

BABYMILLA

“Babymilla” is a sterile, saline solution with physiological pH, for ocular and periocular use.

“Babymilla” is a valid support for the removal of periocular and ocular secretions on newborns, since the first days of life, infants and children (from 0 to 6 years old). The product can also be used by children aged over 6 years, adolescents, adults and older people, even in the presence of soft contact lenses.

“Babymilla” acts through the instillation and subsequent softening and washing away of the secretions on the ocular surface, in the conjunctival fornixes and the eyelid margin.

“Babymilla” has a diluting, decongestant and hydrating action increasing the tear film volume.

“Babymilla” contains distilled waters of Echinacea and Eye Bright which contribute to the humectant effect thanks to their moisturizing action.

“Babymilla” is compatible with soft contact lenses.

INTENDED USE

“Babymilla” is intended for the removal of periocular and ocular secretions on newborns, since the first days of life, infants, and children (from 0 to 6 years old). The product can also be used by children aged over 6 years, adolescents, adults and elderly people (i.e., over 65 years).

“Babymilla” is also intended to soothe minor eye discomfort.

INDICATIONS

Babymilla is indicated:

- For daily cleansing of eyelids and eyes of newborns, infants and children and for eye cleansing also in case of neonatal conjunctivitis;
- To facilitate the removal of eye secretions or dirt residues due to thickening mucus or environmental factors such as dust, pollen, allergens, saltiness;
- To facilitate the removal of ocular and periocular secretions in case of eye inflammation and blepharitis;
- To remove purulent secretions and for the dilution of the tear film in case of stenosis of the lacrimal ducts (frequent in newborns);
- To control the microbiological load on the bandaged eye in case of amblyopia thanks to the increase of tear volume and the consequent dilution of microorganisms. During the treatment the product is instilled in the interval between two bandages and to wet the eye when wearing contact lenses.

“Babymilla” is also indicated for:

- Relieving eye discomfort and conjunctival redness caused by weather conditions such as wind, excessive heat or sunlight;
- Relieving eye discomfort caused by seasonal allergies and different forms of allergic conjunctivitis;
- Relieving burning, discomfort or itchy eyes in case of dry eye caused by environmental factors;
- Reducing dry eye/foreign body sensation following drug therapy.

“Babymilla” can also be used several times a day.

COMPOSITION

Sodium Chloride (0.82%), Vitamin E TPGS, Echinacea Pallida Distilled Water, Eye Bright Distilled Water, Zinc sulfate heptahydrate, Citric Acid Monohydrate, Sodium Citrate Tribasic Dihydrate, Water For Injection.

INSTRUCTION FOR USE

- Wash and dry your hands thoroughly before use;
- Grip the bottle so that the finger that you use for dispensing (index or thumb) is well positioned on the dispenser and does not cover the spraying hole;
- Hold the bottle vertically and exert a firm pressure on the dispenser to atomize the solution;
- In case of direct dispensing into the eye, spray at a distance of about 10 cm from the eye;
- If you are using the product for the first time, dispense a few times until a regular spray of the product is observed;
- In case of storage at temperatures below 15°C and use on children, hold the bottle in your hands for a few moments before use in order to warm it up and avoid the child an unpleasant sensation of cold;
- Use the product as follows:
 - *For eye rinsing instead of conventional wipes moistened or soaked:* spray 1 or 2 sprays of solution on a sterile gauze and use it for immediately and gently cleaning of the area around the eyes, eliminating any secretions. Avoid rubbing hard but soften the dry secretions with the gauze soaked until you are not able to remove them. Use a different gauze for each eye;
 - *For eye rinsing:* spray 1 or 2 sprays of product in each eye, open or closed:
 - a. or by spraying with an open eye, the blinking caused by the increase in volume of the tear fluid allows the product to wash eye surface by removing foreign particles together with liquid excess;
 - b. or by spraying with the eyes closed, the liquid that remains trapped in the eyelid rim, thanks to the blinking, comes into contact with the ocular surface, increasing the volume of the tear fluid and thus allowing the product to wash the eye surface away from foreign particles together with liquid excess;
 - *To relieve sensations of discomfort or redness:* spray 1 or 2 sprays of product in each eye;
- After the first opening, content of the bottle can be re-used within 3 months.

WARNINGS AND PRECAUTIONS

- The product is for ophthalmic or periocular use only;
- Product is for single patient use;

- Do not use the product if the bottle is damaged or not perfectly closed when you open it for the first time;
- During use, do not touch the eye or other surfaces with the spraying area of the dispenser;
- Do not use the product after the expiry date indicated on the package;
- In case of side effects during use, interrupt the treatment and consult a doctor;
- Do not use the product in case of known incompatibility towards any of the component of the formulation and/or Asteraceae plants and/or Orobanchaceae plants;
- No interactions with drugs or other eye drops are reported; however, leave at least 15 minutes between administrations of any other eye drops;
- Dispose of the product according to your local waste management regulations;
- Keep out of the reach of children;
- Consult your doctor before you use this product if you are pregnant or breast-feeding;
- For external use, do not swallow;
- Do not tamper with or damage the bottle and its mechanisms;
- “Babymilla” do not replace any drug therapy prescribed by your doctor;
- It is necessary to report any serious incident occurred in relation to the device to the manufacturer and the Competent authority of the Member state in which you are established.

SIDE EFFECTS

No undesirable side-effects are known so far.

STORAGE CONDITIONS

Store in a dry place, away from sources of heat, and direct exposure to sunlight, at a temperature between 2°C and 30°C. Store unused single doses in the aluminum pouch.

PACKAGING

One bottle of 10 ml with a spray dispenser of sterile solution preservative free.

VALIDITY

With unopened packaging, do not exceed the expiry date shown on the package.



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C.O.C. Farmaceutici S.r.l.
Via Modena, 15 - 40019
Sant'Agata Bolognese (BO)
Italy

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C.O.C. Farmaceutici srl
Via Modena, 15
40019 - S. Agata Bolognese (BO) ITALIA
Via Chiesa Sud, 156 C/D/E/F/G
41016 - Rovereto s/S - Novi di Modena (MO) ITALIA

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ITALIA

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