

## **SUMMARY OF PRODUCT CHARACTERISTICS**

## **1. NAME OF THE MEDICINAL PRODUCT**

Kataria 4 g Granules

## **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each sachet (5.6 g of granules) contains: Sodium citrate BP ..... 4.0 g  
For the full list of excipients, see section 6.1.

## **3. PHARMACEUTICAL FORM**

White to off-white free-flowing granules.

## **4. CLINICAL PARTICULARS**

### **4.1 Therapeutic indications**

Kataria is indicated for relief from the symptoms of cystitis.

### **4.2 Posology and method of administration**

#### Posology

#### Adults

Dissolve the contents of one sachet in a glass of water. Take orally 1 sachet 3 times per day during 48 hours. The prepared solution should be used immediately.

#### Method of administration

Oral

### **4.3 Contraindications**

Hypersensitivity to Sodium Citrate and other components of this medicine. It is contraindicated to patients with diabetes, heart disease, arterial hypertension, renal disease or patients who are on a low salt diet.

### **4.4 Special warnings and precautions for use**

If symptoms persist after two days of treatment it is necessary to consult a doctor.

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

None are known.

### **4.6 Fertility, pregnancy and lactation**

It is contraindicated during pregnancy and lactation.

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

Not determined.

### **4.8 Undesirable effects**

Single cases of skin rash and abdominal pain.

#### 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 EFDA yellow Card Scheme, online at <https://primaryreporting.who-umc.org/ET> or toll free call 8482 to Ethiopian food and drug authority (EFDA).

#### **4.9 Overdose**

Symptomatic treatment should be used in case of unwanted over dosage of this product.

### **5. PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: Drugs used in urology., ATC code: G04B X

Sodium Citrate is metabolised into bicarbonate, which facilitates regression dysuria which is observed in cystitis.

The authority/EFDA will review new information on this medicinal product at least every year and this SmPC will be updated as necessary.

#### **5.2 Pharmacokinetic properties**

Reduces the acidity of urine, causing its alkalization.

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

None stated.

### **6. PHARMACEUTICAL PARTICULARS**

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

Sucrose, Saccharin Sodium and Cranberry flavour 191121.

#### **6.2 Incompatibilities**

None known.

#### **6.3 Shelf life**

3 years.

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

Store below 30°C.

Keep all medicines out of reach of children.

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

Sodium Citrate Granules packed in a Glassine paper sachets and each sachet contains 5.6 gm of granules. 6 sachets along with instruction for medical use in a carton.

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

No special requirements for disposal.

## **7. MARKETING AUTHORISATION HOLDER**

Kusum Healthcare Pvt. Ltd.  
SP-289(A), RIICO Industrial Area,  
Chopanki, Bhiwadi, Dist. Alwar, Rajasthan, India

## **8. MARKETING AUTHORISATION NUMBER(S)**

04848/07067/NMR/2018

## **9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

19 December 2019

## **10. DATE OF REVISION OF THE TEXT**

08/2023

## **11. REFERENCES**

SmPC published on electronic medicines compendium  
<https://www.medicines.org.uk/emc#gref>

The MHRA published product information  
<https://products.mhra.gov.uk/>

Human medicine European public assessment report  
<https://www.ema.europa.eu/en/medicines>