



פברואר 2025

רוקח/ת נכבד/ה, רופא/ה נכבד/ה,

חברת פרופארם בע"מ מודיעה על העדכונים הבאים בעלון לרופא של התכשיר:

BACLOFENE BIOINDUSTRIA L.I.M 10 MG/5 ML

בקלופן ביואינדוסטריה אל.אי.אמ. 10מ"ג/5 מ"ל

חומר פעיל: BACLOFEN 10 MG/5 ML

צורת מינון: Solution for Injection

צורת המתן: Intrathecal

עדכונים בעלון לרופא

התוויה כפי שאושרה בתעודת הרישום:

Baclofene Bioindustria L.I.M. 10mg/5ml is indicated in patients with severe chronic spasticity resulting from trauma, multiple sclerosis or other spinal cord disorders, who are unresponsive to oral baclofen or other orally administered antispastic agents and/or those patients who experience unacceptable side effects at effective oral doses.

Baclofene Bioindustria L.I.M. 10mg/5ml is effective in adult patients with severe chronic spasticity of cerebral origin, resulting e.g. from cerebral palsy, brain trauma or cerebrovascular accident; however, clinical experience is limited.

Pediatric population:

Baclofene Bioindustria L.I.M. 10mg/5ml is indicated in patients aged 4 to <18 years with severe chronic spasticity of cerebral origin or of spinal origin (associated with injury, multiple sclerosis, or other spinal cord diseases) who are unresponsive to orally administered antispastics (including oral baclofen) and/or who experience unacceptable side effects at effective oral doses.

ברצונינו להודיע שהעלון לרופא עודכן, בפירוט שלהלן כלולים העדכונים העיקריים בלבד(תוספות/שינויים מסומנים באדום והחמרות/מידע חדש על רקע צהוב):

4.2 Posology and method of administration

Delivery specifications

Baclofene Bioindustria L.I.M. 10 mg/5 ml ampoules of 5ml containing 2 mg (2000 micrograms)/ml are intended for use with infusion pumps. ~~The concentration to be used depends on the dose requirements and size of pump reservoir. Use of the more concentrated solution obviates the need for frequent re-filling in patients with high dosage requirements~~

4.4 Special warnings and precautions for use

Psychotic disorders, schizophrenia, confusional states or Parkinson's disease

[...] **Caution should be exercised in patients with a history of peptic ulcers and based** on observations after oral baclofen therapy, **in those with** pre-existing sphincter hypertonia.

[...]

Treatment withdrawal (including associated with catheter or device malfunction)

Abrupt discontinuation of Baclofene Bioindustria L.I.M. 10 mg/5 ml, regardless of cause, manifested by increased spasticity, pruritus, paraesthesia and hypotension, has resulted in sequelae including a hyperactive state with rapid uncontrolled spasms, hyperthermia, **tachycardia.**

4.5 Interaction with other medicinal products and other forms of interaction

Antihypertensives and other drugs known to lower blood pressure: Since concomitant treatment with **drugs that lower blood pressure** baclofen and anti-hypertensives is likely to increase the fall in blood pressure, **it may be necessary to reduce the dosage of concomitant medication should be adjusted accordingly.**



4.8 Undesirable effects

Immune system disorders- Not known: Hypersensitivity

4.9 Overdose

Symptoms of overdose: excessive muscular hypotonia, drowsiness, light-headedness, dizziness, somnolence, seizures, loss of consciousness, hypothermia, excessive salivation, nausea, vomiting **tachycardia and tinnitus.**