Clean Patient Information Leaflet for Axim Polibar ACB

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

AXIM POLIBAR ACB, Powder for rectal suspension

Barium sulphate

Read all of this leaflet carefully before you are given AXIM POLIBAR ACB.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

What is in this leaflet

1. What AXIM POLIBAR ACB is and what it is used for
2. What you need to know before you receive AXIM POLIBAR ACB
3. How AXIM POLIBAR ACB will be administered
4. Possible side effects
5. How to store AXIM POLIBAR ACB
6. Contents of the pack and other information.

1. What AXIM POLIBAR ACB is and what it is used for

AXIM POLIBAR ACB contains the active substance barium sulphate.

AXIM POLIBAR ACB is a contrast medium for use in diagnostic X-ray visualisation of the lower gastrointestinal tract (GI)(such as your bowels/intestines). A radiographic (X-ray) examination of the lower GI is made visible on X-ray film by filling your bowel with the liquid suspension called

AXIM POLIBAR ACB. Certain areas in your body can be highlighted and a clearer picture can be created.

2. What you need to know before you receive AXIM POLIBAR ACB

AXIM POLIBAR ACB should not be administered to you:

- If you are hypersensitive (allergic) to barium sulphate or any of the other ingredients of AXIM POLIBAR ACB (see section 6).
- If you have an obstruction of the colon or suspect that perforation (a small hole that develops through the wall of your intestines) of the GI tract is likely to occur soon.
- If you suffer from GI bleeding or GI ischaemia (blood flow through the major arteries that supply blood to your intestines slows or stops).
- If you have a megacolon or toxic megacolon (an abnormal dilation of the colon).
- If you have severe constipation or have problems with your gut movement which could lead to a build-up or blockage.
- If you have a serious disease that affects your intestines.
- If you have had infection or inflammation in your GI tract which caused a fistula to form (an abnormal connection between two body parts).
- If you are at risk of developing perforation, infection or inflammation of your intestines after undergoing biopsies or diagnostic testing.
- If you have had radiotherapy to the rectum or prostate, you should not receive AXIM POLIBAR ACB for up to six weeks afterwards.
- If you have an injury or have suffered from chemical burn of your GI tract.

Warnings and precautions

AXIM POLIBAR ACB is for diagnostic use only.

AXIM POLIBAR ACB is only administered in hospitals or clinics.

Tell your doctor or health care provider before you are given the rectal suspension:

- If you have any underlying conditions or disease, especially conditions affecting your digestive tract.
- If you have any known hypersensitivities.
- If you have a history of bronchial asthma (a lung disease causing difficulty in breathing) or a family history of being allergic.
- If you have atopy (a problem with your immune system that makes you more likely to develop allergic diseases) and when you have developed allergies such as hay fever and eczema (skin inflammation).
- If you have ever developed a previous allergic reaction after using contrast medicines.

Special care should be taken with AXIM POLIBAR ACB:

- If you suffer from a condition such as pyloric stenosis (the muscle between the stomach and intestines swells or becomes thickened, which blocks food from entering the intestines) or lesions which may lead to obstruction.
- If you currently suffer from diseases such as known carcinomas (a type of cancer), inflammatory intestinal disease or any complications of the intestines, including infection or illness. These diseases are factors that may increase your risk of perforation (a small hole that develops through the wall of your bowel)(see section 2, “AXIM POLIBAR ACB should not be administered to you”).
- If you suddenly become unwell, after having received the treatment, especially if you are an older adult, the possibility of intravasation (barium sulphate moving into your systemic circulation) should be considered and the diagnosis should be confirmed.
- If you are dehydrated, have previously had constipation, or if you suffer from any other condition or treatment that may affect your gut motility and put you at risk of developing severe constipation (see section 2, “AXIM POLIBAR ACB should not be administered to you”).You should drink plenty of fluid and hydrate properly. It is recommended to receive additional measures such as saline cathartics (e.g. laxatives) on a routine basis.

- If you have previously had head injuries, brain tumour or if you have a condition in which the pressure in your skull has increased.
- If you experience vasovagal reactions (e.g. fainting), cardiac dysrhythmia (abnormal or irregular heartbeat) or other cardiovascular side effects.
- If you experience emotions of feeling tense and anxious about the treatment, you may develop weakness, ringing in the ears, pale colour of the skin and lowered blood pressure. It is advised that you should be assisted to lie flat for an additional 10 to 30 minutes and be closely observed.
- If you suffer from electrolyte disturbances (changes in the salt levels in the body such as low calcium, low potassium, high phosphate or high sodium levels), then you may be at risk of developing abdominal pain or obstruction, caused by the formation of baroliths (when your stool becomes thickened and hindered with barium).
- If you have problems with your GI movement or are eating low-fibre foods, then you may be at risk of developing abdominal pain or obstruction, caused by the formation of baroliths (when your stool becomes thickened and hindered with barium).

Elderly patients

- If you are an elderly patient, proper hydration should be maintained to reduce the risk of developing abdominal pain or obstruction, caused by the formation of baroliths (especially if you have problems with your GI movement, are eating low-fibre foods or have electrolyte disturbances).
- If you are an elderly patient and you have pre-existing heart disease.

Other medicines and AXIM POLIBAR ACB

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

It is not known if AXIM POLIBAR ACB interacts with other medicines.

Pregnancy and breastfeeding

If you are pregnant, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before you receive AXIM POLIBAR ACB.

Driving and using machines

It is not always possible to predict to what extent AXIM POLIBAR ACB may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which AXIM POLIBAR ACB affects you.

3. How AXIM POLIBAR ACB will be administered

You will not be expected to give yourself AXIM POLIBAR ACB. It will be given to you by a person who is qualified to do so.

AXIM POLIBAR ACB will be given to you as a rectal suspension (enema) by your doctor. AXIM POLIBAR ACB will be inserted into the back passage (rectum), where it will remain throughout the procedure.

Your dosage will depend on the technique used and the desired type of examination.

If you receive more AXIM POLIBAR ACB than you should

Since a health care provider will administer this medicine, he/she will control the dosage. However, in the event of overdosage, your doctor will manage the overdosage.

4. Possible side effects

AXIM POLIBAR ACB can have side effects.

Not all side effects reported for AXIM POLIBAR ACB are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving AXIM POLIBAR ACB, please consult your health care provider for advice.

If any of the following happens, stop receiving AXIM POLIBAR ACB and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to AXIM POLIBAR ACB. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Chest pain or changes in your blood pressure such as bradycardia (slow heart rate) or tachycardia (rapid or irregular heart rate).
- Bronchospasm (where your airways go into spasm making it difficult to breathe, which may cause wheezing or coughing).
- Intestinal ischaemia (when the blood flow through the major arteries that supply blood to your intestines slows or stops).
- Perforation (a small hole that develops through the wall of your bowel) or if you develop severe inflammation, ulcers or obstruction of your GI tract.

Tell your doctor if you notice any of the following:

Rare side effects:

- Abdominal pain.
- Nausea, vomiting.
- Bacteraemia (presence of bacteria in your blood).
- Intestinal abscess (a collection of pus or infected fluid that is surrounded by inflamed tissue inside the belly).

- Liver abscess (a pus-filled pocket of fluid within the liver).
- Peritoneal infection (an inflammation of the inside of your abdomen) or appendicitis (a condition in which the appendix becomes inflamed, swollen or infected, causing pain in the lower right side of your torso).
- Swelling of lymph nodes (small glands responsible for regulating your immune system).
- Low blood sugar.
- Confusion.
- Nervousness.
- Agitation.
- Dizziness.
- Headache.
- Low muscle tone.
- Swelling of your eyes.
- Ringing in ears.
- Cyanosis (a blue discolouration of the skin).
- Pale skin.
- Hypotension (low blood pressure).
- Dyspnoea (sensation of uncomfortable breathing).
- Throat tightness, throat irritation or pain.
- Cough.
- Constipation or diarrhoea.
- Swollen tongue.
- Feeling bloated.
- Inflammation of the skin.
- Excessive sweating.
- Painful urination.
- Weakness.
- Feeling ill or feverish.

- Formation of baroliths, when your stool becomes thickened and hindered with barium.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the 6.04 Adverse Drug Reaction Reporting Form, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of AXIM POLIBAR ACB.

5. How to store AXIM POLIBAR ACB

Store all medicines out of reach of children.

Store at or below 25 °C.

Protect from moisture.

AXIM POLIBAR ACB should be used immediately following reconstitution and must not be stored.

ALWAYS RESHAKE PRIOR TO USE.

6. Contents of the pack and other information

What AXIM POLIBAR ACB contains

The active substance is barium sulphate.

Each 100 g contains AXIM POLIBAR ACB powder contains 96,48 g of barium sulphate.

Each bag of 397 g AXIM POLIBAR ACB powder contains 383,02 g barium sulphate.

Each bag of 570 g AXIM POLIBAR ACB powder contains 549,99 g barium sulphate.

Each bag of 680 g AXIM POLIBAR ACB powder contains 656,06 g barium sulphate.

The other ingredients are citric acid anhydrous, pectin, polysorbate 80, simethicone, sodium

citrate, sorbitol and tragacanth.

What AXIM POLIBAR ACB looks like and contents of the pack

Dense, off-white, tasteless, bulky powder, without grittiness, odour or flavour.

Contents of the pack:

Frosty and clear polyvinyl chloride film enema bag. Each bag is marked with graduations in increments of 500 mL. The bag is equipped with a polyvinyl chloride rectal tube and an enema tip.

Pack sizes:

Polyvinyl chloride bag containing either 397 g, 570 g or 680 g of AXIM POLIBAR ACB powder.

Not all pack sizes may be marketed.

Holder of the certificate of registration

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This leaflet was last revised in:

To be allocated by SAHPRA.

Registration number

35/28/0129