شركة الأصول الطبية التجارية
Alosool Medical Trading Co.

Direct Healthcare Practitioners Communication (DHPC) Letter

Date: 01-06-2026

Subject:

Flindix 5mg Tablets (Isosorbide Dinitrate): Absence of Arabic and English labelling information on the outer packaging of Batch no. 3024.

Dear healthcare providers,

Alosool Medical Trading Company, in agreement with Saudi Food and Drug Authority (SFDA), would like to inform the healthcare professionals about packaging defect affecting batch no 3024 of Flindix 5mg Tablets where the outer packaging lacks Arabic and English labelling information.

Summary:

Expiry date	Batch No.	Product Name
31/12/2027	3024	Flindix

As per the quality report received by the pharmaceutical sector regarding this product, the following details were included:

- **The issue (Packaging defect)**
  The outer packaging of the affected batch contains labelling information in a language other than Arabic or English, resulting in the absence of accessible product information for healthcare professionals and patients in Saudi Arabia.

- **The affected batch**
  The following batch number is affected as per SFDA notification: **3024**

- **The corrective and preventive actions (CAPA's)**
  As a corrective action, Alosool Medical Trading Company is providing this DHPC with the approved English Packaging leaflet for the affected batch to ensure the appropriate product use until corrective labeling measured are completed.

Further safety information:

Healthcare professionals are advised to:

1- Review the enclosed package leaflet prior to dispensing the product.
2- Ensure the patient receive appropriate counseling regarding product use.
3- Exercise caution when dispensing the affected batch due to the lack of Arabic and English labelling information.

Call for Reporting Any Quality Defects or Side Effects:

Healthcare professionals are encouraged to report any suspected adverse reactions, medication errors, or quality defects associated with this product to National Pharmacovigilance Centre (NPC- Saudi Food and Drug Authority (SFDA):

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

E-mail: npc.drug@sfda.gov.sa
SFDA call center: 19999

Alosool Medical Trading company Contact point:
Name: Alhanouf Alabdulaziz In his capacity as: QPPV
E-mail: QPPV@omc-ksa.com
Mobile: 0535120254

For Medical Information enquiries, please contact:
Mobile: 0552040019
Email: Abdalkreem@omc-ksa.com

Annexes:
Flindix 5mg Tablets Leaflet

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

Best regards
Alhanouf Alabdulaziz
QPPV

Information leaflet: Information for the user

Flindix 5 mg tablet

isosorbide dinitrate

Read this leaflet carefully before taking this medicine.

Keep this leaflet. You may need to reread it.
If you have any further questions, ask your doctor or pharmacist.

This medicine has been prescribed for you. You should not give it to you to others; the medicine may be harmful to them even if they have the same symptoms.
If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this brochure:

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

Flindix belongs to the group of vasodilators used as antianginals.

It is indicated in:

- treatment and prophylaxis of all forms of angina: exertional, vasospastic, mixed, unstable, post-infarction angina and angina associated with heart failure.

- treatment and prophylaxis of silent ischemia.
- treatment of acute myocardial infarction.
- adjuvant treatment of heart failure and *cor pulmonale.*

Sublingual administration of Flindix tablets has specific indications: acute treatment of anginal attack of any etiology, immediate prevention of anginal attack and in the adjuvant therapy of acute pulmonary edema.

Note: Flindix is available in another form, in extended-release capsules containing 20 or 40 mg of isosorbide dinitrate - Flindix Retard. Flindix Retard is indicated for maintenance therapy as soon as it is possible to do so with a long-acting nitrate.

2. Before taking Flindix

Do not take Flindix

If you are allergic (hypersensitive) to isosorbide dinitrate or any of the other ingredients of Flindix.

Flindix is contraindicated in cardiogenic shock and in all clinical situations accompanied by arterial hypotension (systolic blood pressure below 90 mm Hg), in the absence of adequate hemodynamic monitoring.

Nitrates should generally not be administered to patients with angina due to obstructive hypertrophic cardiomyopathy, except for diagnosis, cardiac tamponade, constrictive pericarditis and whenever the reduction in venous return further compromises ventricular filling, as in the case of inferior infarction with right ventricular involvement.

The combination of organic nitrates, and therefore isosorbide dinitrate, with selective phosphodiesterase type 5 inhibitors (sildenafil, tadalafil and vardenafil) is formally contraindicated, as this combination can lead to very pronounced drops in blood pressure values.

Take special care with Flindix

In patients with severe liver failure, bioavailability may increase, and it is advisable to reduce the doses of Flindix.

Prolonged administration of high doses of nitrates, regardless of the route or formulation used, can induce tolerance. Controlled clinical studies have shown that the risk of developing nitrate tolerance can be minimized by a dosing regimen that provides a period with a low circulating nitrate dose, achieved by spacing the interval between two administrations by 10 to 12 hours.

It may be necessary to associate another antianginal drug to ensure protection in the subtherapeutic nitrate concentration phase, with the preference for the calcium antagonist based on its specific efficacy against the vasopastic component of angina.

Nitrodependence may also arise as a result of prolonged administration of Flindix, which is why therapy with this drug should not be suspended abruptly.

Taking Flindix with food

The absorption of any of the Flindix formulations is not significantly altered by the presence of food in the stomach.

Taking Flindix with other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Flindix does not present any clinically relevant drug interactions, particularly with digitalis, diuretics, antiplatelet agents, anticoagulants and thrombolytics, drugs commonly used in cardiovascular therapy.

Regarding other antianginal, vasodilator, or hypotensive drugs, such as beta-blockers and calcium channel blockers, there is also no true drug interaction. However, as expected, Flindix potentiates the effects of these drugs, and dosage adjustments may be necessary.

Alcohol can enhance the vasodilatory effect of nitrates.

As already mentioned, the combination of organic nitrates, and therefore isosorbide dinitrate, with selective phosphodiesterase type 5 inhibitors (sildenafil, tadalafil and vardenafil) is formally contraindicated, as this combination can lead to very pronounced drops in blood pressure values.

Pregnancy and breastfeeding

Consult your doctor or pharmacist first before taking any medicine if you are pregnant or planning to become pregnant.

There are no controlled studies on the use of isosorbide dinitrate in pregnant women. It is also unknown whether it is excreted in breast milk.

Therefore, as with any other drug, its administration in these situations must be done under medical supervision, always taking into account potential risks, even if remote.

The safety and efficacy of isosorbide dinitrate in children has not yet been established.

Driving and using machines Not applicable.

Important information about some of the ingredients of Flindix

Flindix tablets contain lactose. If your doctor has told you that you have an intolerance to some sugars, contact your doctor before taking this medication.

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3. How to take Flindix

Always take Flindix exactly as your doctor has told you. Talk to your doctor or pharmacist if you have any questions.

Flindix tablets are intended for oral administration.

The usual dose is:

Ischemic heart disease

- Treatment of anginal crisis:

One 5 mg tablet applied sublingually, to be repeated after a few minutes if the pain persists.

The total dose of 15 mg should not be exceeded in 30 minutes.

- Immediate crisis prophylaxis:

One 5 mg tablet sublingually, before exertion.

- Long-term treatment and prophylaxis of angina attacks and silent ischemia:

5 to 10 mg sublingually every 4 or 6 hours.

10 to 20 mg tablets, orally, up to 3 times a day.

- Acute myocardial infarction:

The dosage and route of administration must be individually adjusted according to the patient's symptoms and hemodynamic study.

Heart failure:

- Acute pulmonary edema:

One 5 mg tablet administered sublingually, to be repeated after a few minutes, according to clinical progress, not exceeding 15 mg in 30 minutes.

- Adjuvant treatment of heart failure and cor *pulmonale:*

5 to 10 mg, sublingually, every 4 or 6 hours, depending on the therapeutic response.

It is advisable to start therapy with low doses, adjusting them progressively according to the clinical response and the patient's tolerability.

Use in the elderly

There is no need for dosage adjustments in elderly patients, except those resulting from the existence of possible severe liver failure that requires a reduction in dosage.

If you take more Flindix than you should

In case of overdose, two types of manifestations may occur: generalized
vasodilation, hypotension and circulatory collapse, anoxia and cyanosis due to methemoglobinemia.

Treatment may include gastric lavage, placing the patient in *Trendlenburg* position (lying with feet elevated), oxygenation, assisted ventilation and other measures to control circulatory collapse, depending on the severity of the clinical condition.

If methemoglobinemia is detected, administer 1% methylene blue at a dose of 1 to 2 mg/kg intravenously.

If you forget to take Flindix

If one or more doses are missed, the patient must maintain the therapeutic regimen defined by their doctor.

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

If you stop taking Flindix

If you have any further questions about using this medicine, talk to your doctor or pharmacist.

4. Possible side effects

Like all medicines, Flindix can cause side effects in some people.

The side effects of administering Flindix, as with other nitrates, result almost exclusively from its pharmacological actions at the cardio-circulatory level, in particular its peripheral vasodilatory effect.

Central nervous system:

- Headache, dizziness.

Pulsating headache is the predominant adverse effect and may, although rarely, be accompanied by nausea and vomiting. It usually subsides after the first week of treatment, but a temporary reduction in the nitrate dose or co-administration of a simple analgesic may be necessary.

Cardiovascular system:

- Flushing, palpitations, tachycardia, postural hypotension and syncope.
- Rare cases of bradycardia in patients with acute myocardial infarction.

Hematology:

- In prolonged treatment or with high doses, some cases of methemoglobinemia have been reported, which can be treated with intravenous administration of methylene blue.

Before:

- Occasionally, a rash may occur.

Several:

- Adynamia, pallor, halitosis (in sublingual administration).

- Alcohol consumption can enhance the hypotensive effect. nitrate tensor.

5. How to store Flindix

Store in original packaging to protect from light and moisture.

Store at a temperature below 25°C.

Keep out of the reach and sight of children.

Do not use Flindix after the expiry date stated on the outer packaging.

The expiration date corresponds to the last day of the indicated month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer require. These measures will help protect the environment.

6. Other information

What is the composition of Flindix?

The active substance is isosorbide dinitrate.

The other ingredients are: lactose monohydrate, cornstarch, talc, sodium carboxymethyl starch (Type A) and magnesium stearate (vegetable).

What Flindix looks like and contents of the pack

Packaging with 20, 60 or 90 units.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Faes Farma Portugal. SA
Elias Garcia Street, 28
2700-327 Amadora

Manufacturer:

Faes Farma, SA
Maximo Aguirre, 14
48940 Lejona, Vizcaya • Spain

For any information about this medicine, please contact the Marketing Authorization Holder.

This brochure was last approved in January 2023.

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