

Direct Healthcare Professional Communication (DHPC)

Date: 26-11-2025

Subject: Direct Healthcare Professional Communication (DHPC) Quality Defect in Buscopan 20 mg/ml (Affected Batches: 3J2164, 3J2233, 3J2551, 3J2231)

Dear Healthcare Professional,

Enmaeyat Trading Company, in agreement with the Saudi Food and Drug Authority (SFDA) in the Kingdom of Saudi Arabia, would like to inform you of the following important information.

Summary:

- A quality defect has been identified in one unit of Buscopan 20 mg/ml (Batch 3J2164 – 3J2233 – 3J2551 – 3J2231).
- The defect involves foreign-language outer packaging and a missing/non-English Patient Information Leaflet (PIL).
- This communication is being issued in alignment with SFDA requirements.

Further information on the safety concern and recommendations:

the following batches (3J2164 – 3J2233 – 3J2551 – 3J2231) of Buscopan 20 mg/ml was found to contain foreign-language labeling and a missing/non-English PIL. This appears to be an isolated handling error during preparation.

Healthcare professionals are advised to verify that any Buscopan 20 mg/ml pack dispensed includes the correct English leaflet.

Placing the risk in context of the benefit:

The defect is limited to labeling/PIL and does not affect the product's safety, quality, or efficacy.

Further information:

Additional updates will be provided if further findings emerge.

Call for reporting:

Healthcare professionals are encouraged to report any suspected adverse reactions or quality defects through The National Pharmacovigilance Centre (NPC) at SFDA:

Website: <https://ade.sfda.gov.sa>

- SFDA Call Center: 19999
- E-mail: npc.drug@sfda.gov.sa

Company Contact Point:

Pharmacovigilance Department – Enmaeyat Trading Company

Email: <regulatory@enmaeyat.com.sa>

Phone: <0500312000>

Annexes:

- English Patient Information Leaflet (PIL)

Package leaflet: information for the patient

BUSCOPAN 20 mg/ml solution for injection Joscine N-butylbromide

Read this leaflet carefully before using this medicine because it contains important information for you.

- Keep this sheet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has only been prescribed for you. Do not give it to other people, even if the symptoms of the disease are the same as yours, because it could be dangerous.
- If you experience any side effects, including those not listed in this leaflet, ask your doctor or pharmacist. See section 4.

In this sheet:

1. What Buscopan is and what it is used for
2. What you need to know before you use Buscopan
3. How to use Buscopan
4. Possible side effects
5. How to store Buscopan
6. Package contents and other information

1. What Buscopan is and what it is used for

Buscopan contains the active substance N-butylbromide of joscine, which belongs to a group of medicines called semi-synthetic nightshade alkaloids used for disorders of the motility of the stomach, intestines and biliary tract (gastrointestinal tract) and genitourinary tract.

Buscopan is indicated in **adults** in cases of:

- pain and spasms in the stomach and intestines,
- pain and spasms due to obstacles in the flow of the urinary tract and biliary tract (where bile, a substance involved in some digestive processes, flows).

Talk to your doctor if you do not feel better or if you feel worse after using the medicine.

2. What you need to know before you use

Buscopan Do not use Buscopan

- if you are allergic to the active substance N-butylbromide in joscine or any of the other ingredients of this medicine (listed in section 6);
- if you suffer from a severe form of glaucoma, i.e. eye disease caused by an increase in the pressure of the fluid contained inside it (acute angle glaucoma), for which you are not taking any medicine;
- if you suffer from an increase in the volume of the prostate (prostatic hypertrophy) associated with the inability of the urinary bladder to empty completely (urinary retention);
- if you suffer from narrowing of the pylorus, the terminal portion of the stomach (pyloric stenosis) or narrowing of other areas of the stomach and intestines (stenosis of other tracts of the gastrointestinal system);
- if you suffer from bowel disease, associated with disorders of bowel movements (paralytic or obstructive ileus), dilation of the colon (megacolon) and chronic inflammatory bowel disease (ulcerative colitis);
- if you suffer from a disorder caused by frequent regurgitation of stomach contents into the esophagus, the duct through which food reaches the stomach (reflux esophagitis);
- if you are elderly or if your physical condition is weak and you suffer from a lack of bowel movements, which cause intestinal obstruction (intestinal atony);

- if you suffer from muscle weakness (myasthenia gravis);
- if you suffer from an increased heart rate (tachycardia);
- if you have heart rhythm disorders (cardiac tachyarrhythmias).

If you are taking medicines used to reduce or stop the formation of blood clots (anticoagulants), do not use Buscopan for injection into muscle but talk to your doctor, who will give you the medicine into a vein or under the skin to prevent bruising.

Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine.

Contact your doctor if you experience severe pain in your belly area (abdominal pain) for no reason, which persists or worsens or is accompanied by symptoms such as fever, nausea, vomiting, bowel movement problems, bowel sensitivity, decreased blood pressure, fainting or blood in your stool. Your doctor will carry out appropriate tests to determine the cause of your symptoms.

Use Buscopan with caution:

- if he is elderly,
- if you suffer from a disorder in the nerves that maintain control of the proper functioning of glands and organs (autonomic nervous system),
- if you have high blood pressure (high blood pressure),
- if your heart does not have sufficient and adequate strength to pump blood into the circulation (congestive heart failure),
- if you suffer from an alteration in the functioning of the thyroid gland that can lead to weight loss, fatigue, weakness (hyperthyroidism),
- if you suffer from liver and/or kidney disease,
- if you suffer from a lung disease (chronic or obstructive inflammation of the respiratory system),
- if you have a fever.

If you experience pain and redness in your eyes with loss of vision after injecting Buscopan, contact your ophthalmologist urgently as you may have a severe form of glaucoma, i.e. eye disease caused by an increase in the pressure of the fluid contained within it (acute angle glaucoma), which you have not been diagnosed with and, consequently, has been treated.

Medicines such as Buscopan can prolong the time the stomach is empty by stagnating substances.

Do not stop treatment with high doses abruptly. Your doctor will assess your dose to control mild side effects or stop taking care of serious side effects.

As cases of severe allergic reactions have been observed after administration of Buscopan by injection, your doctor will monitor you after injecting you with the medicine.

If you have heart problems and are being parenterally treated with Buscopan, your doctor will monitor you.

Other medicines and Buscopan

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Use this medicine with caution and only under close medical supervision in the following situations:

- if you are taking medicines such as antidepressants (especially tri- and tetracyclic antidepressants), phenothiazines (medicines used for allergies or mental disorders), butyrophenones (medicines used for mental disorders and vomiting), antihistamines (medicines used for allergies), antipsychotics (medicines used for mental disorders), quinidine (medicine for the heart), amantadine (medicine for diseases of the central nervous system that involve a loss of control of the movements, such as Parkinson's disease), disopyramide (medicine for the heart) and other medicines for respiratory diseases (such as tiotropium, ipratropium), substances similar to atropine (a substance that acts at the level of the nervous system), because their effect can be increased by Buscopan;

- if you are taking medicines for vomiting and nausea, such as metoclopramide, because both their effect and Buscopan's may decrease;
- if you are taking anticoagulant medicines, which are used to reduce or stop the formation of blood clots (see section "Do not use Buscopan");
- if you are taking beta-adrenergic medicines (medicines used to treat asthma) because Buscopan may increase your tachycardia.

Buscopan with alcohol

Do not take alcohol while taking Buscopan.

Pregnancy, lactation and fertility

If you are pregnant, think you may be pregnant or plan to become pregnant, or breast-feeding, ask your doctor or pharmacist for advice before using this medicine.

If you are pregnant or breastfeeding, it is best to avoid using Buscopan. Your doctor will consider whether the use of this medicine is strictly necessary.

Driving and using machines

Medicines such as Buscopan can cause visual disturbances, dizziness and drowsiness, which you should be aware of if you are driving vehicles or machines or carrying out work that requires attention and alertness.

Buscopan contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dose, i.e. it is virtually 'sodium-free'.

3. How to use Buscopan

Always use this medicine exactly as your doctor or pharmacist has told you. If you are not sure, talk to your doctor or pharmacist.

Adults

The recommended dose is:

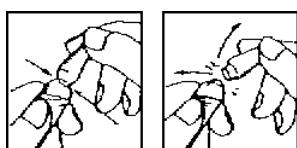
- 1 ampoule several times a day by injection into a muscle or vein.

Buscopan solution should be injected slowly.

Do not use Buscopan daily and regularly or for prolonged periods without being investigated for the cause of your belly pain.

How to use:

1. Break the vial at the point where the pre-break line is as shown in the figure, the file is not needed.



2. Proceed with administration by slow injection into a vein or muscle.

If you use more Buscopan than you should

If you accidentally take too much Buscopan, tell your doctor immediately or go to your nearest hospital.

Symptoms

Effects such as difficulty in the bladder emptying completely (urinary retention), dry mouth, increased number of heartbeats per minute (tachycardia), mild laziness and transient visual disturbances have been observed when taking an overdose.

Therapy

Your doctor will prescribe the appropriate treatment.

If you forget to use Buscopan

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

If you stop taking Buscopan

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

If you are taking high doses of Buscopan, do not stop treatment abruptly (see section "Warnings and precautions").

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Possible side effects are listed below as follows:

Common (may affect up to 1 in 10 people)

- difficulty in focusing on images (accommodation disorders),
- increased number of heartbeats per minute (tachycardia),
- dizziness
- dry mouth.

Frequency not known (frequency cannot be estimated from the available data)

- severe allergic reactions (anaphylactic reactions up to anaphylactic shock that can lead to death),
- difficulty breathing (dyspnoea),
- skin reactions (e.g., skin rash, itching, hives, skin irritation),
- pupil dilation (mydriasis),
- increased pressure of the liquid contained in the eye,
- decreased blood pressure,
- redness of the skin,
- alterations in sweating,
- inability of the urinary bladder to empty completely (urinary retention).

The following side effects have also been reported:

- sleepiness
- constipation
- difficulty urinating.

High doses may lead to signs of central nervous system stimulation, such as motor agitation and irritability, and interference with the state of consciousness and function of the heart and lungs.

Pain at the injection site occurs rarely, especially following intramuscular administration.

Reporting of side effects

If you experience any side effects, including those not listed in this leaflet, ask your doctor or pharmacist.

You can also report side effects directly via the national reporting system at

<https://www.aifa.gov.it/content/segnalazioni-reazioni-avverse>.

By reporting side effects you can help provide more information about the safety of this medicine.

5. How to store Buscopan

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

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

This medicinal product does not require any special storage conditions.

Do not dispose of any medicines in wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. This will help protect the environment.

6. Package contents and other information

What's in Buscopan

- The active substance is Joscin N-butylbromide 20 mg.
- The other ingredients are: sodium chloride, water for injections.

What Buscopan looks like and contents of the pack

Buscopan comes in glass vials.

It is available in packs of 6 vials of 1 ml.

Marketing Authorisation Holder and Manufacturer

Opella Healthcare Italy S.r.l.

Viale L. Bodio, 37/B

20158 Milan (Italy)

Producer

Boehringer Ingelheim Espana S.A.,
San Cugat del Vallès, Barcelona Spain

Sanofi S.r.l.

Via Valcanello, 4
03012 Anagni (FR)
Italy

This leaflet was last updated on