

Sodium Chloride 1mmol/ml Oral Solution

Frequently Asked Questions:

1. *For what age range is the product licensed?*

The product is indicated for infants. The term infant is typically applied to young children between the ages of 1 month and 12 months; however, definitions may vary between birth and one year of age, or even between birth and 2 years of age. A significant proportion of the patients observed in the application clinical study were neonates. Therefore, the wider definition from birth is applicable to this age range.

2. *Is the product sterile?*

The product is non-sterile and complies to the European Pharmacopoeia standards for non-sterile oral solutions.

3. *Does the product contain antimicrobial preservatives?*

Yes, the product contains 0.1%w/v (1mg per ml) (equivalent to 0.75mg per ml sorbic acid) potassium sorbate as an antimicrobial preservative. This has been determined to be the lowest effective concentration. This preservative is considered appropriate by the regulatory authorities for the age group indicated for treatment with this product.

4. *Why is the product non-sterile and why does it contain preservatives?*

As soon as the product is opened it can become contaminated with microorganisms. Unless the product is suitably preserved with antimicrobial preservatives there is potential for these microorganisms to multiply. It is very difficult to assess the potential for microorganism growth in unpreserved solutions, even if the product is stored in a refrigerator. Producing the product non-sterile and adding preservatives enables control over microorganism growth after opening.

5. *How long can the product be stored after first opening?*

One month at room temperature, in the original container with the cap replaced.

6. *How much potassium does the product contain?*

Sodium Chloride 1mmol/ml Oral Solution contains 6.6 micromol (6.6×10^{-3} mmol), equivalent to 0.26 milligrams (260 micrograms) of potassium per ml of product.

7. *Why does the product contain citric acid.*

Citric acid is added to regulate the pH which is required to optimise preservative efficacy.

8. *Are there any flavours or colours added to Sodium Chloride 1mmol/ml Oral Solution*

The product is designed to be added to formula feed or breast milk, therefore no colours or flavours have been added to this product.