Date: 04/14/2026

Direct Healthcare Professional Communication (DHPC)

Manidon (Manidon 2.5 mg/ml solution for injection) Notification to Healthcare Professionals Regarding Packaging and Leaflet Deficiency

Dear Healthcare Professionals,
Greetings,

This information is being communicated in agreement with the Saudi Food and Drug Authority (SFDA). With reference to a report received from a healthcare institution regarding a packaging defect in Manidon 2.5 mg/ml solution for injection (Batch No. 303261A), and following review of the batch release data, we would like to inform you of the following.

Summary:

It has been found that the outer packaging and patient information leaflet of the affected batch are written in a foreign language other than English or Arabic, and no versions in Arabic or English were provided. This is non-compliant with SFDA requirements for ensuring clarity of information for users.

Further information on the safety concern and the recommendations:

- Coordination is ongoing with NUPCO to implement the necessary corrective actions.
- The English patient information leaflet was already distributed to all distributors together with the product batch to ensure availability of the required product information.

Recommendations:

- All healthcare professionals are kindly requested to refer to the English version of the Patient Information Leaflet for this batch to ensure that all necessary information is clearly communicated for safe and effective use.
- If you require more details regarding this batch, please contact the company at 0548365798 or via email at **Regulatory@aodci.com.sa**
- If you notice any packaging with unclear information for any other batch, please report it immediately to the SFDA reporting system: https://ade.sfda.gov.sa/Home/Report

Attachments:

- Please refer to the Patient Information Leaflet provided in Annex 1.

Call for Reporting

If you experience any adverse events or have concerns related to *Manidon 2.5 mg/ml solution for injection,* please report via:

- **Marketing Authorisation Holder (MAH):**
  Viatris Healthcare Limited
  Damastown Industrial Park, Mulhuddart, Dublin 15, Dublin, Ireland
  Tel: +44 (0) 800 121 8267, Email (PV): pv.ireland@viatris.com
- **National Pharmacovigilance Center (NPC) – Saudi Food & Drug Authority (SFDA):**
  Call Center: **19999**
  Email: **npc.drug@sfda.gov.sa** Website: **https://ade.sfda.gov.sa**

We appreciate your commitment to patient safety and quality care, and we thank you for your continued cooperation.
Sincerely,
Arabian Oasis for Development and Commercial Investment Company

This document is approved by The Executive Directorate of Pharmacovigilance, at SFDA.

ANNEX 1 Package leaflet: information for the user

Manidon 2.5 mg/ml solution
for injection

Verapamil hydrochloride

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.
- This medicine is prescribed only for you, and you should not give it to others even if they have the same symptoms as you, as it may harm them.
- 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 Insert Contents

1. What is Manidón and what is it used for?

Manidon belongs to the group of drugs called calcium channel blockers, with preferential cardiac action. These medications are used to treat angina, high blood pressure, or irregular heartbeat.

Injectable manidon is used in the treatment of supraventricular tachycardias, including:

-Paroxysmal supraventricular tachycardia, including that associated with accessory conduction pathways (Wolf-Parkinson-White syndrome, Lown-Ganong-Levine syndrome). When clinically justified, maneuvers aimed at stimulating vagal tone should be performed as a first step.

-Flutter or atrial fibrillation, except when associated with the existence of accessory conduction pathways (Wolf-Parkinson-White syndrome, Lown-Ganong-Levine syndrome).

2. What you need to know before you start Manidon

Do not use Manidon

- If you are allergic to verapamil hydrochloride or any of the other ingredients of this medicine (listed in section 6).
- If you have any of the following heart conditions:
  - Cardiogenic shock (the heart is unable to pump enough blood that the body needs).
  - Severe hypotension.
  - Second- or third-degree atrioventricular block (disorder in electrical conduction between the atria and the cardiac ventricles), except if a pacemaker is implanted.
  - Sinus disease (heart rhythm problems), except if a pacemaker is implanted.
  - Insufficiency Cardiac Congestive severe, except if it is secondary to One supraventricular tachycardia that can be treated with verapamil.
  - Flutter or atrial fibrillation (abnormal heart rhythms).
  - Ventricular tachycardia.

- If you are receiving intravenous beta-adrenergic blocking drugs.
- If you are taking a medicine that contains ivabradine to treat certain heart conditions.

Warnings and Precautions

Talk to your doctor, pharmacist, or nurse before using Manidon.

Manidon intravenous injection should be administered very slowly, for a time of not less than two minutes with blood pressure and electrocardiogram monitored.
A small proportion of patients who received Manidon experienced life-threatening adverse reactions.

Your doctor will need to take special care when giving this medication:

- If you have any of the following heart problems: acute phase of myocardial infarction complicated by bradycardia, marked hypotension, or left ventricular dysfunction; heart block, first-degree atrioventricular block, bradycardia, or systole.
- If you are taking a beta-blocker medicine for heart arrhythmias.
- If you are taking digoxin along with Mandon.
- If you have heart failure.
- If you have hypotension.
- If you have any of the following conditions that cause muscle weakness: myasthenia gravis, Lambert- Eaton syndrome, or advanced Duchenne muscular dystrophy.
- If you are taking digitalis medications at the same time.
- If you are taking quinidine.
- If you are taking flecainide.
- If you are taking disopyramide, as it should not be administered 48 hours before or 24 hours after taking disopyramide,
- If you have any kidney disease.
- If you have severe liver disease.

Other Medications and Manidon

tell your doctor or pharmacist if you are using, have recently used, or may need to use any other medications. Some drugs, if taken in conjunction with Manidon, may vary their effect. If you use or have ever used any of the following drugs, ask your doctor:

- Prazosin, terazosin (to treat high blood pressure).
- Flecainide, quinidine, disopyramide (for heart arrhythmias).
- Theophylline (for bronchial asthma).
- Carbamazepine (for seizures), phenytoin (antiepileptic).
- Imipramine (to treat depression).
- Glyburide (for diabetes).
- Metformin: Verapamil may reduce the hypoglycemic effect of metformin.
- Colchicine (for gout).
- Clarithromycin, erythromycin, rifampicin, telithromycin (antibiotics).
- Doxorubicin (for cancer).
- Phenobarbital (for seizures and as a sedative).
- Buspirone, midazolam (sedatives used for insomnia and anxiety).
- Metoprolol, propranolol (to treat hypertension and heart disorders).
- Digitoxin, digoxin (for heart disorders).
- Cimetidine (for the treatment of stomach ulcers).
- Cyclosporine, everolimus, sirolimus, tacrolimus (immunosuppressive drugs to lower the body's defenses).
- Atorvastatin, lovastatin, simvastatin (medicines to lower high cholesterol levels).
- Almotriptan (for migraine symptoms).
- Sulfinpyrazone (for gouty arthritis).
- Grapefruit juice.

- St. John's wort (medicine to treat depression).
- AIDS medicines, such as ritonavir.
- Lithium (for bipolar disorders).
- Neuromuscular blocking agents (used as adjuvants in anaesthesia).
- Aspirin.
- Alcohol.
- Antihypertensives (to lower high blood pressure), diuretics (medicines for urination), vasodilators (medicines for circulatory disorders).
- Inhalation anesthetics.
- Dabigatran (medicine to prevent blood clots)
- Other direct oral anticoagulants (medicines to prevent blood clots)

Pregnancy, breastfeeding and fertility
If you are pregnant or breastfeeding, think you might be pregnant, or intend to become pregnant, talk to your doctor or pharmacist before using this medicine.
There is no experience of using Manidon during pregnancy, especially. Talk to your doctor if you become pregnant while using Manidon.

Verapamil is excreted in breast milk in small amounts. Limited data from human studies suggest that verapamil use may be compatible with breastfeeding. Manidon should only be administered during breastfeeding if it is essential to the mother's health because of possible serious adverse reactions in infants.

Driving and using machines
Be careful when driving or using any dangerous tools or machinery as Manidon may reduce the ability to react, especially at the beginning of treatment, when the dose is increased, when changing when another medication was being used and with alcohol consumption.

Mandondon 2.5 mg/ml solution for injection contains sodium chloride
This medication contains less than 23 mg sodium (1 mmol) per dose; that is, essentially "sodium-free".

3. How to use Manidon

Follow the instructions for this medication as directed by your doctor or pharmacist exactly. If in doubt, consult your doctor or pharmacist again.

Remember to have your medicine given.

Your doctor will tell you how long you are taking Manidon to take you. Do not stop treatment beforehand.

Manidon is given by intravenous injection. Your doctor will decide which dosage of Manidon is best for you.

Adults:
The recommended dose for adults is as follows:
Starting dose: 5-10 mg (0.075-0.15 mg/kg) by slow injection in no less than two minutes.
If the previous dose is not enough, 10 mg (0.15 mg/kg) should be given 30 minutes after the first dose.

Elderly patients:
The dose should be administered for at least three minutes to minimize the adverse effects of the drug.

Use in children and adolescents
The recommended dose in children is as follows:
Children under 1 year of age: Initial dose: 0.1-0.2 mg/kg (0.75-2 mg) as a single dose. If necessary, the same dose will be repeated after 30 minutes. Perform administration under electrocardiographic monitoring.

Children 1-15 years: Starting dose: 0.1-0.3 mg/kg (2-5 mg) in a single dose for at least two minutes. Do not exceed 5 mg. If necessary, the same dose will be repeated after 30 minutes

If you think that the action of Manidon is too strong or weak, tell your doctor or pharmacist.

If you use more Manidon than you should
In case of an overdose of Manidon you may notice any of the following symptoms: feeling tired, shortness of breath, dizziness, weakness, chest pain, feeling like you are going to pass out, trouble thinking, intense thirst, dry and pasty mouth, urge to urinate, drowsiness, blurred vision, difficulty speaking or moving, nausea, vomiting, diarrhea, disorientation.

If you use more Manidon than you should, the doctor will stop the administration and apply the necessary measures because in case of severe poisoning it can cause death.

In case of overdose or accidental ingestion, consult your doctor or pharmacist or call the Poison Information Service, telephone 91.562.04.20, indicating the medication and the amount ingested.

4. Possible side effects

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

The following adverse events have resulted from clinical studies with verapamil or from post-marketing follow-up.

The most frequently reported adverse effects are headache, dizziness, gastrointestinal disturbances: nausea, constipation and abdominal pain, as well as bradycardia (decreased heartbeat), tachycardia (increased heartbeat), palpitations, hypotension (decreased blood pressure), hot flashes, peripheral edema (swelling in the feet, legs and ankles) and fatigue.

The following side effects have been observed at the following frequencies:

Common side effects (may affect up to 1 in 10 patients):

- Constipation
- Nausea
- Bradycardia
- Low blood pressure
- Hot flashes
- Seasickness
- Headache
- Peripheral edema

Rare side effects (may affect up to 1 in 100 patients):

- Abdominal pain
- Tachycardia
- Palpitations
- Fatigue

Rare side effects (may affect up to 1 in 1,000 patients):

- Vomiting
- Sleepiness
- Burning sensation
- Tingling or puncture (paresthesia)
- Tremor
- Ringing in the ears
- Excessive sweating

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

- Intestinal Occlusion
- Increased gums (gingival hyperplasia)
- Abdominal discomfort
- Bronchospasm
- Involuntary movements (extrapyramidal disorder)
- Paralysis (tetraparesis)*
- Seizures
- Abnormal enlargement of the breasts
- Impotence
- Milk secretion
- Vertigo
- Allergic reactions
- Muscle weakness
- Muscle pain
- Joint pain
- Angioedema
- Redness of the skin (erythema multiforme)
- Stevens-Johnson syndrome (more severe erythema)
- Maculopapular rash (rash with spots and papules)
- Hair loss
- Hives
- Purpura (glitter spots on skin and mucous membranes)
- Pruritus (itching)
- Increased liver enzymes
- Increased blood prolactin (a hormone that stimulates breast development and makes milk produced)
- First-, second- and third-degree atrioventricular block (blockage in the heart)
- Heart failure
- Sinus pause

- Sinus bradycardia
- Asystole
- Hyperkalemia
- Dyspnea (shortness of breath)
- Kidney failure

*There has been one report of paralysis when verapamil was taken with colchicine, so it is not recommended for combined use.

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

5. Manidon Conservation

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

Do not store at a temperature above 30ºC.
Store in the original packaging to protect it from light.

Do not use this medicine after the expiry date which is stated on the carton after DKA or EXP. The expiry date is the last day of the month indicated.

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 Manddon
The active substance is verapamil (as hydrochloride). Each ampoule contains 5 mg of the active ingredient. The other ingredients (excipients) are: sodium chloride, 10% hydrochloric acid and water for injection.

Product appearance and packaging contents
Manidón comes in clear colorless glass ampoules. Each pack contains 5 ampoules of 2 ml of aqueous and transparent solution for injection.

Marketing authorisation holder and person responsible for manufacturing Holder:
Viatris Healthcare
Limited Damastown
Industrial Park
Mulhuddart, Dublin
15 Dublin
Ireland

Responsible for manufacturing:

Famar Health Care Services Madrid,
S.A.U. Avda. de Leganés, 62.
28923 Alcorcón-Madrid.

You can request more information regarding this medicine by contacting the local representative of the marketing authorisation holder:

Viatris
Pharmaceuticals, S.L.
C/ General Aranaz,
86 28027
Madrid, Spain

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