רופא/ה נכבד/ה,
רוקח/ת נכבד/ה,

אוקטובר 2024

Phenergan 50mg/2ml

חברת ביומד-יר מבקשת להודיע על עדכונים 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.

מרכיב פעיל: PROMETHAZINE (AS HYDROCHLORIDE) 25 MG/1 ML

צורת המתן של התכשיר: Solution for injection

העדכונים המהותיים בעלון מפורטים למטה. תוספות בקו תחתי, מחיקות בקו חוצה, החמרות מסומנות בצבע צהוב. בעלון נעשו שינויים נוספים שאינם מפורטים כאן.

עדכונים בעלון לרופא נעשו בסעיפים הבאים:

4.8 Undesirable effects

- Phenergan should not be given to patients with a known hypersensitivity to promethazine, other phenothiazines, or to any of the excipients listed in section 6.1

4.4 Special warnings and precautions for use

Hypersensitivity reactions including anaphylaxis, urticaria and angioedema have been reported with Phenergan use. In case of allergic reaction, treatment with Phenergan must be discontinued and appropriate symptomatic treatment initiated (see section 4.8).

Phenergan should be avoided in patients with liver or renal dysfunction, Parkinson's disease, hypothyroidism, cardiac failure, pheochromocytoma, myasthenia gravis, or prostate hypertrophy, or in patients with a history of narrow angle glaucoma or agranulocytosis.

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Caution must be exercised when using H1-antihistamines such as Phenergan due to the risk of sedation. Combined use with other sedative medicinal products is not recommended (see section 4.5).

Close monitoring is required in patients with epilepsy or a history of seizures, as phenothiazines may lower the seizure threshold.

Phenothiazines may be additive with, or may potentiate the action of, other CNS depressants such as opiates or other analgesics, barbiturates or other sedatives, general anesthetics, or alcohol.

The occurrence of unexplained infections or fever may be evidence of blood dyscrasia (see section 4.8), and requires immediate hematological investigation.

All patients should be advised that, if they experience fever, sore throat or any other infection, they should inform their physician immediately and undergo a complete blood count. Treatment should be discontinued if any marked changes (hyperleukocytosis, granulocytopenia) are observed in the blood count.

4.5 Interaction with other medicinal products and other forms of interaction

Cytochrome P450 2D6 Metabolism: Some phenothiazines are moderate inhibitors of CYP2D6. There is a possible pharmacokinetic interaction between inhibitors of CYP2D6, such as phenothiazines, and CYP2D6 substrates. Co administration of promethazine with amitriptyline/amitriptylinoxide, a CYP2D6 substrate, may lead to an increase in the plasma levels of amitriptyline/amitriptylinoxide. Monitor patients for dose-dependent adverse reactions associated with amitriptyline/amitriptylinoxide.

Phenergan should be avoided in patients taking monoamine oxidase inhibitors within the previous 14 days, and monoamine oxidase inhibitors should be avoided while using Phenergan.

Seizure threshold-lowering drugs: Concomitant use of seizure-inducing drugs or seizure threshold-lowering drugs should be carefully considered due to the severity of the risk for the patient (see section 4.4).

Gastro-intestinal agents that are not absorbed (magnesium, aluminium and calcium salts, oxides and hydroxides): Reduced gastro-intestinal absorption of phenothiazines may occur. Such gastro-intestinal agents should not be taken at the same time as phenothiazines (at least 2 hours apart, if possible).

4.6 Fertility, pregnancy and lactation

Pregnancy

~~Phenergan injection should not be used in pregnancy unless the physician considers it essential.~~ The use of Phenergan is not recommended during pregnancy and in women of childbearing potential not using contraception, unless the potential benefits outweigh ~~in the 2 weeks prior to delivery~~ the ~~2 weeks prior to delivery~~potential risks. When promethazine has been given in high doses during late pregnancy, promethazine has caused prolonged neurological disturbances in the infant.

Advise patients to inform their healthcare provider of a known or suspected pregnancy. Advise patients to avoid becoming pregnant while receiving this medicine. Advise female patients of reproductive potential to use effective contraception.

4.7 Effects on ability to drive and use machines

Ambulant patients receiving Phenergan for the first time should not be in control of vehicles or machinery for the first few days until it is established that they are not hypersensitive to the central nervous effects of the drug and do not suffer from disorientation, confusion, blurred vision or dizziness.

4.8 Undesirable effects

Immune system disorders

Frequency not known: Allergic reactions, including ~~urticaria, rash, pruritus and~~ anaphylactic ~~reactions have been reported~~reaction, urticaria, angioedema.

Nervous system disorders

Very common: Sedation or s~~S~~omnolence.~~,~~

Frequency not known: D~~d~~izziness, headaches, extrapyramidal effects including restless legs syndrome, muscle spasms and tic-like movements of the head and face.

Frequency not known: Dystonia, including oculogyric crisis, usually transitory are commoner in children and young adults, and usually occur within the first 4 days of treatment or after dosage increases.

Frequency not known: Anticholinergic effects such as ileus paralytic, risk of urinary retention, dry mouth, constipation, accommodation disorder.

Psychiatric disorders

~~Restlessness, nightmares, and disorientation.~~

Frequency not known: Agitation, confusional state, anxiety.

Frequency not known: Infants, newborns ~~Newborn~~ and premature ~~infants~~ are susceptible to the anticholinergic effects of promethazine, while other children may display paradoxical hyperexcitability, restlessness, nightmares, disorientation.

Respiratory, thoracic and mediastinal disorders
Frequency not known: Respiratory depression (see section 4.4), nasal congestion

Blood and lymphatic system disorders
Frequency not known: Blood dyscrasias including haemolytic anaemia ~~rarely occur~~, agranulocytosis, leukopenia, eosinophilia, thrombocytopenia (including thrombocytopenic purpura).

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

בברכה,
חברת ביומד-יר בע"מ