

## Direct Healthcare-Professional Communication (DHPC)

10 September 2025

### Salbuair 2.5 mg/2.5 ml (Salbutamol Sulfate) Nebuliser Solutions – Packaging Language Compliance Update

**Dear Healthcare Professional,**

Esnad Medical Trading, in agreement with the Saudi Food and Drug Authority, would like to inform you of the following:

#### Summary

- **This DHPC is issued solely to update packaging language compliance—no changes to formulation, safety profile, or efficacy.**
- **This communication informs you that English Patient Information Leaflets (PILs) and labels are now included with Salbuair products in Saudi Arabia to ensure compliance with SFDA packaging requirements.**
- **English labels have been affixed to all outer cartons for improved compliance.**
- **Affected batch: AU124B.**

#### Background:

- Therapeutic indication: Relief of bronchospasm in chronic obstructive airway disease and acute asthma.
- The update ensures alignment with SFDA requirements that PILs be available in English.
- Dissemination at this point ensures prompt awareness among healthcare professionals that English PILs and labels are now in circulation.

#### Call for reporting

Healthcare professionals are reminded to report suspected adverse reactions:

- SFDA Call Center: 19999
- E-mail: [npc.drug@sfda.gov.sa](mailto:npc.drug@sfda.gov.sa)
- Website: <https://ade.sfda.gov.sa>



#### Company contact point

Purpose	Phone	E-mail
Pharmacovigilance / QPPV	+966 551 961 722	<a href="mailto:Eman.Alhowiriny@esnadmedical.com">Eman.Alhowiriny@esnadmedical.com</a>
Medical Information Support	+966 565 820 002	<a href="mailto:ashraf.ashour@esnadmedical.com">ashraf.ashour@esnadmedical.com</a>

**QPPV & Head of Quality Assurance – Esnad Medical Trading**

**Signature:** .....

This letter has been reviewed and approved by the Saudi Food and Drug Authority.

## **Annex :**

### **PACKAGE LEAFLET: INFORMATION FOR THE USER**

#### **Salbuair 2.5 mg nebuliser solution** Salbutamol sulphate

##### **Read all of this leaflet carefully before you start taking this medicine:**

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any

##### **What is in this leaflet:**

- 1. What Salbuair 2.5 mg is and what it is used for**
- 2. What you need to know before you take Salbuair 2.5 mg**
- 3. How to take Salbuair 2.5 mg**
- 4. Possible side effects**
- 5. How to store Salbuair 2.5 mg**
- 6. Contents of the pack and other information**

#### **1. WHAT SALBUAIR 2.5 mg IS AND WHAT IT IS USED FOR**

This medicine comes in ampoules containing an aqueous nebuliser solution. Salbuair 2.5 mg contains 2.5 mg of salbutamol (equivalent to 3 mg of salbutamol sulphate) dissolved in 2.5 ml of sterile isotonic saline solution.

The active substance in this medicine, salbutamol, belongs to a group of medicines called bronchodilators, which relax the muscles of the airway walls in the lungs. This helps the opening of the airways so that you can breathe more easily.

It is indicated in the treatment of chronic bronchospasm (closure of the airways in the lungs) that does not respond to conventional therapy and in the treatment of acute severe asthma.

#### **2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE SALBUAIR 2.5 mg**

##### **Do not take Salbuair 2.5 mg:**

- If you are allergic (hypersensitive) to salbutamol or any of the other ingredients of Salbuair 2.5 mg.
- Salbuair 2,5 mg should not be used during preterm labour or the threat of abortion.

**Warnings and precautions**

Talk to your doctor before taking Salbuair 2.5 mg:

- If you have heart disease, irregular heart rate or angina.
- If you have an over-active thyroid gland.
- If you have high blood potassium levels.
- If you have diabetes.
- If you have high blood lactate levels (lactic acidosis), because an increase in these levels can worsen respiratory problems.
- If you use salbutamol and ipratropium bromide together, because this combination can cause eye disorders like narrow-angle glaucoma.

**Other medicines and Salbuair 2.5 mg**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including over-the-counter medicines.

Some medicines may interact with Salbuair 2.5 mg. It is important to inform your doctor if you are taking any of the following medicines:

- Medicines containing non-selective beta-blockers, such as propranolol.
- Certain medicines used to treat depression (known as monoamine oxidase inhibitors and tricyclic antidepressants).
- Medicines containing anticholinergics (used to treat asthma, irritable bowel syndrome, Parkinson's disease and incontinence).
- Other medicines that help to make breathing easier such as terbutaline.

**Pregnancy and breast-feeding**

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

If administering Salbuair 2.5 mg during pregnancy or breast-feeding is necessary, your doctor will carefully assess the potential benefits and risks according to the severity of your condition.

**Driving and using machines**

No effects of Salbuair 2.5 mg on the ability to drive and use machines have been reported.

**Use in athletes**

Athletes are informed that this medicine contains salbutamol, which may give a positive result in a doping test (see references in section 4.4 of the Summary of Product Characteristics).

### **3. HOW TO TAKE SALBUAIR 2.5 mg**

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

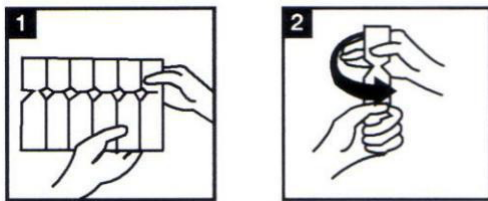
#### **Use in adults and children:**

The recommended dose is 2.5 mg up to four times a day. Your doctor may increase this dose to up to 5 mg four times a day. Your doctor may tell you to use your nebuliser regularly, daily or only when you are wheezy or are short of breath.

Salbuair 2.5 mg should be used with suitable nebuliser devices. The mist produced is inhaled through the mask or mouthpiece. Your doctor will tell you which nebuliser to use and how to use it.

#### **Instructions for correct administration of the medicine:**

Your medicine is for inhalation through a nebuliser and should not be injected or swallowed.



1. Prepare your nebuliser according to the instructions given by the manufacturer and your doctor. Make sure the nebuliser device is clean.
2. Take a plastic strip with ampoules from the box, open it out and remove one of the ampoules (Fig. 1). Leave the remaining ampoules on the strip and put it back into the box.
3. Take the ampoule and open it by turning the top (Fig. 2).
4. Unless your doctor gives you other instructions, add all the liquid from the plastic ampoule into the nebuliser solution container.
5. Use the nebuliser according to your doctor's instructions. Throw the empty plastic ampoule away.
6. After using the nebuliser, clean it according to the manufacturer's instructions.

If you think that the effect of Salbuair 2.5 mg is too strong or too weak, talk to your doctor or pharmacist.

**If you take more Salbuair 2.5 mg than you should**

If you take more than you should, you may develop abnormal heart rate, palpitations, tremor, rise or fall in blood pressure, abnormal pulse, angina, hot flushes, dry mouth and visual impairment.

In the event of overdose or accidental intake, contact your doctor or pharmacist immediately indicating the medicine and the amount taken. Contact your doctor or nearest hospital. Take this package leaflet or an ampoule of this medicine with you so that the doctor who treats you knows what you are taking.

**If you forget to take Salbuair 2.5 mg**

If you forget to take Salbuair 2.5 mg, take the next dose when it is due or earlier if you start feeling short of breath.

Do not take a double dose to make up for a forgotten dose.

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

Like all medicines, Salbuair 2.5 mg can cause side effects, although not everybody gets them.

Although it is not known exactly how common it is, some people may occasionally experience chest pain (due to heart problems like angina). Tell your doctor if you develop these symptoms while you are taking Salbuair 2.5 mg, but do not stop taking this medicine unless directed to do so by your doctor.

The following side effects have been reported:

**Common** (affects less than 1 in 10 people but more than 1 in 100 people)

- Headache
- Tremor
- Tachycardia

**Uncommon** (affects less than 1 in 100 people but more than 1 in 1,000 people)

- Palpitations
- Sore throat and mouth
- Muscle cramps

**Rare** (affects less than 1 in 1,000 people but more than 1 in 10,000 people)

- Low potassium levels in the blood (hypokalaemia).
- Dilation of the size of peripheral blood vessels (peripheral vasodilation).

**Very rare** (affecting fewer than 1 in 10,000 people)

- Allergic reactions (hypersensitivity), including angio-oedema and urticaria, bronchospasm, hypotension and collapse.
- Hyperactivity
- Arrhythmias, including atrial fibrillation, supraventricular tachycardia and extrasystoles (heart rhythm disorders).
- Paradoxical bronchospasm

**Frequency not known**

- Myocardial ischaemia (lack of blood supply to a part of the heart muscle).
- Lactic acidosis.

#### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system. By reporting side effects you can help provide more information on the safety of this medicine.

### **5. HOW TO STORE SALBUAIR 2.5 mg**

Keep this medicine out of the sight and reach of children.

Do not store above 25 °C. Store in the outer carton to protect from light.

The ampoules should be opened immediately before use and any remaining solution should be discarded. The ampoules should be used within 3 months after opening the aluminium pouch.

Do not use this medicine after the expiry date which is stated on the bottle after "EXP". The expiry date refers to the last day of that month.

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 protect the environment.

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

#### **What Salbuair 2.5 mg contains**

- The active substance is salbutamol sulphate. Each ampoule contains 2.5 mg of salbutamol (equivalent to 3 mg of salbutamol sulphate) dissolved in 2.5 ml of sterile isotonic saline solution.

- The other ingredients are: sodium chloride, water for injection and sulphuric acid.

**What Salbuair 2.5 mg looks like and contents of the pack:**

Salbuair 2.5 mg is packed in strips of 10 ampoules containing a colourless or pale yellow solution inside an aluminium pouch.

Each box contains 60 ampoules.

**Marketing Authorisation Holder:**

Laboratorio ALDO-UNIÓN, S.L.

Baronesa de Maldá, 73

08950 Esplugues de Llobregat

Barcelona (Spain)

**Manufacturer:**

Laboratoire Unither

Espace Industriel Nord

151 rue André Durouchez-CS 28028

80084 AMIENS Cedex 2

France

**Other pack sizes:**

Salbuair 5 mg nebuliser solution.

**This leaflet was last revised in June 2013**

**To report any side effect(s):**

**. Saudi Arabia**

- The National Pharmacovigilance and Drug Safety Centre (NPC)
- Fax: +966-11-205-7662
- Call NPC at +966-11-2038222, Exts: 2317-2356-2353-2354-2334-2340.
- Toll free phone: 8002490000
- E-mail: npc.drug@sFDA.gov.sa
- Website: [www.sFDA.gov.sa/npc](http://www.sFDA.gov.sa/npc)

**Other GCC States**

- Please contact the relevant competent authority.

### **This is a Medicament**

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.