**SCHEDULING STATUS:**

S4

**PROPRIETARY NAME (AND DOSAGE FORM):**

**AXIM E-Z-CAT** (Suspension)

**COMPOSITION:**

Each 100 ml contains:

| | |
|---|---|
| Barium sulphate | 4,8710 g (4,6 % m/m) |
| *Preservatives:* | |
| Methyl hydroxybenzoate | 0,0490 % m/v |
| Potassium sorbate | 0,0565 % 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 E-Z-CAT** is indicated for the opacification of the gastro-intestinal tract prior to computerised axial tomography.

## CONTRA-INDICATIONS:

Hypersensitivity to any of the ingredients.

**AXIM E-Z-CAT** should not be used in patients where Barium sulphate is contra-indicated. It should not be given to patients with intestinal obstruction. It is contra-indicated in patients with gastro-intestinal perforation and should be avoided, particularly when given rectally, in those at risk of perforation as in acute ulcerative colitis or diverticulitis and following rectal biopsy or colonic biopsy, sigmoidoscopy, or radiotherapy.

## DOSAGE AND DIRECTIONS FOR USE:

Adults and the elderly: 350 - 450 ml of diluted suspension 30 minutes prior to scan and the same volume 5 minutes prior to scan or as directed by physician.

Children: The quantity of **AXIM E-Z-CAT** given should be determined, from experience, by the physician and will be dependent on the age and weight of the child.

Mixing instructions:

1. Pour **AXIM E-Z-CAT** contents of one bottle, 225 ml of **Axim E-Z-Cat** suspension into **[**~~the~~**]** a graduated one litre mixing container **[**~~supplied~~**]** purchased separately. Add water to give a total volume of 900 ml.
2. Shake well.
3. This will yield 900 ml of 1,1 % m/m barium sulphate suspension.

4. Alternatively, **AXIM E-Z-CAT** barium sulphate suspension may be mixed to yield different density. Some suggestions are as follows:
   (a) Add **AXIM E-Z-CAT** contents into the mixing container and water to 700 ml level. Yield 1,4 % m/m suspension.
   (b) Add water to the 600 ml level. Yields 1,7 % m/m suspension.
   (c) Add water to the 500 ml level. Yields 2,0 % m/m suspension.

**SIDE-EFFECTS AND SPECIAL PRECAUTIONS:**

Nausea has been reported and less frequently, retching, diarrhoea and constipation.

Constipation may occur after oral or rectal barium sulphate administration; impaction, obstruction and appendicitis have occurred. Cramping and diarrhoea have also been reported. Venous interaction has led to the formation of emboli; deaths have occurred.

Perforation of the bowel has led to peritonitis, adhesions, granulomas, and a high mortality rate.

ECG abnormalities have occurred during the use of barium sulphate enemas. Accidental aspiration into the lungs has led to pneumonitis or granuloma formation.

Care is needed in those conditions such as pyloric stenosis or lesions which may predispose to obstruction. Adequate hydration should be ensured after the procedure to prevent severe constipation.

The product should be used under medical supervision.

Whilst this product is not contra-indicated in pregnancy, it should be noted that radiographic procedures may be harmful to the foetus.

Barium sulphate is not absorbed systemically and is, therefore, not contra-indicated during lactation.

An allergic reaction would most likely be diffuse erythema or urticaria. This generally will respond to an antihistamine. In the more serious allergic reactions, rhinitis, laryngeal oedema or bronchospasm could develop. This should be treated immediately with 0,3 to 0,5 ml of 1:000 Epinephrine subcutaneously. If bronchospasm predominates 0,25 to 0,5 g of Aminophylline should be given slowly intravenously. ACTH and the adrenocortical steroids, even if given intravenously, exert no significant effect on the acute allergic reaction for two or more hours.

The administration of these agents should not be regarded as emergency measures for the treatment of acute allergic reactions. Apprehensive patients may develop weakness, pallor, ringing in ears, sweating and bradycardia following the administration of any diagnostic agent. Such reactions are not allergic in nature and best treated by the patient lying down for an additional ten to fifteen minutes and observed with appropriate reassurance.

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

See side-effects and special precautions. Treatment is symptomatic and supportive.

**IDENTIFICATION:**

A white, viscous, aqueous suspension with a sweet orange flavor without grittiness.

**PRESENTATION:**

**AXIM E-Z-CAT** barium sulphate suspension is packed in 240 ml or 300 ml white high density polyethylene bottles with screw on caps. Each bottle contains 225 ml **AXIM E-Z-CAT.**

## STORAGE INSTRUCTIONS:

Store in a cool place below 25 °C.

Keep well closed.

Do not refrigerate.

Avoid freezing.

**Axim E-Z-Cat** should be used immediately following dilution and must not be stored.

KEEP OUT OF REACH OF CHILDREN.

## REGISTRATION NUMBER:

35/28/0126

## NAME AND BUSINESS ADDRESS OF APPLICATION:

Axim Pharmaceuticals (Pty) Ltd

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## DATE OF PUBLICATION OF THIS PACKAGE INSERT:

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