

**MODULE-1 ADMINISTRATIVE  
INFORMATION FOR AXAMOL**

**PATIENT INFORMATION LEAFLET (PIL)**

**Read this entire leaflet carefully before you starts taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any of the side effects gets serious, or if you notice any possible side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist.

**What is in this leaflet:**

- 1. What AXAMOL is and what it is used for**
- 2. What you need to know before you use AXAMOL**
- 3. How to use AXAMOL**
- 4. Possible side effects**
- 5. How to store AXAMOL**
- 6. Contents of the pack and other information**

**1. WHAT AXAMOL IS AND WHAT IT IS USED FOR**

Salbutamol nebulizer solution contain a medicine called salbutamol. This belongs to a group of medicines called fast-acting bronchodilators.

- Bronchodilators help the airways in your lungs to stay open. This makes it easier for air to get in and out.
- They help to relieve chest tightness, wheezing and cough.

Salbutamol nebulizer solution are used to treat breathing problems in people with asthma and other chest illnesses. They are usually given to people who suffer quite badly from these conditions when other forms of treatment do not help enough. Salbutamol nebulizer solution are also given to treat severe attacks of asthma.

A Nebule is a small plastic container that contains a liquid. The liquid is put into a machine called a nebulizer. This machine makes a fine mist for you to breathe in through a face mask.

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**2. WHAT YOU NEED TO KNOW BEFORE YOU USE AXAMOL**

Do not use **AXAMOL** if:

- you are allergic to salbutamol sulfate or any of the other ingredients of this medicine (listed in Section 6).
- you unexpectedly go into early labour (premature labour) or threatened abortion.

**Warnings and precautions**

Talk to your doctor, nurse or pharmacist before taking **AXAMOL** if:

- your asthma is active (for example you have frequent symptoms or flare ups or limited physical ability). Your doctor may start or increase a medicine to control your asthma such as an inhaled corticosteroid.
- you have high blood pressure
- you are diabetic
- you have an overactive thyroid gland
- you have a history of heart problems such as an irregular or fast heartbeat or angina
- you use another nebulizer solution e.g. ipratropium bromide, make sure the mist does not get in your eyes. This can be prevented by using a mouthpiece instead of a face mask or goggles.
- you are taking xanthine derivatives (such as theophylline) or steroids to treat asthma.
- you are taking water tablets (diuretics), sometimes used to treat high blood pressure or a heart condition.
- If you have taken other drugs used to relieve stuffy nose (such as ephedrine or pseudoephedrine) or other medicines used to treat asthma,

**Other medicines and AXAMOL**

Tell your doctor, nurse or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. This includes herbal medicines. Remember to take this medicine with you if you go to hospital.

In particular, tell your doctor, nurse or pharmacist if you are taking:

- medicines for an irregular or fast heartbeat
- other medicines for your asthma.

**AXAMOL** with food and drink

You can use **AXAMOL** at any time of day, with or without food.

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**Pregnancy, breast-feeding and fertility**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor, nurse or pharmacist for advice before taking this medicine.

**Driving and using machines**

AXAMOL are not likely to affect you being able to drive or use any tools or machines.

You should not drive or use machinery while using the nebulizer as this makes the mist for you to inhale.

**3. HOW TO USE AXAMOL**

Always use this medicine exactly as your doctor has told you. Check with your doctor, nurse or pharmacist if you are not sure.

**Using this medicine**

- **do not inject or swallow the liquid.** AXAMOL should only be inhaled using your Nebulizer
- **do not let the liquid, or the mist produced by the Nebulizer get into your eyes.** You can wear glasses or goggles to protect them
- your doctor, nurse or pharmacist should show you how to use your medicine
- each small plastic container (Nebulizer) contains some liquid
- the liquid is put into a Nebulizer. This makes a fine mist for you to breathe in through a face mask or mouthpiece
- use your Nebulizer in a well ventilated room as some of the mist will be released into the air and may be breathed in by others.

Children under 18 years should only use a Nebulizer to take reliever medications under the care of a doctor with expertise in the management of asthma so that deterioration in asthma control can be detected and treated without delay.

Only use the Nebulizer recommended by your doctor and supervise your child while they are using the Nebulizer.

Seek urgent medical assistance if the nebulised medication is not working, even if there is short-term recovery following use of prescribed nebulised medication.

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**Adults, adolescents aged 12 years and over and children 4 to 11 years of age**

- The usual starting dose is 2.5 mg up to four times daily. Increased to 5 mg up to four times daily if required.

**Using your Nebulizer**

1. Your Nebulizer are in a flow wrap. Do not open the flow wrap pack until you need to use it
2. Open the flow wrap by tearing downwards from the tear point, located on the right hand side of the seal at the top of the pack.
3. Hold the strip of Nebulizer in one hand, with your other hand hold the last Nebulizer in the row
4. Twist the Nebulizer downwards and away from you
5. Return the remaining nebulizer to the flow wrap pouch. Write the discard date in the “discard after” box on the pouch, as a reminder. The discard date is 3 months from the date you opened the flow wrap pouch. Return the opened flow wrap pouch to the box.
6. Hold the top of the Nebulizer you have just removed. Twist the body to open it
7. Put the open end of the Nebulizer into the Nebulizer bowl and squeeze slowly. Make sure that all the contents are emptied into the Nebulizer
8. Assemble the Nebulizer and use it as directed

**Diluting your Nebulizer**

- do not dilute the contents of a Nebulizer unless you are told to by your doctor
- if your doctor has told you to dilute the solution, empty the contents of the Nebulizer into the nebulizer bowl
- add the amount of sterile normal saline your doctor has told you to use
- put the top on the Nebulizer bowl and shake gently to mix the contents.

If dilution is necessary then only sterile normal saline should be used.

**After use**

- use a fresh Nebulizer for each dose. Only open a new one when you are ready to use it.

If there is any liquid left over, throw it away. Do not save it to use again

- throw away any solution remaining in the Nebulizer bowl
- clean your Nebulizer in the recommended way.

If you use more AXAMOL than you should

If you use more than you should, talk to a doctor as soon as possible.

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The following effects may happen:

- your heart beating faster than usual
- you feel shaky.
- hyperactivity

These effects usually wear off in a few hours.

If you forget to use AXAMOL

- If you forget a dose, take it as soon as you remember it.
- However, if it is time for the next dose, skip the missed dose.
- Do not take a double dose to make up for a forgotten dose.

If you stop using AXAMOL

Do not stop using AXAMOL without talking to your doctor.

If you have any further questions on the use of this medicine, ask your doctor, nurse or pharmacist.

#### **4. POSSIBLE SIDE EFFECTS**

**If your breathing or wheezing gets worse straight after taking this medicine, stop using it immediately, and tell your doctor as soon as possible.**

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Allergic Reactions (may affect up to 1 in 10,000 people)

If you have an allergic reaction, stop taking AXAMOL and see a doctor straight away.

Signs of an allergic reaction include: swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing, itchy rash, feeling faint and light headed, and collapse.

Talk to your doctor as soon as possible if:

- you feel your heart is beating faster or stronger than usual (palpitations). This is usually harmless, and usually stops after you have used the medicine for a while
- you may feel your heartbeat is uneven or it gives an extra beat
- these may affect up to 1 in 10 people.

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If any of these happen to you, talk to your doctor as soon as possible. **Do not stop using this medicine unless told to do so.**

Tell your doctor if you have any of the following side effects which may also happen with this medicine:

**Common** (may affect up to 1 in 10 people)

- feeling shaky
- headache.

**Uncommon** (may affect up to 1 in 100 people)

- mouth and throat irritation
- muscle cramps.

**Rare** (may affect up to 1 in 1,000 people)

- a low level of potassium in your blood
- increased blood flow to your extremities (peripheral dilatation).

**Very rare** (may affect up to 1 in 10,000 people)

- changes in sleep patterns and changes in behaviour, such as restlessness and excitability.

**The following side effects can also happen but the frequency of these are not known:**

- chest pain, due to heart problems such as angina. Tell your doctor, nurse or pharmacist if this occurs. Do not stop using this medicine unless told to do so
- a condition known as lactic acidosis which may cause stomach pain, hyperventilation, shortness of breath even though there may be improvement in your wheezing, cold feet and hands, irregular heartbeat or thirst.

## **5. HOW TO STORE AXAMOL**

Keep out of the reach and sight of children.

If the flow wrap has not been opened, do not use AXAMOL after the expiry date, which is stated on the carton, labels and flow wrap after 'EXP'. The expiry date refers to the last day of that month.

Store below 30°C. Protect from light. Do not refrigerate or freeze.

If you are told to stop taking this medicine return any unused AXAMOL to your pharmacist to be destroyed

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Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

**6. CONTENTS OF THE PACK AND OTHER INFORMATION**

What **AXAMOL** contains

- The active substance is salbutamol sulphate.
- Each 2.5 ml respules contains Salbutamol Sulphate which is equivalent to Salbutamol 2.5 mg
- The other ingredients are sodium chloride, Disodium Edetate, sodium citrate, citric acid & water for injections.

**What AXAMOL looks like and contents of the pack**

Clear & colourless solution.

**Pack:** 4 x 5 x 2.5 ml LDPE Respule wrapped in a foil pouch packed in a Unit Carton, along with the pack insert.

**7. Manufacturer & Marketing Authorization Holder**

**AXA PARENTERALS LIMITED**

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