

SWASH[®] SHAMPOO CAP – FRAGRANCE FREE

GENERAL INFORMATION

Article number	Do4077-1
Basic UDI-DI	PP10417HAIR.CARE21
UDI-DI	111666465311
Intended use	Intended for a complete hair wash of bedridden patients as an infection prevention measure.
Content of package	1 cap
Content of box	52 packages
Manufacturer	Arion Manufacturing B.V. – The Netherlands Rutherford 11, 6422 RE Heerlen
Issue date	07/2020
Revision date	N.A.

PRODUCT INFORMATION

Type of product	Medical device class 1 (2017/745/EC)
Composition cap	Polyester & Lyocell
Production method cloth	Needle punch
Box weight	ca. 6823 gram
Net waste weight cap	ca. 30 gram
Net waste weight foil	ca. 4 gram
pH-value	5 – 6
Dimensions cap	30 cm x 30 cm
Dimensions package	22 cm x 12 cm

INGREDIENTS LOTION (INCI)	PURPOSE	CONCENTRATION (%)
Aqua	Solvent in which the other ingredients are dissolved.	75-100
Propylene Glycol	Water-attracting ingredient that reduces dehydration of the skin. Next to that, it is a solvent and it determines the viscosity of the lotion.	1-5
Sodium Lauroyl Sarcosinate	Surfactant; cleansing and foaming effect because it lowers the surface tension. Also used in many baby products.	0.1-1
Caprylyl Glycol	Skin conditioner. Also has preservative properties.	0.1-1
Cocamidopropyl Betaine	Gives the shampoo a cleansing and lathering property.	0.1-1
Glyceryl Caprylate	Humectant. Also has preservative properties.	0.1-1
Potassium Sorbate	Natural preservative.	0.1-1
Dipropylene Glycol	Solvent for the preservative system.	0.1-1
Tocopherol	Increases shelf life of the product by preventing oxidation. Also used as moisturizer.	<0,1
Sodium Chloride	Additive.	<0.1

INSTRUCTION FOR USE



Heat the Swash[®] Shampoo Cap in the microwave for approximately 20 seconds (800 Watt).

Test temperature before use.

Pull the heated cap over the patient's head and make sure the cap fully covers the patient's hair.

Massage hair through Swash[®] Shampoo Cap for 2 to 3 minutes until the patient's hair is fully saturated with the lotion.

Then remove the cap. There is no need to wash off the lotion.

The patient's hair can be dried and styled as usual.

For single use only. Do not reheat.

Do not flush down the toilet.

TEST RESULTS

Eye irritation test

Results show that the lotion does not cause any irritation of the cornea and the iris. In addition, the conjunctiva do not swell or turn red.

Skin irritation test

Results show that the Swash[®] Shampoo Cap does not cause any irritation of the skin. There was no sign of edema or red skin during or after the test.