



Feb-2021

רופא/ה, רוקח/ת נכבד/ה,

**הנדון: Replagal® 1mg/mL – עדכון עלון לרופא**

חברת טקדה מבקשת להודיעך כי העלון לרופא של התכשיר שבנדון עודכן בינואר 2021.

**התכשיר רשום בישראל להתוויה הבאה:**

Replagal is indicated for long-term enzyme replacement therapy in patients with a confirmed diagnosis of fabry disease (alfa-galactosidase A deficiency).

**מרכיב פעיל:** AGALSIDASE ALFA 1mg/mL

פרטי העדכון העיקריים הינם:

(טקסט שנוסף מסומן בכחול, טקסט שהושמט מסומן בטקסט **אדום עם קו חוצה**, טקסט המהווה החמרה מודגש **בכחול**)

**2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

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**Excipient(s) with known effect**

**This medicinal product contains 14.2 mg sodium per vial.**

**4.4 Special warnings and precautions for use**

**Traceability**

In order to improve the traceability of biological medicinal products, the name and batch number of the administered product should be clearly recorded.

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**Sodium**

**This medicinal product contains 14.2 mg sodium per vial, equivalent to 0.7 % of the WHO recommended maximum daily intake of 2 g sodium for an adult.**

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**4.8 Undesirable effects**

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Table 1				
System organ class	Adverse reaction			
	Very common	Common	Uncommon	Not known
Metabolism and nutrition disorders	peripheral oedema	peripheral oedema		
Nervous system disorders	headache, dizziness, neuropathic pain, tremor, hypoesthesia, paraesthesia	dizziness, dysgeusia, neuropathic pain, tremor, hypersomnia, hypoesthesia, paraesthesia	parosmia	



Eye disorders		corneal reflex decreased, lacrimation increased	corneal reflex decreased	
Ear and labyrinth disorders	tinnitus	tinnitus, tinnitus aggravated		
Cardiac disorders	palpitations	tachycardia, palpitations atrial fibrillation	tachyarrhythmia	cardiac arrhythmias (atrial fibrillation, ventricular extrasystoles, tachyarrhythmia), myocardial ischaemia, heart failure, ventricular extrasystoles,
Vascular disorders	flushing	Hypertension, hypotension, flushing		hypotension
Respiratory, thoracic and mediastinal disorders	dyspnoea, cough, nasopharyngitis, pharyngitis,	cough, hoarseness, throat tightness, dyspnoea, nasopharyngitis, pharyngitis, throat secretion increased, rhinorrhoea	oxygen saturation decreased, throat secretion increased	
Gastrointestinal disorders	vomiting, nausea, abdominal pain, diarrhoea	Diarrhea, vomiting, abdominal pain/discomfort		
Skin and subcutaneous tissue disorders	rash	Urticaria, acne, erythema, pruritus, acne, hyperhidrosis rash, livedo reticularis	angioneurotic oedema, urticaria, livedo reticularis	hyperhidrosis
Musculoskeletal, connective tissue and bone disorders	arthralgia, pain in limb, myalgia, back pain	musculoskeletal discomfort, myalgia, back pain, limb pain, peripheral swelling, arthralgia, joint swelling	sensation of heaviness	
Immune system disorders		hypersensitivity	Anaphylactic reaction, hypersensitivity	
General disorders and administration site conditions	chest pain, rigors, pyrexia, pain, asthenia and discomfort, fatigue	chest tightness, fatigue aggravated, feeling hot, feeling cold, asthenia, chest pain, chest tightness, influenza like illness, discomfort, injection site rash, malaise	injection site rash,	



למידע נוסף, יש לעיין במאגר התרופות שבאתר משרד הבריאות.  
כמו כן, ניתן לקבל העתק מודפס של העלוניס באמצעות פנייה לבעל הרישום:  
טקדה ישראל בע"מ, רח' אפעל 25, פתח-תקווה, טל': 03-3733140

בברכה,

טלי סרי  
רוקחת ממונה  
טקדה ישראל בע"מ