APPROVED PACKAGE INSERT

**SCHEDULING STATUS:**

S4

**PROPRIETARY NAME (and dosage form):**

**AXIM READICAT 2% SUSPENSION**

**COMPOSITION:**

Each 100 ml contains:

| | |
|---|---|
| Barium sulphate | 2,0898 g (2% m/v) |
| Preservatives: | |
| Potassium sorbate | 0,2091% m/v |
| Sodium benzoate | 0,1254% m/v |

**PHARMACOLOGICAL CLASSIFICATION:**

A 28 Contrast media

**PHARMACOLOGICAL ACTION:**

Barium sulphate is an insoluble radiopaque material, which provides a positive contrast of the gastro-intestinal tract during CT scanning. Barium sulphate is inert, not absorbed or metabolised by the body and is eliminated unchanged from the body.

**INDICATIONS:**

**AXIM READICAT 2%** is used for the opacification of the gastro-intestinal tract, prior to computerized axial tomography.

**CONTRA-INDICATIONS:**

Hypersensitivity to barium sulphate or any other ingredient of this barium sulphate formulation.

**AXIM READICAT 2%** should not be used in patients with real or suspected perforation of the gastro-intestinal tract, or cases where barium sulphate is contra-indicated.

Do not use in patients with obstructing lesions of the gastro-intestinal tract and in those at risk of perforation such as acute diverticulitis and acute ulcerative colitis, and following rectal or colonic biopsy, sigmoidoscopy or radiotherapy.

**WARNINGS:**

This product should always be used under direct medical supervision.

**INTERACTIONS:**

This product should be used with care if the patient is on any other treatment that can cause constipation.

**PREGNANCY AND LACTATION:**

Whilst this product is not contra-indicated in pregnancy, it should be noted that radiographic procedures might be harmful to the foetus. Barium sulphate is not absorbed systemically and is therefore not contra-indicated during lactation.

**DOSAGE AND DIRECTIONS FOR USE:**

**AXIM READICAT 2%** is intended for oral and rectal administration, undiluted. The dosage will be dependent upon the patient and technique involved, and will be determined from experience by the radiologist

**Adults and elderly:**

**Suggested 30 minute barium administration protocol for abdominal studies:**

Administer 300ml of contrast 30 minutes prior to the scan and 150ml immediately before the scan.

**Suggested 90 minutes barium administration protocol for abdomen / pelvis studies:**

Administer 450ml of contrast 90 minutes prior to the scan, another 300ml 30 minutes before the scan, and finally, 150ml immediately before the scan.

**Children:**

The quantity of **AXIM READICAT 2%** should be determined from experience by the physician and will be dependent on the age and weight of the child.

**SIDE EFFECTS AND SPECIAL PRECAUTIONS:**

**Side effects:**

The following side effects have been reported:

**Gastro-intestinal:**

*Less frequent:* occasional nausea, vomiting, diarrhoea, impaction, appendicitis and obstruction have occurred.

*Frequent:* constipation and cramping have been reported.

**Allergic reaction:**

*Less frequent:* mild allergic reactions (approximately 1 in 250 000) can include generalised pruritis, erythema and urticaria. Such reactions may generally respond to an antihistaminic such as 50 mg diphenhydramine or equivalent.

More serious reactions (approximately 1 in 1 000 000) can include laryngeal oedema, bronchospasm, peripheral vasodilation, hypotension, reflex tachycardia, dyspnoea, agitation, confusion and cyanosis, progressing to unconsciousness. Treatment should be initiated immediately with 0,3 to 0,5 ml of 1:1 000 epinephrine, subcutaneously. If bronchospasm predominates, 0,25 to 0,5 g of intravenous aminophylline should be given slowly. Appropriate vasopressors might be required. Adrenocorticosteroids, even if given intravenously, exert no significant effect on the acute allergic reactions for a few hours. The administration of steroid agents should not be regarded as emergency measures for the treatment of allergic reactions. Apprehensive patients may develop weakness, pallor, tinnitus, diaphoresis and

bradycardia following the administration of any diagnostic agents. Such reactions are non-allergic in nature (vasovagal) and are best treated by having the patient lie flat for an additional ten to thirty minutes under observation.

The frequency of side effects experienced during allergic type reactions are:

**Cardiac disorders:**

*Less frequent:* cardiac arrhythmia and reflex tachycardia have been reported.

**Skin and subcutaneous tissue disorders:**

*Less frequent:* mild allergic reactions (approximately 1 in 250 000) can include generalised pruritis, erythema and urticaria.

**Respiratory, thoracic and mediastinal disorders:**

*Less frequent:* the more serious reactions (approximately 1in 1 000 000) can include laryngeal oedema, bronchospasm, dyspnoea, agitation, confusion and cyanosis which can progress to unconsciousness.

**Vascular disorders:**

*Less frequent:* peripheral vasodilation and hypotension have been reported.

Other side effects can include the following but frequencies are unknown:

**Investigations:**

Electrocardiographic abnormalities have been reported.

Deaths have occurred with the use of **AXIM READICAT 2%.**

**During or following a barium enema procedure, complications can occur. These may include constipation, barium impaction, intestinal perforation, which may be followed by peritonitis, adhesions and granuloma, intravasation and embolisation.**

**Precautions:**

Care should be taken when administering **AXIM READICAT 2%** to children, the elderly or to the debilitated. **AXIM READICAT 2%** should be used cautiously in elderly patients with pre-existing heart disease. Care is also needed in those with conditions such as pyloric stenosis or lesions which may predispose to obstruction. Adequate hydration should be ensured after the procedure to prevent severe constipation. Accidental aspiration into the lungs has led to pneumonitis or granuloma formation. This product should be used under medical supervision.

**KNOWN SYMTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:**

(see "**SIDE EFFECTS AND SPECIAL PRECAUTIONS")**

Severe stomach cramps and diarrhoea may occur. Treatment is symptomatic and supportive.

**IDENTIFICATION:**

A low viscosity, white, aqueous suspension with a sweet orange and vanilla flavour, without grittiness.

**PRESENTATION:**

**AXIM READICAT 2%** suspension is packed in translucent two litre, one litre and 500ml high-density polyethylene containers, containing 1 900 ml, 900 ml and 450ml **AXIM READICAT 2%** respectively, with a polypropylene screw-on cap.

**STORAGE INSTRUCTIONS:**

Store in a cool, dry place below 25 °C. Keep well closed.

Do not refrigerate. Do not freeze.

**Keep out of reach of children.**

**REGISTRATION NUMBER:**

37/28/0521

**NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:**

Axim Pharmaceuticals (Pty) Ltd

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