

# SUMMARY OF PRODUCT CHARACTERISTICS

## 1 NAME OF THE MEDICINAL PRODUCT

BariClear<sup>®</sup> 94.6% w/w Granules

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Barium Sulphate 94.6% w/w

## 3 PHARMACEUTICAL FORM

Granules to prepare an aqueous suspension for oral or rectal use as a radiopaque.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

BariClear<sup>®</sup> 94.6% w/w Granules is an X-ray contrast medium for use in the radiological examination of the gastrointestinal tract.

### 4.2 Posology and method of administration

#### Posology

#### Adult:

Part of GI Tract	Method	Volume (ml)	Concentration % w/v
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Oesophagus	Oral	10-150	50-200
Stomach & Duodenum	Oral, Double-Contrast, Distension Filling & Relief	10-300	30-200
Small Intestine	Oral	100-300	30-150
Colon	Enema	200-2000	20-130

**Children and infants:**

As for adults but in proportion to body weight.

**Method of Administration**

After reconstitution with water to make a suspension, BariClear® 94.6% w/w Granules is either taken by mouth as a barium meal or given rectally as an enema.

**4.3 Contraindications**

Oral use: Suspected perforation of intestinal organs. Haemorrhage in digestive organs.

Enema use: Suspected perforation of intestinal organs. Haemorrhage in digestive organs: Extreme exhaustion.

**4.4 Special warnings and precautions for use**

BariClear® 94.6% w/w Granules should be used with great caution in:

Oral use: Suspected or known fistula in digestive organs. Stricture or signs suggesting obstruction.

Enema use: Suspected or known fistula in digestive organs. Stricture or signs suggesting obstruction: Diseases of internal organs that could lead to perforation (e.g. appendicitis, diverticulitis, ulcerative colitis, invagination tumour, parasitic disease etc).

Water and laxatives should be given to patients to prevent constipation.

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

None stated.

#### **4.6 Fertility, Pregnancy and lactation**

At the discretion of the physician.

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

None stated.

#### **4.8 Undesirable effects**

May cause constipation, transient diarrhoea, abdominal pain, anal pain and bleeding.

#### **4.9 Overdose**

Treat symptomatically.

### **5 PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

Not applicable - barium sulphate is not absorbed from the gastrointestinal tract.

## **5.2 Pharmacokinetic properties**

Not applicable - barium sulphate is not absorbed from the gastrointestinal tract.

## **5.3 Preclinical safety data**

No formal preclinical studies have been undertaken. Barium sulphate is a well established pharmaceutical substance that has been available for many years. It is also the subject of a recognised pharmacopoeial monograph.

# **6 PHARMACEUTICAL PARTICULARS**

## **6.1 List of excipients**

Potato starch, soluble

Acacia

Silicon resin emulsion

Sodium benzoate

Green apple oil

Carmellose sodium

Hydrogenated maltose starch syrup, powdered

Purified water

## **6.2 Incompatibilities**

None stated.

## **6.3 Shelf life**

36 months.

**6.4 Special precautions for storage**

Store in a dry place.

**6.5 Nature and contents of container**

Polyethylene - cellulose bags 200 g pack.

**6.6 Special precautions for disposal**

None stated.

**7 MARKETING AUTHORISATION HOLDER**

Red Knights Pharma Ltd.  
5300 Lakeside  
Cheadle Royal Business Park,  
Cheadle SK8 3GP  
UK

**8 MARKETING AUTHORISATION NUMBER(S)**

PL 55644/0002

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

30/01/2009

**10 DATE OF REVISION OF THE TEXT**

10/02/2025