notified body	N° of Notified body
I	5	Annex VII	n.a.	n.a.

Description of product types and possible accessories			
Product internal code	Commercial name	Size	Sterile
GYNEPINKRELIEF.100	GYNEPINK RELIEF	5 bottles with vaginal dispenser 100 ml each	no
Any applicable harmonized reference standards			
UNI CEI EN 980:2009	Graphic symbols for medical device labeling		
UNI EN ISO 10993	Biological evaluation of medical devices		
UNI CEI EN ISO 14971:2009	Application of risk management to medical devices		
UNI EN 1041:2000	Information that the Manufacturer must provide		
European Pharmacopoeia	Current edition		

Maintenance procedures
The MD is not subject to maintenance procedure.

Precautions for use and handling
<ul style="list-style-type: none"> do not use in case of evident allergy and/or hypersensitivity to any of the ingredients. keep out from the reach of children prolonged use of topical/local skin products can lead to sensitization processes: if irritation occurs, it is recommended to discontinue the treatment and consult a physician do not use after the expiry date the expiry date is referred to product in its intact correctly stored package do not use the product if packaging is damaged no interactions known at the given instructions of use do not use during pregnancy or lactation

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Do not use without carefully reading and understanding the instructions for use given with the product

Contraindications

Do not use in case of evident allergy and/or hypersensitivity to any of the ingredients. No interactions known at the given instructions of use.

Indications regarding toxicity

The substances used in the formulation and packaging materials guarantee the non-toxicity of the product.

Transport precautions

Store in cool dry place away from direct light and heat sources.

Disposal method

In general, there are no particular indications regarding the disposal of this device after use: it is considered urban waste. In any case, refer to the Municipal Waste Management Regulations or the Local Waste Management Body Regulations.
For use in hospitals throughout the country, refer to laws on waste management, in addition to any local regulations in force.

Approved QMS

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