PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

AXIM E-Z-CAT (barium sulfate (4,6 % m/m) suspension)

Please read this leaflet carefully before taking AXIM E-Z-CAT.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT AXIM E-Z-CAT CONTAINS:

The active ingredient is barium sulfate.

The inactive ingredients are sorbitol solution, pectin, xanthan gum, simethicone emulsion, orange flavourant, sodium saccharin, methyl paraben, potassium sorbate, sodium citrate dihydrate, citric acid anhydrous and purified water.

2. WHAT AXIM E-Z-CAT IS USED FOR:

AXIM E-Z-CAT is used as a contrast agent: This suspension is ingested into the body to make certain tissues more visible during bowel and intestinal scanning to determine if you have any stomach or bowel disease.

3. BEFORE YOU TAKE AXIM E-Z-CAT:

Do not take AXIM E-Z-CAT:

- If you are hypersensitive (allergic) to barium sulfate or any of the inactive ingredients in the product.
- If you have gastro-intestinal diseases such as perforation (holes in the lining of the gastro-intestinal tract), ulcerative colitis (inflammation of the lining of the large intestine) or diverticulitis (inflammation of the diverticula in the large intestine).

Take special care with AXIM E-Z-CAT:

- **AXIM E-Z-CAT** should only be used under medical supervision.
- **AXIM E-Z-CAT** should be given with special care to children, elderly patients with pre-existing heart disease and patients with gastro-intestinal conditions which may predispose to obstruction.
- Take the medicine carefully to ensure that you do not accidentally aspirate it into your lungs.
- Ensure that you take in sufficient water after the procedure to prevent severe constipation.
- If you experience an allergic reaction, it would most likely appear as redness of the skin and raised itchy bumps spread over a wide area.

Pregnancy and breastfeeding:

Inform your doctor, pharmacist or other healthcare professional if you are pregnant or breastfeeding your baby before taking **AXIM E-Z-CAT. AXIM E-Z-CAT** can be used during pregnancy, but radiographic procedures may be harmful to the foetus.

AXIM E-Z-CAT may be used during breastfeeding.

Driving and using machinery:

No known effect on the ability to drive or operate machinery.

Important information about some of the ingredients of AXIM E-Z-CAT:

AXIM E-Z-CAT contains 15,9 g sorbitol. It may cause stomach upset and diarrhoea. Patients with the rare hereditary condition of sorbitol intolerance should not take **AXIM E-Z-CAT.**

Using other medicines with AXIM E-Z-CAT:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **AXIM E-Z-CAT** with these medicines may cause undesirable interactions. Tell your doctor or pharmacist if you are taking any medicines, including any you have bought at your pharmacy, supermarket or health food shop.

AXIM E-Z-CAT may alter the absorption of other medicines if taken together. In order to minimise the potential change in absorption, your other medicines may have to be taken a while before or after the **AXIM E-Z-CAT** is administered.

4. HOW TO TAKE AXIM E-Z-CAT:

AXIM E-Z-CAT suspension will be administered to you orally.

The dosage of **AXIM E-Z-CAT** will be determined by the radiologist, depending on the type of examination, equipment and technique employed.

If you take more AXIM E-Z-CAT than you should:

The radiologist will determine your dosage. However, in the event of over dosage, the symptoms, such as stomach cramps and diarrhoea, will be treated.

5. POSSIBLE SIDE EFFECTS

AXIM E-Z-CAT can have side effects. Not all side effects reported for this medicine are included in the leaflet. Should your general health worsen or if you experience any toward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

Some of these may be serious and must be reported to your doctor. Other effects may not be serious, but may cause concern.

Check with your doctor immediately if any of the following side effects occur:

- Allergic reactions of the skin such as itchiness or rash of the skin, shortness of breath, dizziness (low blood pressure), fast heart rate.
- Severe stomach pain.

Other side effects that frequently occur may include:

- Constipation
- Stomach cramps

Side effects that may occur less frequently may include:

- Nausea
- Vomiting
- Diarrhoea

6. STORAGE AND DISPOSAL OF AXIM E-Z-CAT

Store in a cool dry place, at or below 25 °C.

Keep well closed. Do not refrigerate. Do not freeze.

Keep all medicine out of reach and sight of children.

Return all unused medicines to your healthcare professional.

Do not dispose of unused medicines in drains and sewerage systems (e.g. toilets)

7. PRESENTATION OF AXIM E-Z-CAT:

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

8. IDENTIFICATION OF AXIM E-Z-CAT:

AXIM E-Z-CAT is a white, viscous, aqueous suspension with a sweet orange flavor without grittiness.

9. REGISTRATION NUMBER:

35/28/0126

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

Axim Pharmaceuticals (Pty) ltd

63 Old Pretoria Main Road

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11. DATE OF PUBLICATION:

To be allocated by Council.