SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

BariClear® 100% w/v Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Barium Sulphate 100 %w/v

3 PHARMACEUTICAL FORM

Barium Sulphate Suspension

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

BariClear® 100% w/v Suspension is an X-ray contrast medium for use in the radiological examination of the gastrointestinal tract.

4.2 Posology and method of administration

Oral or by enema in accordance with the parts to be examined and examination methods

Adults and Elderly

Part of GI Tract	Method	Volume (ml)	Concentration (% w/v)

Oesophagus	Oral	10-150	50-100
Stomach & Duodenum	Oral, Double-Contrast, Distension Filling & Relief	10-300	30-100
Small Intestine	Oral	100-300	30-100
Colon	Enema	200-2000	20-100

Children

As for adults but in proportion to body weight.

Infants

As for adults but in proportion to body weight.

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® 100% w/v Suspension should be used with great caution in:

Oral use:

Suspected or known fistula in digestive organs.

Stricture or signs suggesting obstruction.

Suffering from extreme exhaustion.

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).

Water and laxatives should be given to patients after investigation 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.

5.2 Pharmacokinetic properties

Not applicable.

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

Carmellose sodium

Tragacanth

Sodium saccharin

Glycine

Sodium ascorbate

Silicon resin emulsion

Sodium benzoate

Sodium dehydroacetate

Cream soda essence flavour

Purified water

6.2 Incompatibilities

None known

6.3 Shelf life

36 months.

6.4 Special precautions for storage

None stated.

6.5 Nature and contents of container

300ml sealed can

Steel body and bottom with an aluminium top. The top is coated internally with polyester film laminate and the body and bottom with epoxy resin.

6.6 Special precautions for disposal

None stated.

7 MARKETING AUTHORISATION HOLDER

Red Knights Pharma Ltd.
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UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 55644/0001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

09/12/2010

10 DATE OF REVISION OF THE TEXT

10/02/2025