

B. Braun Melsungen AG
Division Hospital Care
CoE Pharmaceuticals
34209 Melsungen

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To whom it may concern

Product Information Sheet – Ecolav® container for Topical Irrigation

Dear Sir or Madam,

Thank you very much for your request concerning our Topical Irrigation container Ecolav®. NaCl 0,9% B.Braun and Aqua B.Braun solution for Irrigation are sterile solutions and are compliant with the requirements and limits of the European Pharmacopoeia (Ph.Eur.)

Below you'll find the main information regarding our product:

Product NaCl 0,9% B.Braun and Aqua B.Braun Solution for Irrigation in Ecolav®

Product Picture



Product description Ecolav® is an irrigation solution container with a twist-off cap for the indications for:

- irrigation and cleansing during surgical intervention.
- irrigation of wounds and burns.
- moistening wound tamponades, cloths and dressings.
- rinsing and cleansing of bladder catheters.
- irrigation and cleansing in stoma care.
- rinsing and cleansing of instruments and equipment.
- mechanical irrigation of the eyes (the use of 30 ml container is recommended).
- nasal irrigation (the use of 30 ml container is recommended)

Chairman of Supervisory Board:
Prof. Dr. h.c. Ludwig Georg Braun

Executive Board:
Prof. Dr. Heinz-Walter Große
(Chairman)
Dr. Annette Beller
Anna Maria Braun, LL.M.

Dr. Meinrad Lugin
Caroll H. Neubauer, LL.M.
Dr. Joachim Schulz
Markus Strotmann

Corporate Office: Melsungen
Register Court: Local Court Fritzlar
HRB 11 000
WEEE-Reg.-No. DE 42690900

Address:
B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen
Germany

Product benefits The flow of the irrigation solution can be easily addressed to the target area by applying a slight pressure to the container.
And thanks to the container nozzle, the irrigation flow can be precisely applied to the target area.
The wide range of volume sizes (30, 100, 250, 500 and 1.000 ml) allows to suit all requirements without incurring in unnecessary waste of solution.

Material composition Ecolav® is an irrigation solution made of polyethylene.
The container material is Latex-free, PVC-free and DEHP-free.

Classification IIa

Applicable legislation 93/42/CEE

Notifying Institute TÜV Süd Product Service GmbH

Manufacturer B.Braun Melsungen AG
Carl-Braun- Straße 1
34212 Melsungen
Germany

Product references	Reference	Product	No. of units per box
	number		
	387872	AQUA B.BRAUN 100ML	20
	387873	AQUA B.BRAUN 250ML	20
	387874	AQUA B.BRAUN 500ML	10
	387875	AQUA B.BRAUN 1000ML	10
	3570310	NACL 0,9% B.BRAUN 30ML	100
	3570350	NACL 0,9% B.BRAUN 100ML	20
	3570380	NACL 0,9% B.BRAUN 250ML	20
	3570410	NACL 0,9% B.BRAUN 500ML	10
	3570440	NACL 0,9% B.BRAUN 1000ML	10

Warning and precautions Do not use for infusion.
Only use the solution if the seal is undamaged and the solution is clear.
Opened containers must not be saved, quantities left over must be discarded. Re-use of single-use devices creates a potential risk of patient or user.

Shelf life

The shelf life of Ecolav® at ambient temperature (25°C) is 3 years and is based on stability studies which comply with internationally recognized standards and guidelines of the ICH (The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use).

Storage at elevated temperature

In specific circumstances and if required by the procedure NaCl 0,9% B.Braun and Aqua B.Braun irrigation solutions in Ecolav® may be stored in dedicated heaters for a maximum period of two weeks at a temperature of up to 40°C without negative impact on the quality.

Sterilization method

Autoclave

Method of utilization

- open the container by twisting off the cap counterclockwise
- let the solution flow by applying pressure to the container
- the container nozzle permits to precisely direct the solution flow to the target area
- the 30 ml mini-dose container allows the pinpoint application (especially indicated for the irrigation of the eyes)



Please do not hesitate to contact us if you have any further questions.

Yours sincerely,

B. Braun Melsungen AG

i. A.

A handwritten signature in blue ink, appearing to read 'Ming Ming Chung'.

Ming Ming Chung
Product Manager
Irrigation solution and LVP bags

i. V.

A handwritten signature in blue ink, appearing to read 'Loredana Tamburello'.

Loredana Tamburello
Product Manager
LVP – Ecoflac Plus

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