

January 2023

רופא/ה נכבד/ה,
רוקח/ת נכבד/ה,

Phenergan 50mg/2ml

חברת ביומד-יר מבקשת להודיע על עדכון בעלון לרופא של התכשיר שבנדון.

התווית התכשיר:

Phenergan is indicated:

- As symptomatic treatment for allergic conditions of the upper respiratory tract and skin including allergic rhinitis, urticaria and anaphylactic reactions to drugs and foreign proteins.
- For sedation and treatment of insomnia in adults.
- As an adjunct in preoperative sedation in surgery and obstetrics.
- As a paediatric sedative.
- For prevention and control of nausea and vomiting associated with certain types of anaesthesia and surgery.

PROMETHAZINE (AS HYDROCHLORIDE) 25 MG/1 ML **מרכיב פעיל:**
Solution for injection: **צורת המתן של התכשיר:**

בעלון נעשה שינוי המהווה החמרה המודגש **בצהוב**

עדכונים בעלון לרופא נעשו בסעיפים הבאים:

4.4 Special warnings and precautions for use

[...]

Phenothiazine derivatives may potentiate QT interval prolongation which increases the risk of onset of serious ventricular arrhythmias of the torsade de pointes type, which is potentially fatal (sudden death). QT prolongation is exacerbated, in particular, in the presence of bradycardia, hypokalaemia, and acquired (i.e. drug induced) QT prolongation. If the clinical situation permits, medical and laboratory evaluations should be performed to rule out possible risk factors before initiating treatment with a phenothiazine derivative and as deemed necessary during treatment (see section 4.8).

4.5 Interaction with other medicinal products and other forms of interaction

[...]

Special caution is required when promethazine is used concurrently with drugs known to cause QT prolongation (such as antiarrhythmics, antimicrobials, antidepressants, antipsychotics) to avoid exacerbation of risk of QT prolongation.

4.8 Undesirable effects

[...]

Other side-effects include anorexia, gastric irritation, palpitations, hypotension, arrhythmias, QT prolongation, torsade de pointes, extrapyramidal effects, restless legs syndrome, muscle spasms and tic-like movements of the head and face.

4.9 Overdose

[...]

High doses (supratherapeutic doses) can cause ventricular arrhythmias including QT prolongation and torsade de pointes (see section 4.8).

8. MANUFACTURER

Haupt Pharma Livron

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For:

Frilab

104, Boulevard Auguste Blanqui, 75013 Paris, France

העלון לרופא מפורסם במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלו מודפס על ידי פניה לבעל הרישום, חברת ביומד-יר, רחוב היסמין 28 תל-מונד, או בטלפון 09-7746004

בברכה,

גלי קיסר
רוקחת ממונה