



א.י.א.פ.י. אורפן פרמצבטיקה ישראל בע"מ
AOP ORPHAN PHARMACEUTICALS ISRAEL LTD

אוגוסט 2025

רוקח/ת נכבד/ה,
רופא/ה נכבד/ה,

הנדון: עדכון עלון לרופא עבור התכשיר
ESMOLOL AMOMED 100 MG/10 ML
אסמולול אמומד 100 מ"ג/10 מ"ל

תמיסה להזרקה / Solution for Injection

בעל רישום התכשיר חברת א.י.א.פ.י. אורפן פרמצבטיקה ישראל בע"מ ויבואן התכשיר - חברת גד מדיקל מכשור רפואי בע"מ מבקשות להודיע שהעלון לרופא של התכשיר אסמולול אמומד 100 מ"ג/10 מ"ל עודכן באוגוסט 2025.

Active ingredient:

החומר הפעיל:

ESMOLOL HYDROCHLORIDE (10 mg/ml)

ההתוויה המאושרת לתכשיר:

Esmolol Amomed 100 mg/10 ml is indicated for supraventricular tachycardia (except for pre-excitation syndromes) and for the rapid control of the ventricular rate in adult patients with atrial fibrillation or atrial flutter in perioperative, postoperative, or other circumstances where short-term control of the ventricular rate with a short-acting agent is desirable. Esmolol Amomed 100 mg/10 ml is also indicated for tachycardia and hypertension occurring in the perioperative phase and non-compensatory sinus tachycardia in adult patients where, in the physician's judgement the rapid heart rate requires specific intervention. Esmolol Amomed 100 mg/10 ml is not intended for use in chronic settings.

בהודעה זו מצוינים העדכונים המהותיים בלבד. לעדכונים נוספים יש לעיין בעלון לרופא של התכשיר.

העלון המעודכן נשלח לפרסום במאגר התרופות שבאתר האינטרנט של משרד הבריאות וניתן לקבלו מודפס ע"י פנייה לבעל הרישום: א.י.א.פ.י. אורפן פרמצבטיקה ישראל בע"מ, רחוב ריזה 10, עשרת 7685800. מספר טלפון: 03- 6527300

טקסט שנמחק מסומן בקו חוצה (טקסט), טקסט שהוסף מסומן בקו תחתי (טקסט).
עדכוני בטיחות מסומנים **בצהוב**.

4.3 Contraindications

-Hypersensitivity to the active substance \oplus , to any of the excipients listed in section

6.1 **or other beta-blockers (cross sensitivity between beta-blockers is possible);**

[...]

- Concomitant or recent intravenous administration of verapamil. Esmolol Amomed 100 mg/10 ml must not be administered within 48 hours of discontinuing verapamil (see section 4.5);

[...]

4.4 Special warnings and precautions for use

[...]

The most frequently observed side effect is hypotension, which is **rapidly-dose related but can occur at any dose.** **This can be severe.** In the event of a hypotensive episode the infusion rate should be

lowered or, if necessary, be discontinued. Hypotension is usually reversible ~~with dosage reduction~~ (within 30 minutes after discontinuation of administration of Esmolol Amomed 100 mg/10 ml). In some cases, additional interventions may be necessary to restore blood pressure. In patients with a low systolic blood pressure, extra caution is needed when adjusting the dosage and during the maintenance infusion.

Bradycardia, including severe bradycardia, and cardiac arrest has occurred with the use of Esmolol Amomed 100 mg/10 ml. Esmolol Amomed 100 mg/10 ml should be used with special caution in patients with low pretreatment heart rates and only when the potential benefits are considered to outweigh the risk.

Esmolol Amomed 100 mg/10 ml is contraindicated in patients with pre-existing severe sinus bradycardia (see section 4.3). If the pulse rate decreases to less than 50-55 beats per minute at rest and the patient experiences symptoms related to bradycardia, the dosage should be reduced or administration stopped.

[...]

Due to its negative effect on conduction time, beta-blockers should only be given with caution to patients with first degree heart block or other cardiac conduction disturbances (see section 4.3).

Esmolol Amomed 100 mg/10 ml should be used with caution and only after pre-treatment with alpha-receptor blockers in patients with pheochromocytoma (see section 4.3).

Caution is required when Esmolol Amomed 100 mg/10 ml is used to treat hypertension following induced hypothermia.

[...]

Precautions

Esmolol Amomed 100 mg/10 ml should be used with caution in diabetics or in case of suspected or actual hypoglycaemia. Beta-blockers may mask the prodromal symptoms of a hypoglycaemia such as tachycardia. However, dizziness and sweating may not be affected. Concomitant use of beta-blockers and antidiabetic agents can increase the effect of the antidiabetic agents (blood glucose-lowering) (see section 4.5).

[...]

In hypovolemic patients, Esmolol Amomed 100 mg/10 ml can attenuate reflex tachycardia and increase the risk of circulatory collapse. Therefore, Esmolol Amomed 100 mg/10 ml should be used with caution in such patients.

[...]

Some beta-blockers, especially those administered intravenously, including Esmolol Amomed 100 mg/10 ml, have been associated with increases in serum potassium levels and hyperkalemia. The risk is increased in patients with risk factors such as renal impairment and those on haemodialysis.

Beta-blockers may increase both the sensitivity toward allergens and the seriousness of anaphylactic reactions. Patients using beta-blockers may be unresponsive to the usual doses of epinephrine used to treat anaphylactic or anaphylactoid reactions (see section 4.5).

[...]

Beta-blockers have been associated with the development of psoriasis or psoriasiform eruptions and with aggravation of psoriasis. Patients with a personal or family history of psoriasis should be administered beta-blockers only after careful consideration of expected benefits and risks.

Beta-blockers, such as propranolol and metoprolol, may mask certain clinical signs of hyperthyroidism (such as tachycardia). Abrupt withdrawal of existing therapy with beta-blockers in patients at risk or suspected of developing thyrotoxicosis may precipitate thyroid storm and these patients must be monitored closely.

4.5 Interaction with other medicinal products and other forms of interaction

Care should always be exercised whenever Esmolol Amomed 100 mg/10 ml is used with other antihypertensive agents or other drugs that may cause hypotension or bradycardia: the effects of Esmolol Amomed 100 mg/10 ml may be enhanced or the side-effects of hypotension or bradycardia may be exacerbated.

[...]

Concomitant use of Esmolol Amomed 100 mg/10 ml and insulin or oral anti-diabetic drugs may intensify the blood sugar lowering effect (especially non-selective beta-blockers). Beta-adrenergic blockade may prevent the appearance of signs of hypoglycemia (tachycardia), but other manifestations such as dizziness and sweating may not be masked.

[...]

When using beta-blockers, patients at risk of anaphylactic reactions may be more reactive to allergen exposure (accidental, diagnostic, or therapeutic). Patients using beta-blockers may be unresponsive to the usual doses of epinephrine used to treat anaphylactic reactions (see section 4.4).

The effects of Esmolol Amomed 100 mg/10 ml may be counteracted by sympathomimetic drugs having beta-adrenergic agonist activity with concomitant administration. The dose of either agent may need to be adjusted based on patient response, or use of alternate therapeutic agents considered.

[...]

Use Concomitant use of elonidine and beta-blockers increase with moxonidine or alpha-2-agonists (such as clonidine), increases the risk of withdrawal rebound hypertension. If clonidine or moxonidine are used in combination with a beta-blocker and both treatments have to be discontinued, the beta blocker should be discontinued first and then the clonidine or moxonidine after a few days.

~~The use of beta-blockers, such as propranolol, treatment with clonidine should be continued for some time after treatment, when the beta-blocker has been discontinued with ergot derivatives may result in severe peripheral vasoconstriction and hypertension.~~

[...]

Esmolol 100 mg/10 ml moderately prolonged the clinical duration (18.6%) and recovery index (6.7%) of mivacurium.

Although the interactions observed in studies of warfarin, digoxin, morphine, suxamethonium chloride or mivacurium are not of major clinical importance, Esmolol Amomed 100 mg/10 ml should be titrated with caution in patients being treated concurrently with warfarin, digoxin, morphine, suxamethonium chloride or mivacurium.

[...]

בטבלה מטה מצוינות תופעות הלוואי שנסופו ומהוות החמרה בלבד. לכלל תופעות הלוואי יש לעיין בעלון לרופא.

4.8 Undesirable effect

[...]

System Organ Class	Frequency				
	Very common	Common	Uncommon	Very rare	Not known
Metabolism and nutrition disorders		Anorexia			<u>Hyperkalemia</u> <u>Metabolic acidosis</u>
Cardiac disorders			Bradycardia Atrioventricular block <u>Pulmonary arterial pressure increased</u> <u>Cardiac Failure</u> <u>Ventricular extrasystoles</u> <u>Nodal rhythm</u> <u>Angina pectoris</u>	Sinus arrest Asystole	<u>Accelerated idioventricular rhythm</u> <u>Coronary arteriospasm</u> <u>Cardiac arrest.</u>
Skin and subcutaneous tissue disorders	Diaphoresis ¹		Skin discolouration ² Erythema ²	Skin necrosis ² (due to extravasation)	Psoriasis ³ <u>Angioedema</u> <u>Urticaria</u>
General disorders and administration site conditions		Asthenia Fatigue Injection site reaction Infusion site reaction Infusion site inflammation Infusion site induration	Chills Pyrexia Oedema ² Pain ² Infusion site burning <u>Infusion site ecchymosis</u>		<u>Infusion site phlebitis</u> <u>Infusion site vesicles</u> <u>Blistering ²</u>

¹ Dizziness and diaphoresis are in association with symptomatic hypotension. ² In association with Injection and Infusion site reactions.

³ Beta-blockers as a drug class can cause psoriasis in some situations, or worsen it. ⁴ Including midscapular pain and costochondritis

בברכה,

א"י.א.פי. אורפן פרמצבטיקה ישראל בע"מ (בעל רישום)
גד מדיקל מכשור רפואי בע"מ (יבואן ומשווק)