DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION (DHPC)

Date: 11th of August 2025

Subject: Atropine sulphate, Atropine B. Braun 1 mg/ml solution for injection – Packaging Leaflet Language Issue

Dear Healthcare Professional:

Nupco in agreement with the Saudi Food and Drug Authority (SFDA), would like to inform you about an issue related to the packaging language for certain batches of Atropine Sulfate.

Summary:

- It has come to our attention that the following batches of Atropine Sulfate were distributed with packaging information and a package insert written in Spanish only.
- The English-language patient information leaflet was not included as required.
- This issue is limited to the language of the labeling and does not affect the quality, safety, or efficacy of the product itself. However, the absence of English-language instructions may pose a risk of misinterpretation or misuse.
- Corrective and Preventive Actions have been taken to avoid any future similar events.
- The English version of the package leaflet is attached for your reference and use to provide it to patients who have received the affected batches to ensure correct usage.

Manufacturer	Batch Number	Product Name
B BRAUN	• 2305311 • 2310114 • 2249711	Atropine Sulfate 1 mg/ml solution for injection

Note: The attached English patient leaflet should be used as the reference until the correct packaging is available. *(Annex 1)*

Further information:

Atropine B. Braun is an injectable solution. The active substance in this medicine is atropine sulphate, which belongs to a group of medicines called anticholinergics. These medications reduce saliva production and secretions from the bronchial tubes, help muscles relax (such as those in the intestine), and increase the heartbeat.

This medicine is used as:

- Pre-anesthetic: medication used before general anesthesia
- Spasmolytic: to treat liver and kidney colic. It is used to help treat irritable bowel syndrome (irritable bowel, mucous colitis, and spastic colon)
- Heart-stimulant: (when the heartbeat is slow)
- Antidote in poisoning by certain insecticides or other anticholinesterases

Reporting Adverse Events:

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system.

- To reports any side effect(s):

- **Saudi Arabia:**

- The National Pharmacovigilance Centre (NPC):

- SFDA Call Center: 19999
- E-mail: npc.drug@sfda.gov.sa
- Website: https://ade.sfda.gov.sa/
- QR Code:

Nupco Quality Liaison Officer

- Mobile: +966-59-463-4446
- Email: abamutairi@nupco.com

Best Regards,
Abdulkarim A. Almutairi
Quality Liaison Officer

Annex 1: Atropine Sulfate Package Leaflet (English Version)

Package leaflet: patient information

Atropine B. Braun 1 mg/ml solution for injection
Atropine sulphate

Read the entire package leaflet carefully before you start using this medicine because it contains information that is important to you.
- Keep this leaflet, as you may have to re-read it.
- If you have any questions, ask your doctor, pharmacist, or nurse.
- If you experience side effects, consult your doctor, pharmacist or nurse, even if they are side effects that are not listed in this leaflet. See section 4

Package Leaflet Contents:

1. What is Atropine B. Braun 1 mg/ml and what is it used for?

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2. What you need to know before using Atropine B. Braun 1

mg/ml Do not use Atropine B. Braun 1 mg/ml

- if you are allergic (hypersensitive) to Atropine sulfate or any of the other components of Atropine B. Braun
- in patients with alterations in the functioning of the heart
- in patients with glaucoma (an eye disease that can cause vision loss accompanied by pain and redness)

- in patients with prostate problems, which can cause urinary retention
- in patients with myatenia gravis (disease that causes extreme tiredness and muscle weakness).

Warnings and Precautions

Talk to your doctor, pharmacist, or nurse before you start using Atropine B. Braun. Tell your doctor

about any allergies or medical problems you have or have ever had, especially:
- if you have Dawn syndrome
- if your heart beats faster than normal
- if you have inflammation of the esophagus (reflux esophagitis)
- if you have obstruction of the gastrointestinal tract (blockage in the stomach or intestine)
- if you have chronic lung disease
- in elderly patients and children
- if you have brain injuries, especially in children.

Use of Atropine B. Braun 1 mg/ml with other medicinal products

Tell your doctor or pharmacist if you are using, have recently used, or might need to use any other medications.

Administration of Atropine B. Braun together with the following medications may require a dose change or discontinuation of treatment.
- other anticholinergics (a type of muscle relaxant),
- antacids (a type of medicine to treat heartburn) or adsorbent antidiarrheals (a type of medicine to treat diarrhea),
- urinary alkalizing drugs (medicines that increase the pH of the urine),
- ketoconazole (used to treat fungal infections),
- metoclopramide (used in stomach emptying and to prevent vomiting or nausea), cisapride and domperidone.
- glucocorticoids (a corticosteroid that metabolizes carbohydrates), corticotropin (hormone from the adrenal glands), and haloperidol (used in the treatment of a type of mental illness)
- Cyclonapone (an anesthetic)
- opioid analgesics,
- potassium chloride,
- antiparkinsonians, anticholinergics (a class of medications to treat Parkinson's disease),
- major tranquilizers, such as phenotizaines (used to treat mental illness),
- antidepressants belonging to two groups: a) tricyclic antidepressants and b) monominooxidase inhibitors,
- antiarrhythmics (quinidine and procainimide),
- drugs that require long periods of time to dissolve in the digestive tract, such as digoxin.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, or think you might be pregnant or intend to become pregnant, consult your doctor or pharmacist before using this medicine.

Your doctor should weigh the benefits against the risks of this type of medication.

It may be found in low concentrations in breast milk, so breast-feeding should be avoided while using this medication.

Driving and using machines
Administration of atropine may produce effects such as confusion, blurred vision, sleepiness, etc., which may affect the ability to drive and use machines. If you notice these effects, do not drive or operate machines

3. How to use Atropine B. Braun 1 mg/ml

This medicine will always be administered by healthcare personnel.
This medication may be given intravenously, intramuscularly, or subcutaneously.

Your doctor will advise you on the most appropriate dose for you and the duration of your treatment based on the indication, age and body weight.

Use in children:
Strict supervision of medication is recommended in infants and children because they are especially sensitive to the toxic effects of this type of medication.
When given in places where the ambient temperature is high, there is a risk that the body temperature will rise rapidly.
High doses of this type of medication can produce an unusual reaction characterized by hyperexcitability.

Use in elderly patients:
They may respond to the usual doses of these types of medications with excitement, restlessness, agitation, drowsiness, or confusion.

They are also especially sensitive to the side effects of this type of medication (constipation, dry mouth and urinary retention). They can also precipitate undiagnosed glaucoma and impair memory in geriatric patients.

If you use more Atropine B. Braun 1 mg/mg than you should

The following may apply:
- dry mouth with difficulty swallowing and speaking,
- thirst
- mydriasis (dilation of the pupils),
- paralysis in visual accommodation and photophobia (phobia of light),
- increased eye pressure,
- dry skin,
- decreased heart rate followed by increased heart rate with palpitations and disturbances in the heart rhythm,
- constipation
- difficulty urinating,
- occasional vomiting,

In case of overdose or accidental ingestion, consult your doctor or pharmacist immediately or call the Poison Information Service telephone: 91 562 04 20, indicating the medicine and the amount used. Take this prospectus with you.

4. Possible side effects

Like all medications, Atropine B. Braun can cause side effects, although not everyone gets them.

The frequency of adverse effects is classified into the following categories:

Very common: (may affect more than 1 in 10 people) Frequent:
(may affect up to 1 in 10 people) Uncommon:
(may affect up to 1 in 100 people) Rare:
(may affect up to 1 in 1000 people) Very rare:
(may affect up to 1 in 10000 people)
Adverse events of unknown frequency (cannot be estimated from available data The following

adverse effects have been reported:

Eye disorders*:*
- Very common: blurred vision.
- Common: accommodation disorders, mydriasis, photophobia, glaucoma.

Metabolism and nutrition disorders:
- Very common: dry mouth.
- Common: taste alterations.

Gastrointestinal disorders:
- Common: nausea, vomiting, swallowing problems (dysphagia), constipation, blockage in the intestine (paralytic ileus).

Kidney and urinary disorders:
- Common: urinary retention.

Heart disorders:
- Common: palpitations, decreased heart rate (bradycardia - after low doses), increased heart rate (tachycardia - after high doses), and atrial palpitations and arrhythmias.

***Skin and connective tissue disorders*:**
- Common: Urticaria, a severe allergic reaction that causes a drop in blood pressure or shortness of breath (anaphylactic reaction).

Nervous system disorders:
- Common: headache, mental confusion or excitement (especially in older people), drowsiness.
- Uncommon: Insomnia.

Ear and labyrinth disorders:
- Uncommon: Dizziness.

Reproductive and breast disorders:
- Uncommon: impotence.

Respiratory, thoracic and mediastinal disorders:
- Uncommon: nasal congestion.

Reporting of adverse effects
If you experience any side effects, consult your doctor or pharmacist, even if they are possible side effects that are not listed in this leaflet. You can also report them directly through the Pharmacovigilance System for Medicinal Products for Human Use: www.notificaRAM.es By reporting adverse events you can help provide more information about the safety of this medicine.

5. Storage of Atropine B. Braun 1 mg/ml

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

It does not require special storage conditions.

Do not use Atropine B. Braun after the expiry date stated on the package (after EXP). The expiry date is the last day of the month indicated.

The contents of the ampoules should be used immediately after opening. Once the container is opened, discard the unused portion of the solution.

Medicines should not be thrown down the drains or in the trash. Deposit the containers and the medicines that you do not need at the SIGRE Point of the pharmacy. If in doubt, ask your pharmacist how to dispose of containers and medicines you don't need. In this way you will help protect the environment.

6. Contents of the package and additional

information Composition of Atropine B. Braun

1 mg/ml:

The active substance in Atropine B. Braun is atropine sulfate.
Each 1 ml ampoule contains 1 mg of atropine sulfate.

The other ingredients are: water for injections.

Product appearance and packaging contents

It comes in containers containing 10 and 100 glass ampoules of 1 ml.

Marketing authorisation holder and responsible for manufacturing
B. Braun Medical, S.A.

Ctra. de Terrassa, 121
08191-Rubí (Barcelona)
Spain

Manufacturing Manager

B. BRAUN MEDICAL, S.A.
Ronda de los Olivares, Plot 11. Los Olivares Industrial Estate. 23009 - Jaén (Jaén) - Spain

Date of last revision of this prospectus: June 2015

Detailed information on this medicine is available on the website of the Spanish Agency for Medicines and Health Products (AEMPS). http//www.aemps.gob.es

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This information is intended only for physicians or healthcare professionals

Dose:

Pre-anesthetic medication

Intramuscularly or subcutaneously one hour before anesthesia or intravenously immediately before anesthesia.

Adults: 0.3 to 0.6 mg.

Children: 0.01-0.02 mg/kg body weight (maximum 0.6 mg per dose). The dose is adjusted according to the patient's response and tolerance...

Spasmolytic:

Adults: intravenously, intramuscularly or subcutaneously: 0.4 to 0.6 mg intervals of 4-6 hours.

Vagal-induced bradycardia and bradycardia in which inhibition of vagal tone is indicated.

Adults: 0.5 - 1 mg (0.5 - 1 ml).

Children: 0.01-0.02 mg/kg body weight up to a maximum of 0.6 mg per dose. The dose will be adjusted according to the patient's response and tolerance

Anticholinesterase Antidote

Adults: 2 mg, preferably intravenously

Children: 0.05 mg/kg intravenously or intramuscularly

Repeat the administration every 5-10 minutes until the symptoms of atropine poisoning disappear

Organo-phosphorus antidote

Adults: 2 mg, intravenously or intramuscularly

Children: 0.05 mg/kg intravenously or intramuscularly

Repeat every 10-30 minutes until muscarinic signs and symptoms disappear

Overdose Treatment

The central and peripheral toxic effects of Atropine can be controlled with physostigmine salicylate 1-2 mg, injected subcutaneously, intramuscularly or intravenously; Due to its short duration of action, the injection can be repeated every 1 –2 hours if necessary.

Subcutaneous or intramuscular injection of neostigmine methylsulfate only controls peripheral effects. Arousal can be controlled with small doses of short-acting barbiturates such as thiopentone sodium (100 mg).

Treatment of atropine poisoning may require assisted breathing and oxygen, ice packs for hyperpyrexia (especially in children), catheterization, and fluid administration.