

אוקטובר 2022

רוקח/ת נכבד/ה,
רופא/ה נכבד/ה,

הנדון: עדכון העלון לרופא לתכשיר

Beriglobin P (125-38-29064)
Solution for Injection

Active ingredient:

חומר פעיל:

Human normal immunoglobulin 160 mg/ml

להלן נוסח ההתוויה המאושר:

Substitution in

- Primary antibody deficiency syndromes resulting from defective antibody synthesis.
- Protracted transitory hypogammaglobulinaemia especially in premature infants.

Prophylaxis of hepatitis A

- Before exposure
- Within 2 weeks after exposure

חברת ג'נמדיקס מבקשת להודיע כי העלון לרופא לתכשיר בריגלובין P עודכן באוקטובר 2022 על פי הנחיות משרד הבריאות.

בהודעה זו מצוינים סעיפים בהם נעשו עדכונים המהווים החמרות: החמרה מודגשת בצהוב (טקסט), טקסט שהורד מסומן בקו חוצה (טקסט), טקסט שהוסף מסומן באדום (טקסט). בעלון קיימים עדכונים נוספים שאינם מהווים החמרות.

העלון לרופא נשלח למשרד-הבריאות לצורך העלאתו למאגר התרופות שבאתר משרד הבריאות וניתן לקבלו מודפס על ידי פנייה לבעל הרישום: ג'נמדיקס, רח' בית הראשונים 12, פארק תעשיות עמק חפר 3877701, טלפון: 03-9373753.

בברכה,

דורית פרידלר

רוקחת ממונה, ג'נמדיקס

4.3 Contraindications

[...]

~~Beriglobin P~~ It must also not be administered intramuscularly in cases of **severe thrombocytopenia** and in other disorders of haemostasis.

4.4 Special warnings and precautions for use

[...]

Aseptic Meningitis Syndrome (AMS)

Aseptic meningitis syndrome has been reported to occur in association with subcutaneous immunoglobulin treatment; the symptoms usually begin within several hours to 2 days following treatment. Discontinuation of immunoglobulin treatment may result in remission of AMS within several days without sequelae.

Patients should be informed about first symptoms which encompass severe headache, neck stiffness, drowsiness, fever, photophobia, nausea, and vomiting.

[...]

4.7 Effects on ability to drive and use machines

~~There are no indications that Beriglobin P may impair the ability to drive or use machines.~~

The ability to drive and operate machines may be impaired by some adverse reactions associated with Beriglobin P. Patients who experience adverse reactions during treatment should wait for these to resolve before driving or operating machines.

4.8 Undesirable effects

פרק תופעות הלוואי נערך מחדש. שכיחות תופעות הלוואי מוצגת עתה בטבלה המפרטת שכיחויות במתן S.C. ובמתן I.M. של התכשיר. הטבלה מובאת להלן:

[...]

Frequencies have been evaluated according to the following convention: Very common ($\geq 1/10$); common ($\geq 1/100$ to $< 1/10$); uncommon ($\geq 1/1,000$ to $< 1/100$); rare ($\geq 1/10,000$ to $< 1/1,000$); very rare ($< 1/10,000$), not known (cannot be estimated from the available data).

[...]

Frequency of Adverse Reactions (ADRs) with Beriglobin P

| MedDRA System Organ Class (SOC) | Adverse Reaction | Frequency | |
|--|--|------------------------|------------------------|
| | | s.c. administration | i.m. administration |
| Immune system disorders | Hypersensitivity (including blood pressure decrease) | Common [‡] | Not known |
| | Anaphylactic shock/anaphylactic reactions (including dyspnoea, skin reaction) | Not known | Not known |
| Nervous system | Headache | Common [‡] | Common [‡] |
| | Syncope, dizziness | Common [‡] | Not known |
| Cardiac disorders | Cardiovascular disorder [†] | Not known | Not known |
| Vascular disorders | Thromboembolism (including myocardial infarction, ischaemic stroke, deep venous thrombosis and pulmonary embolism) [^] | Not known | (---) |
| Respiratory, thoracic and mediastinal disorders | Bronchospasm | Common [‡] | Not known |
| Gastrointestinal disorders | Nausea, vomiting | Not known | Not known |
| Skin and subcutaneous tissue disorders | Rash | Common [‡] | Not known |
| Musculoskeletal and connective tissue disorders | Back pain [§] | Common [‡] | Not known |
| General disorders and administration site conditions | Injections site pain [§] | Very common | Very common |
| | Injection site swelling, erythema, induration, warmth, pruritus, bruising, rash [§] | Very common | Not known |
| | Injection site urticaria [†] | (---) | Not known |
| | Pyrexia | Common [‡] | Common [‡] |
| | Chills, malaise | Common [‡] | Not known |
| | Arthralgia | Not known | Not known |

[‡]Reported in single cases from clinical study.

[†]Cardiovascular disorder particularly if the product has been inadvertently injected intravascularly.

[^]Thromboembolism (including myocardial infarction, ischaemic stroke, deep venous thrombosis and pulmonary embolism) has been observed in association with s.c. substitution therapy only.

[§]In a clinical study with s.c. administration frequency of local reactions at the injection site (including pain, swelling, erythema, warmth, pruritus, bruising, rash) declined very rapidly with the first ten infusions, when patients became used to the s.c. form of treatment.

[†]Injection site urticaria has been observed with i.m. administration only.