APPROVED PACKAGE INSERT

SCHEDULING STATUS

S4

PROPRIETARY NAME (AND DOSAGE FORM)

AXIM E-Z-HD (Dry powder for reconstitution)

COMPOSITION

Each 100 g contains 98 g barium sulphate

(packed in 340 g containers)

PHARMACOLOGICAL CLASSIFICATION

A 28 Contrast Media

PHARMACOLOGICAL ACTION

Barium Sulphate is an insoluble radiopaque material, which provides a positive contrast of the gastrointestinal 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-HD is indicated for positive oral contrast for double contrast radiography of the gastro-intestinal tract.

CONTRA-INDICATIONS

Hypersensitivity to any of the ingredients.

AXIM E-Z-HD is a diagnostic reagent for professional use and must only be used at the direction of a physician. It should not be administered to patients with a suspected perforation of any part of the gastro-intestinal tract, paralytic ileus, and pyloric stenosis or in those were the use of barium sulphate is contraindicated. It should be avoided in patients at

risk of perforation as in acute ulcerative colitis or diverticulitis or colonic biopsy, sigmoidoscopy or radiotherapy.

DOSAGE AND DIRECTIONS FOR USE

The contents of one pre-filled container (340 g dry powder) dispersed with 65 ml of water results in 135 ml of suspension (250 % m/v AXIM E-Z-HD) , are swallowed by the patient.

Directions for use:

To each unit dose container containing 340 g add 65 ml water. Secure lid and shake up vigorously for 10 – 20 seconds. Leave for a minimum of 5 minutes. And shake up vigorously. Re-shake prior to use.

Yields 135 ml suspension at 250 % m/v.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS

Serious adverse reactions have been reported with the administration of barium sulphate formulations and are usually associated with faulty technique of administration or with underlying pathological conditions. Constipation may occur after oral administration of barium sulphate. Impaction, obstruction and appendicitis have occurred. Cramping and diarrhoea have also been reported. Venous intravasation 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. Accidental aspiration into the lungs has led to pneumonitis or granuloma formation. ECG changes have been shown to occur following or during barium enemas.

Precaution: Adequate hydration should be ensured after the procedure to prevent severe constipation.

An allergic reaction would most likely be diffuse erythema or urticarial. This generally will respond to an antihistaminic, such as 50 mg I.V. Benadryl or the equivalent of another antihistaminic. 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 1:1000 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 are best treated by having the patient lie down for an additional ten to fifteen minutes and observed with appropriate reassurance.

On occasion after repeated administration, severe stomach cramps and diarrhoea may occur.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

See **"SIDE-EFFECTS AND SPECIAL PRECAUTIONS"**. Treatment is symptomatic and supportive.

IDENTIFICATION

White to off-white, slightly sweet tasting strawberry-cherry flavoured bulky powder with some grittiness. After reconstitution the product is a white, slightly sweet, fruit-flavoured non-gritty suspension..

PRESENTATION

White to off-white powder barium sulphate formulation for suspension is presented in natural 425 ml plastic bottles each containing 340 g powder for reconstitution.

STORAGE INSTRUCTIONS

Store in a cool, dry place below 25 ºC, in a well-closed container.

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KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

35/28/0124

NAME AND BUSINESS ADDRESS OF THE APPLICANT

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