

## Summary of Product Characteristics

### 1. Name of the medicinal product

AQUARINO KIDS

### 2. Qualitative and quantitative composition

Sodium Chloride 0.65 % w/v

#### *Excipient with known effects:*

Benzalkonium Chloride may cause irritation or swelling inside the nose, especially if used for a long time”.

*For a list of excipients, see section 6.1.*

### 3. Pharmaceutical form

Saline Nasal Spray

**Description:** Clear, colourless, odourless liquid having salty taste filled in 30ml plain plastic bottle with plug and cap.

### 4. Clinical particulars

#### 4.1 Therapeutic indications

For relief of dry nasal passages caused by sinus, cold and allergy medications, nasal surgery and dry air. Also relieves congestion by thinning mucus.

#### 4.2 Posology and method of administration

Adults, children and elderly: use as directed by the physician.

It should not be taken orally or administered parenterally.

Each plain plastic bottle contains 30 ml of solution.

Refer to the patient information leaflet of the product that your physician has prescribed you for detailed instructions on use of this solution.

Method of Administration: For children and adults, squeeze bottle twice in each nostril as often as needed or as directed by doctor. Hold bottle upright for spray, horizontally for stream. Follow all directions on the product package. Administration should be in accordance with the manufacturer's instructions for the device.

Try not to touch the container tip to the inside of your nose. If this happens, rinse the tip with hot water and dry with a clean tissue before recapping the container.

#### 4.3 Contraindications

The solution should not be administered orally or parenterally.

#### 4.4 Special warnings and precautions for use

Do not use unless the product is clear and the pack intact. Discard any surplus after use. Use of this container by more than one person may spread infection.

**Benzalkonium Chloride:** “Benzalkonium Chloride may cause irritation or swelling inside the nose, especially if used for a long time”.

**Keep out of reach of children.** In case of accidental ingestion, get medical help or contact a Poison Control Centre right away.

#### 4.5 Interaction with other medicinal products and other forms of interaction

Not known.

#### 4.6 Pregnancy and lactation

As with most medicines, consult your doctor first if you are pregnant or breastfeeding.

#### 4.7 Effects on ability to drive and use machines

Not known.

#### 4.8 Undesirable effects

Saline solution is not expected to cause any undesirable effects in normal use.

#### Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme.

#### **4.9 Overdose**

Substantial oral ingestion may require the use of a diuretic to remove excess sodium.

### **5. Pharmacological properties**

#### **5.1 Pharmacodynamic properties**

Sodium chloride solution is widely used for dilution purposes.

#### **5.2 Pharmacokinetic properties**

Not applicable

#### **5.3 Preclinical safety data**

There are no findings of relevance to the prescriber other than those already mentioned elsewhere in the SmPC. Please refer to the product to be reconstituted.

### **6. Pharmaceutical particulars**

#### **6.1 List of excipients**

Disodium Phosphate (Anhy.)	BP
Sodium acid Phosphate	BP
Benzalkonium Chloride Solution	BP
Distilled Water	IHS

#### **6.2 Incompatibilities**

Not applicable

#### **6.3 Shelf life**

36 months

#### **6.4 Special precautions for storage**

Store at a temperature not exceeding 30°C, protect from light. Keep out of reach of Children.

#### **6.5 Nature and contents of container**

1× 20 ml in a plastic bottle

#### **6.6 Special precautions for disposal and other handling**

No special requirements

### **7. Marketing authorisation holder**

#### **Marketing Authorization Holder:**

Biodeal Pharmaceuticals Private Limited,  
Address: Nalagarh- Ropar Road, Village-Sainimajra, Nalagarh, India.  
E-mail: [gunjankumar@biodealpharma.com](mailto:gunjankumar@biodealpharma.com).

#### **Manufacturer:**

Biodeal Pharmaceuticals Private Limited,  
Address: Nalagarh- Ropar Road, Village-Sainimajra, Nalagarh, India.  
E-mail: [gunjankumar@biodealpharma.com](mailto:gunjankumar@biodealpharma.com).

### **8. Marketing Authorisation Number(s)**

TAN 22 HM 0155

**9. Date of first authorisation/renewal of the authorization**

11/04/2022

**10. Date of Revision of the Text**