شركة الأصول الطبية التجارية
Alosool Medical Trading Co.

Direct Healthcare Practitioners Communication Letter

Date: 02-12-2025

Title: Propranolol Hydrochloride/ Dociton® solution for injection 1 mg/ml. Absence of Arabic and English information on the outer packaging of one batch of Dociton®.

Subject:

Dear healthcare providers,

Alosool Medical Trading Company and Saudi Food and Drug Authority (SFDA) would like to inform you of the following:

Expiry date	Batch No.	Product Name
30/06/2026	210601	Dociton® solution for injection 1 mg/ml.

Summary:

Referring to the quality report received by the pharmaceutical sector regarding this product, which included a quality defect in the information on the outer packaging being written in a foreign language. As a corrective action for that defect, a letter to healthcare practitioners explaining the product's quality defect (the information on the outer packaging is not in Arabic or English), to this batch and including the English leaflet booklet. It is recommended to use the enclosed leaflet in English to mitigate the defect caused by the lack of Arabic and English.

Further safety information:

• The enclosed leaflet should be carefully reviewed before dispensing the product.

Call for Reporting Any Quality Defects or Side Effects:

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 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

شركة الأصول الطبية التجارية
Alosool Medical Trading Co.

Alosool Medical Trading company Contact point:
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For Medical Information enquiries, please contact:
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Annexes:
Dociton® solution for injection 1 mg/ml Leaflet

Best regards
Alhanouf Alabdulaziz
QPPV

Instructions for Use: Information for Users

Dociton® solution for injection 1 mg/ml

Propranolol Hydrochloride

To be used only under clinical inpatient conditions!

Read the entire package leaflet carefully before you start using this medicine because it contains important information.
Keep the package leaflet. You may want to read it again later.
If you have any further questions, ask your doctor, pharmacist or nurse.
This medicine has been prescribed for you personally. Do not give it to anyone else. It may Harm people, even if they have the same symptoms as you.
If you experience any side effects, contact your doctor, pharmacist or medical
This also applies to side effects not listed in this package leaflet. See section 4.

What is in this leaflet

What is Dociton injection solution and what is it used for?
Dociton injection solution is a beta-blocker. Dociton injection solution is used for acutely threatening cardiac arrhythmias with increased heart rate:
supraventricular arrhythmias
additional therapeutic measure for sinus tachycardia due to thyrotoxicosis
paroxysmal supraventricular tachycardia
Atrial fibrillation and atrial flutter (in case of insufficient response to high-dose therapy with cardiac glycosides)
ventricular arrhythmias such as: ventricular extrasystoles, provided the extrasystoles are caused by increased sympathetic activity (physical exertion, induction phase of anesthesia, halothane anesthesia and administration of exogenous sympathomimetics)
ventricular tachycardia and ventricular fibrillation (only preventative, especially if the ventricular Arrhythmias caused by increased sympathetic activity)

Dociton injection solution must not be used
if you are allergic to propranolol hydrochloride, other beta- blockers or any of the other ingredients of this medicine listed in section 6
in case of heart muscle weakness (manifest heart failure efficiency)
if you suffer from Prinzmetal angina (a special form of angina pectoris)
in case of shock
in case of conduction disturbances from the atria to the ventricles (second or third degree AV block)
in the case of sinus node syndrome (sick sinus syndrome-me)
in case of conduction disturbances between the sinus node and the atrium (sino-atrial block)
if you have a resting heart rate of less than 50 beats per Minute before starting treatment (bradycardia)
in case of severely low blood pressure (hypotension)
in case of high blood pressure in the pulmonary circulation (pulmonary Hypertension)
in case of uremia (uremia)
in case of hyperacidity of the blood (acidosis)
when administered concomitantly with MAO inhibitors (except MAO-B inhibitors) in late stages of peripheral circulatory disorders
Therefore, strict indication is required if you have had a severe hypersensitivity reaction in the past or if you are undergoing therapy to weaken or
if you have a tendency to bronchial spasms (bronchial hyperreactivity, e.g. in bronchial asthma) Special note Bronchospasms can usually be treated by beta-2 Sympathomimetics such as salbutamol for inhalation (for Insufficient effect also intravenously). To reverse the beta- blockade induced by propranolol hydrochloride, high doses may be required, which should be titrated according to their effect.
Aminophylline IV, ipratropium bromide as an inhalation mist, or glucagon (1-2 mg IV) may also be used.
In severe cases, oxygen treatment or artificial respiration may be necessary.
The intravenous administration of Dociton Injection Solution in patients receiving calcium antagonists of the verapamil and diltiazem type or other antiarrhythmics (such as disopyramide), as well as their IV administration during treatment with Dociton
Injection Solution, is contraindicated (exception: intensive care). Do not administer verapamil IV until 48 hours after discontinuation of Dociton Injection Solution.

Warnings and precautions
Please talk to your doctor or nurse before using Dociton Injection Solution. The following describes when you should only use Dociton Injection Solution under certain conditions (ie at longer intervals or in a reduced dose and under medical supervision) with special You should use caution .
This also applies if these statements have previously applied to you.
Dociton injection solution should only be used with caution in mild conduction disturbances from the atria to the ventricles (first-degree AV block)
Diabetes mellitus with severe fluctuating blood sugar levels (conditions with severely reduced blood sugar possible) prolonged strict fasting and heavy physical Stress (conditions with severely reduced blood sugar possible) a hormone-producing tumor of the adrenal gland renmarks (pheochromocytoma, prior therapy with alpha-receptor blockers required) impaired liver or kidney function.
If you or someone in your family has ever had psoriasis, beta-blockers (e.g. Dociton injection solution) should only be used after careful risk-benefit assessment.
Beta-blockers can increase the sensitivity to allergens and the severity of anaphylactic reactions (acute general allergic reactions),
Undergo treatment to eliminate the allergic reaction (desensitization therapy; caution: excessive anaphylactic reactions).
Severe liver damage has been observed during treatment with other beta-blockers; therefore, your liver function tests should be checked regularly by your doctor .
Since the warning signs of low blood sugar can be hidden, regular blood sugar checks are necessary.
When wearing contact lenses, attention should be paid to a possible restriction of tear flow .

Children and young people
Dociton injection solution can be used in children and adolescents to treat certain forms of cardiac arrhythmia. The dosage is determined individually by the physician based on body weight and age.
Effects of misuse for doping purposes
The use of Dociton Injection Solution may result in positive results in doping tests . The health consequences of using Dociton Injection Solution as a doping agent cannot be foreseen, and serious health risks cannot be ruled out.

Use of Dociton injection solution together with other medicines
Tell your doctor, pharmacist or healthcare professional if you are taking/using, have recently taken/used or intend to take/use any other medicines.

Insulin or oral antidiabeticsTheir effect can be enhanced or prolonged.
Warning signs of low blood sugar (hypoglycemia), especially increased heart rate (tachycardia) and tremors, are masked or attenuated. Therefore, regular blood sugar monitoring is necessary.
Other antihypertensive drugs, nitroglycerin, diuretics, vasodilators and phenothiazines A significant drop in blood pressure may occur.
Calcium antagonists of the nifedipine type The reduction in blood pressure may be enhanced. Occasionally, heart muscle weakness may occur.
Calcium antagonists of the verapamil or diltiazem type or other antiarrhythmics (e.g. disopyramide)
Increased blood pressure drop (hypotension), severely reduced heart rate (bradycardia) or other cardiac arrhythmias may occur.
Your doctor will therefore monitor carefully .A notice: See section 2. “What should you consider before using Dociton injection?”
Antiarrhythmika The cardiac weakening effects (cardiodepressive effects) of Dociton injection solution and antiarrhythmics can be additive.
Cimetidine The effect of Dociton injection solution is increased.
Quinidine or propafenone, rifampicin, theophylline, warfarin, thioridazine and calcium antagonists such as nifedipine, nisoldipine, nicardipine, isradipine and lacidipine Studies have shown that interactions with propranolol hydrochloride may occur, as the metabolism of these active substances and that of propranolol hydrochloride in the liver may be affected . The concentrations of propranolol hydrochloride
and these active substances in the blood may be altered, so a dosage adjustment may be necessary (see also "Nifedipine- type calcium antagonists").
Cardiac glycosides, reserpine, alphamethyldopa, guanfacine or clonidine A more pronounced drop in heart rate or a delay in cardiac conduction may occur. Abrupt discontinuation of clonidine may cause an excessive increase in blood pressure . Therefore, clonidine should not be discontinued until you have been Dociton Injection Solution has been discontinued beforehand. Clonidine can then be discontinued gradually. Treatment with Dociton Injection Solution may not be initiated until several days after discontinuation of clonidine.
Alcohol Concomitant administration of alcohol may increase the plasma levels of Dociton injection solution.

Ergot alkaloids
Caution should be exercised when administering ergotamine, dihydroergotamine or related compounds in combination with Dociton injection solution, as vasospastic reactions have been reported in a few patients.

Adrenaline or noradrenaline
A significant increase in blood pressure is possible.

Rizatriptan (serotonin receptor agonist)
The plasma concentration of rizatriptan may be increased when Dociton injection solution is administered concomitantly.
Monoaminooxidase (MAO)-Hemmstoffe An excessive increase in blood pressure is possible.
You should not take MAOIs while using Dociton injection solution .
If these medicines are used in combination, an adjustment of the rizatriptan dose may be recommended.

Non-steroidal anti-inflammatory drugs
The concomitant use of prostaglandin synthetase inhibitors (e.g. ibuprofen and indomethacin) may weaken the antihypertensive effect of Dociton injection solution.

Narcotics
A greater reduction in blood pressure may occur. The cardiac weakening effects (negative inotropic effects) of both drugs may be additive. If Dociton Injection cannot be discontinued before procedures under general anesthesia or before the administration of peripheral muscle relaxants, you should inform your anesthetist about your treatment with Dociton Injection.

CNS-active drugs (e.g. sleeping pills, tranquilizers [certain calming drugs], tri-/tetracyclic antidepressants [e.g. fluoxetine, fluvoxamine], neuroleptics)
These medicines lead to an increase in the blood pressure lowering effect.
The simultaneous use of Dociton injection solution and chlorpromazine (neuroleptic) may lead to an increase in the plasma levels of both drugs.
This may lead to an increased antipsychotic effect of chlorpromazine and an increased blood pressure lowering effect of Dociton injection solution .

Barbiturate, Nicotin, Cholestyramin, Antacida These medicines lead to a weakening of the effect of propranolol.
Peripheral muscle relaxants (e.g. suxamethonium, tubocurarine) The neuromuscular blockade can be potentiated by the beta- receptor inhibition of Dociton injection solution.
Antimalarial drugs (halofantrine, mefloquine and quinine) These medicines can cause disturbances in the conduction of excitation and should therefore only be used with caution. In one isolated case, cardiac arrest occurred after a single dose of mefloquine in a patient treated with propranolol.

As a guideline, inject 0.025-0.05 mg/kg body weight slowly, preferably under ECG monitoring. Repeat every 6-8 hours if necessary.

Pregnancy and breastfeeding
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine. Propranolol hydrochloride should only be prescribed during pregnancy after careful benefit-risk assessment.
There are no adequate studies on the use of propranolol hydrochloride in pregnant women. Complications such as intrauterine growth retardation and premature labor, as well as hypoglycemia, bradycardia, and respiratory depression in the newborn have been described in several cases. Therefore, if treated close to the due date, the newborn is to be carefully monitored during the first 48 - 72 hours after birth .Propranolol hydrochloride crosses the placenta and reaches comparable or higher concentrations in umbilical cord blood than in maternal serum. Propranolol hydrochloride passes into breast milk .Although the amount of active ingredient ingested in milk is unlikely to pose a risk to the child, infants should be monitored for drug effects.

Type of application iv application
Dociton injection solution should only be used under clinical inpatient conditions.
The intravenous injections should be administered slowly (1 mg propranolol hydrochloride, corresponding to 1 ml injection solution or 1 ampoule per minute) under continuous monitoring of pulse, blood pressure and ECG. Parenteral medicinal products should be visually inspected before use. Only clear, particulate solutions may be used.

Duration of application
Dociton injection solution may only be used for as long as until the cardiac arrhythmia is under control
Therapy with oral dosage forms should be resumed as soon as possible.

If you have used more Dociton injection solution than you should
Depending on the extent of the overdose, severe drops in blood pressure (hypotension), reduced heart rate (bradycardia) and even cardiac arrest, heart muscle weakness (heart failure) and cardiogenic shock can occur.

Ability to drive and use machines
This medicine may impair your ability to react and operate machinery.

How should Dociton injection solution be used?
dosage
In cases of acutely life-threatening tachycardic cardiac arrhythmias, the single dose and, in the case of multiple doses, the time interval between individual injections should be selected depending on the initial situation and the clinical condition of the patient.

In adults, 1 mg of propranolol hydrochloride (equivalent to 1 ml of injection solution, i.e., 1 ampoule) is usually injected slowly intravenously over 1 minute. If treatment response is insufficient, the injection can be repeated with the same dose at 2-minute intervals until the onset of effect occurs or until the maximum dose is reached (10 mg propranolol hydrochloride in conscious adults, 5 mg propranolol hydrochloride in adults under anesthesia).
In addition, breathing difficulties, bronchospasms, vomiting, impaired consciousness, and occasionally generalized seizures may occur.
In case of overdose or a dangerous drop in heart rate or blood pressure, treatment with Dociton injection solution must be discontinued.
Medical measures:
In addition to general measures for primary poison elimination, monitoring under intensive care
Conditions are indicated. Antidotes can be given:

Atropin 0,5 ÿ 2mg i.v. als Bolus Glucagon initially 1 - 10 mg iv, then 2 - 2.5 mg/h as a continuous infusion Sympathomimetics depending on body weight and effect: dopamine, dobutamine, isoprenaline, Orciprenaline and adrenaline

In cases of therapy-refractory bradycardia, temporary pacemaker therapy should be performed.
In case of bronchospasm, see section 2. “Do not use Dociton injection solution”.
For generalized seizures, slow intravenous administration of diazepam is recommended .

Dosage in children and adolescentsIn children and
In adolescents, intravenous injection is intended exclusively for the emergency treatment of cardiac arrhythmias.

What side effects are possible?
Like all medicines, this medicine can cause side effects, although not everybody gets them .your kidney function should be monitored during treatment with Dociton injection solution); increase or elevation of certain blood values (GOT, GPT,
(HERE).
Not known (frequency cannot be estimated from the available data):

Common (may affect up to 1 in 10 people):
Particularly at the beginning of treatment , fatigue, dizziness, drowsiness, headaches, confusion, nervousness, sweating, sleep disorders, depressive moods, nightmares, delusions (hallucinations), numbness and coldness (paresthesia) in the limbs; temporary gastrointestinal complaints (nausea, vomiting, constipation, diarrhea); increased drop in blood pressure; severe reduction in heart rate (bradycardia); sudden, short-term loss of consciousness (syncope); palpitations; conduction disturbances from the atria to the ventricles or worsening of heart muscle weakness (heart failure); allergic skin reactions (redness, itching, rash [exanthems]) and hair loss.

Hypoglycemia including hypoglycemic seizures.
If you are prone to bronchospastic reactions (particularly in cases of obstructive airway disease), you may experience
shortness of breath due to a possible increase in airway resistance.

Other side effects
In patients with portal hypertension, liver function may deteriorate and hepatic encephalopathy may develop. There
are reports that treatment with propranolol may increase the risk of
developing hepatic encephalopathy.

Occasionally (may affect up to 1 in 100 people):

can.If you have an overactive thyroid (hyperthyroidism), the clinical signs of an excessive increase in thyroid hormones in the blood (thyrotoxicosis), such as increased heart rate or tremors, may be masked.
Pathological muscle weakness or fatigue, dry mouth, restricted tear flow (take this into account when wearing contact lenses), inflammation of the conjunctiva (conjunctivitis), reduced platelet count (thrombocytopenia) or small patches of bleeding into the skin and mucous membranes (purpura).
After prolonged strict fasting or heavy physical exertion, simultaneous treatment
Dociton Injection Solution may cause low blood sugar (hypoglycemic conditions). These may be accompanied by seizures or , in isolated cases , coma.

Very rare (may affect up to 1 in 10,000 people):

Warning signs of low blood sugar, especially increased heart rate and tremors, may be masked.
Lack or severe reduction of white blood cells; temporary increase of certain white blood cells (transient eosinophilia); increase of

existing pathological muscle weakness or -fatigue (myasthenia gravis); increase in Attacks of tightness in the chest area (angina pectoris);
Increased symptoms of peripheral circulatory disorders, including intermittent limping (intermittent claudication) and spasm of the finger arteries (Raynaud's syndrome); triggering aPsoriasis (psoriasis vulgaris); increased Symptoms of this disease; psoriasiform skin rashes; inflammation of the cornea and conjunctiva of the eye (keratoconjunctivitis); Visual disturbances; muscle pain; muscle cramps; Long-term treatment of joint diseases (arthropathy), where one joint (monoarthritis) or several (polyarthritis) ; libido and potency disorders; occurrence of a previously undetectable Diabetes (latent diabetes mellitus) or Worsening of existing diabetes; in case of severe kidney dysfunction Deterioration of kidney function (therefore

Disturbances in lipid metabolism may occur. While total cholesterol levels are generally normal, a reduction in HDL cholesterol and
an increase in triglycerides in the blood have been observed.

Reporting of side effects
If you experience any side effects, please talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.
You can also report side effects directly to the Federal Institute for Drugs and Medical Devices, Dept. Pharmacovigilance, Kurt- Georg-Kiesinger-Allee 3, D-53175 Bonn, website:

How should Dociton injection solution be stored?
Store the ampoules in the outer carton to prevent the contents to protect from light .Keep this medicine out of the reach of children.

Contents of the package and other information

What Dociton Injection Solution contains The active ingredient is: propranolol hydrochloride. 1ml of injection solution contains 1mg propranolol hydrochloride. The other ingredients are: Water for injections tion purposes, anhydrous citric acid (Ph.Eur.).

What Dociton injection solution looks like and contents of the pack

Dociton injection solution is a clear, colorless solution for intravenous injection. The injection solution is contained in colorless glass ampoules.
Dociton injection solution is available in packs of 10 ampoules, each containing 1 ml of injection solution.

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