APPROVED PATIENT INFORMATION LEAFLET

**Please read this leaflet carefully before using AXIM READICAT 2%**

- 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.

**SCHEDULING STATUS:**

S4

**PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:**

**AXIM READICAT 2% SUSPENSION**

## 1. WHAT AXIM READICAT 2% SUSPENSION CONTAINS

The active ingredient is barium sulphate.

The inactive ingredients are citric acid, natural and artificial orange flavour, natural and artificial vanilla powder, potassium sorbate, purified water, saccharin sodium, simethicone emulsion, sodium benzoate, sorbitol and xanthan gum.

## 2. WHAT AXIM READICAT 2% SUSPENSION IS USED FOR

**AXIM READICAT 2%** is used as a contrast agent: a liquid that is injected/ 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 USE AXIM READICAT 2% SUSPENSION

**Do not take AXIM READICAT 2%**

- If you are hypersensitive (allergic) to barium sulphate or any of the inactives in the product.

- If you have gastro-intestinal diseases such as perforation (holes in the lining of the gastro-intestinal tract) or colitis (inflammation of the lining of the large intestine).

**Precautions:**

- **AXIM READICAT 2%** should be used with caution in elderly patients with pre-existing heart disease.
- You must be adequately hydrated (enough water intake) after the procedure to prevent severe constipation.
- Take the medicine carefully to ensure that you do not accidentally have aspiration into your lungs.

**Warnings:**

- This product should only be used under medical supervision.

**Using other medicines with AXIM READICAT 2%**

AXIM READICAT 2% **may interact with other medicines: in particular, those that cause constipation. Concomitant used of such medications may aggravate the constipation.**

Consult your doctor or pharmacist or healthcare professional for advice if you need to take any other medicines. If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **AXIM READICAT 2%** with these medicines may cause undesirable interactions. Tell your doctor or healthcare professional if you are taking any other medicines, including any you have bought at your pharmacy, supermarket or health shop.

**Pregnancy and breast feeding:**

If you are pregnant or breast feeding your baby while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

- **AXIM READICAT 2%** can be used during pregnancy, but radiographic procedures may be harmful to the foetus. Your doctor will decide if a procedure is essential even if you are pregnant.
- **AXIM READICAT 2%** can be used during breast-feeding.

## 4. HOW TO TAKE AXIM READICAT 2%

**AXIM READICAT 2%** is a suspension and will be administered to you either through an enema (rectally) or orally.

Your dosage and the technique involved for using **AXIM READICAT 2%** may be different from other patients and will be determined by the radiologist.

Your dosage will also be dependent on the type of scan you will receive and will be determined by the radiologist.

**If you take more AXIM READICAT 2% than you should:**

Your radiologist will determine your dosage. However, in the event of over dosage, your doctor will treat the symptoms of the side effects, such as stomach cramps and diarrhoea. Please consult your doctor or pharmacist or seek help at the nearest hospital or poison control centre.

## 7. SIDE EFFECTS

**AXIM READICAT 2%,** as all other medicines, may have side effects. Not all side effects reported for this medicine are included in this leaflet.

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, 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

**Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.**

## 8. STORAGE AND DISPOSAL OF AXIM READICAT 2%

Store in a cool, dry place 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 pharmacist.

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

## 9. PRESENTATION OF AXIM READICAT 2%:

**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.

**10. IDENTIFICATION AXIM READICAT 2%:**

**AXIM READICAT 2%** is a low viscosity, white, aqueous suspension with a sweet orange and vanilla flavour, without grittiness.

**11. REGISTRATION NUMBER:**

37/28/0521

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

Axim Pharmaceuticals (Pty) Ltd

63 Old Pretoria Main Road, Halfway House

1685, Midrand

**13. DATE OF PUBLICATION OF THE PACKAGE INSERT:**

22 February 2008