

אוקטובר 2019

רופא/ה, רוקח/ת נכבד/ה,

חברת קמהדע מבקשת להודיע על עידכון רישום כמפורט להלן, עבור התכשיר:

<b>Provocholine ;</b>	<b>פרובוכולין</b>
Powder for solution for inhalation	צורת מינון:
Methacholine chloride powder 100 mg / vial	<b>מרכיבים פעילים בהתאם לרישיון:</b>

### המאשר להתויה:

Provocholine is indicated for the diagnosis of bronchial airway hyperactivity in subjects who do not have clinically apparent asthma.

### מהות השינוי:

1. צבעו של מכסה הפלסטיק של הבקבוקון השתנה מירוק לאפור.
2. עידכון עלון לרופא עם החמרות ושינויים נוספים. בהודעה זו מצוינים השינויים המהווים החמרה בלבד (מודגש בצהוב). להלן הסעיפים בהם חלו החמרות:

#### Serious Warnings and Precautions

- Provocholine is to be administered only by inhalation. **See Warnings and Precautions – General**
- Provocholine is a bronchoconstrictor agent for diagnostic purposes only, and should not be used as a therapeutic agent. **See WARNINGS AND PRECAUTIONS – General**
- Patients with severe hyperresponsiveness of airways can experience bronchoconstriction at the lowest dosages or with the diluent alone. **See WARNINGS AND PRECAUTIONS - Respiratory**
- Test should not be performed on any patient with baseline FEV<sub>1</sub> of less than 1.5 litres or 70% of predicted value. **SEE WARNINGS AND PRECAUTIONS - Respiratory**
- When administered orally or by injection Provocholine is associated with nausea, vomiting, substernal pain or pressure, hypotension, fainting and transient complete heart block. **See ADVERSE REACTIONS**
- When administered orally or by injection overdose can result in a syncopal reaction, with cardiac arrest and loss of consciousness. **See OVERDOSAGE**
- Baseline spirometry must be accurate. If not, the initial FEV<sub>1</sub> may be underestimated, and subsequent falls after inhaling Provocholine solutions may not be detected, resulting in too high a dose and excessive bronchoconstriction. **See WARNINGS AND PRECAUTIONS - General**

## CONTRAINDICATIONS

- Provocholine is contraindicated in patients with known hypersensitivity to the active substance, to any of the excipients listed in section STORAGE AND STABILITY or to other parasympathomimetic agents.
- A repeat challenge test on the same day is contraindicated.
- $\beta$ -agonists, anticholinergics and theophylline may be contraindicated (See DRUG INTERACTIONS)

## WARNINGS AND PRECAUTIONS

### General

The product should be administered under the supervision of a qualified health professional who is experienced in the use of inhalation agents and in the management of patients experiencing severe bronchoconstriction. Appropriate management of therapy and complications is only possible when adequate diagnostic and treatment facilities are readily available.

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### Special Populations

*Geriatrics:* No data is available.

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## DRUG INTERACTIONS

### Overview

Provocholine is a parasympathomimetic (cholinergic) bronchoconstrictor agent to be administered in solution only, by inhalation. Methacholine chloride is the  $\beta$ -methyl homolog of acetylcholine, is slowly hydrolysed by acetylcholinesterase and almost totally resistant to inactivation by non-specific cholinesterase or pseudocholinesterase.

העלון לרופא המעודכן נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות וניתן לקבלו מודפס ע"י פניה לבעל הרישום, חברת קמהדע בע"מ (טל' 08-9406472).

להלן הקישור למאגר התרופות:

<https://data.health.gov.il/drugs/index.html#/byDrug>

בברכה,

פנינה נודל,

רוקחת ממונה