

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;
- Open the protective aluminum pouch;
- Detach the single dose container from the strip;
- In case of storage at temperatures below 15 °C and use on children, hold the vial in your hands for a few moments before use in order to warm it up and avoid the child an unpleasant sensation of cold;
- Twist and remove the cap to break the seal;
- Place the cap taking care to put it on a clean surface;
- The content of a 0.5 ml vial is sufficient for cleaning both eyes. After use, immediately close the vial with the appropriate cap. To close it, you must first turn the cap over;
- Use the product as follows:
 - For rinsing periorcular area instead of conventional wipes moistened or soaked: *pour 4/5 drops of solution on a sterile gauze and use it for immediately and gently cleaning of the area around the eyes, eliminating any secretion. Avoid rubbing hard but softening them dry secretions with gauze soaked until you can remove them. Use one different gauze for each eye.*
 - To rinsing the eye: *gently press the body of the single-dose vial and dispense 1/2 drops to be instilled in every eye; the blinking due to the increase in volume of the liquid tear allows the product to wash the surface of the eye by removing the foreign particles along with excess liquid.*
 - To relieve sensations of discomfort or redness: *instill 1/2 drops in each eye.*
- Information about use of residue solution in the vial:
 - The product is for single use and after opening the vial and using the product by instillation or to soak the gauze, any residue must be eliminated;
 - In case of instillation of the product to alleviate feelings of discomfort or redness in adults, the use of the residue within the 12 hours following the opening of the vial is not contraindicated, provided that the container is duly closed with the special cap. Avoid making the cap come into contact with other surfaces that could contaminate it

and make it a vehicle for microbes capable of contaminating the solution once the vial is closed again.

WARNINGS AND PRECAUTIONS

- The product is for ophthalmic or periocular use only;
- The product is for single patient use;
- Do not use the product if the aluminum pouch is damaged or the single dose is not perfectly closed when you open it for the first time;
- Do not use if there are visible particles and/or changes in the color of the solution;
- During instillation, do not touch the eye or other surfaces with the dispensing end of the vial;
- Do not use the product after the expiry date indicated on the package;
- If side effects occur during use, stop using the product and consult a doctor;
- Do not use the product in case of known incompatibility towards any of the components 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;
- “Babymilla” does not replace any other 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.

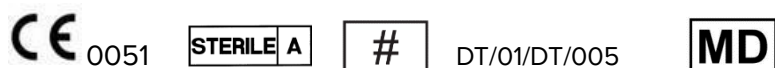
Store unused single doses in the aluminum pouch.

PACKAGING

From 5 to 30 re-closable single dose of 0.5 ml

VALIDITY

See the expiry date reported on the box and on the single doses.





C.O.C. Farmaceutici S.r.l.

Via Modena, 15 - 40019

Sant'Agata Bolognese (BO)

Italy

Last Revision: 02.01 of 10/2022



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

Cap. Soc. € 1.200.000 I.V.
C.F. e Iscr. Reg.
Impr. di Bologna 03541870378
P.IVA IT 01603491208
R.E.A. Bologna N. 299432



Tubilux Pharma S.p.A.

Via Costarica, 20/22
00071 Pomezia (Roma)
ITALIA

cap. soc. € 472.500,00 I.V.
C.F. / P.IVA 05406661008
R.E.A. Roma N. 883476