

יוני 2023

רוקח/ת נכבד/ה,
רופא/ה נכבד/ה,

הנדון: עדכון העלון לרופא לתכשיר

Rhophylac 300 (127-75-30675)

Solution for injection

Active ingredient:

ANTI-D IMMUNOGLOBULINS 150 MCG/ML

חומר פעיל:**להלן נוסח ההתוויה המאושר:**

Prophylaxis of Rh (D) immunisation in Rh (D)-negative women:

Anti-D immune globulin is administered for the prevention of Rh (D) immunization if it has been demonstrated, or if it is suspected, that fetal erythrocytes have entered the circulation of the mother. Treatment is not necessary when it is assured that the child or the father are Rh (D)-negative. Criteria for a rhesus-incompatible pregnancy and the administration of anti-D immune globulin are: a) the mother is Rh (D)-negative; b) the child is either Rh (D)-positive, Rh (D) weak - positive or its rhesus type is not known.

Routine antepartum prophylaxis: To prevent Rh (D) immunisation due to spontaneous fetomaternal haemorrhage (FMH) during the last trimester of pregnancy.

Postpartum prophylaxis: To prevent Rh (D) immunisation of the Rh (D)-negative mother following delivery of a Rh (D)-positive child.

Complications of pregnancy: Interventions during pregnancy, such as invasive prenatal diagnosis (e.g. amniocentesis, chorionic villus sampling, fetal blood sampling) or other intrauterine procedures (e.g. insertion of shunts, embryo reduction), external version of the fetus and therapeutic abortion. Incidents during pregnancy, such as antepartum haemorrhage, spontaneous abortion, ruptured tubal pregnancy, ectopic pregnancy, stillbirths, intrauterine death and abdominal trauma.

Treatment of Rh (D)-negative persons after incompatible transfusions of Rh (D)-positive blood or erythrocyte concentrate:

Prevention of Rh (D) immunisation in Rh (D)-negative persons who for any reason have been given blood or blood components containing Rh (D)-positive red cells.

חברת סי אס אל בהרינג בע"מ מבקשת להודיע כי העלון לרופא לתכשיר רופילק 300 עודכן ביוני 2023 על פי הנחיות משרד הבריאות.

בהודעה זו מצוינים סעיפים בהם נעשה עדכון המהווה החמרה - מודגש **בצהוב**.
טקסט שהוסף מסומן בצבע: **טקסט**. טקסט שהוסר מסומן בקו חוצה: **טקסט**.

בעלונים 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:

CSL BEHRING LTD., 16 Abba Hillel Road, Ramat-Gan, 5250608

בברכה,
רבקה סלונים, רוקחת ממונה

העדכונים העיקריים בעלון לרופא:**4.3 Contraindications**

[...]

Hypersensitivity to human immunoglobulins.**4.4 Special warnings and precautions for use**

In the case of postpartum use, anti-D immunoglobulin is intended for maternal administration. It should not be given to the new-born infant.

The product is ~~not~~ **neither** intended for use in Rh (D)-positive individuals, **nor for individuals already immunised to Rh(D) antigen.**

[...]

Haemolytic reactions

Patients in receipt of incompatible transfusion, who receive very large doses of anti-D immunoglobulin, should be monitored clinically and by biological parameters, because of the risk of haemolytic reaction.

Obesity

There have been reports that the intramuscular administration of Rhophylac in patients with a body mass index (BMI) ≥ 30 is associated with an increased risk of lack of efficacy. Therefore, in patients with a BMI ≥ 30 , intravenous administration should be considered.

[...]

4.8 Undesirable effects**Summary of the safety profile**

The most serious adverse reactions observed during the treatment are hypersensitivity or allergic reactions which may in rare cases progress to a sudden fall in blood pressure and anaphylactic shock even when the patient has shown no hypersensitivity to previous administration.

When anti-D immunoglobulins are administered by the intramuscular route, local pain and tenderness may be observed at the injection site.

פרק פירוט תופעות הלוואי נערך מחדש. הוספה טבלה המציינת עבור כל תופעת לוואי את מערכת הגוף הרלוונטית ואת שכיחות תופעת הלוואי:

Tabulated list of adverse reactions

The following adverse reactions have been reported from 592 patients in clinical studies and

from post-marketing experience. The summary table presented below is according to the MedDRA system organ classification (SOC and Preferred Term Level). Frequency has been evaluated using the following criteria: very common ($\geq 1/10$), common ($\geq 1/100$ to $< 1/10$), uncommon ($\geq 1/1000$ to $< 1/100$), rare ($\geq 1/10,000$ to $< 1/1000$), very rare ($< 1/10,000$).

System Organ Class (SOC, MedDRA)	Adverse Reaction (MedDRA Preferred Term (PT))	Frequency of ADR
Immune system disorders	Hypersensitivity, anaphylactic shock	rare
Nervous system disorders	Headache	uncommon
Cardiac disorders	Tachycardia	rare
Vascular disorders	Hypotension	rare
Respiratory, thoracic and mediastinal disorders	Dyspnoea	rare
Gastrointestinal disorders	Nausea, vomiting	rare
Skin and subcutaneous tissue disorders	Skin reaction, erythema, pruritus	uncommon
Musculoskeletal and connective tissue disorders	Arthralgia	rare
General disorders and administration site conditions	Pyrexia, malaise, chills	uncommon
	At injection site: swelling, pain, erythema, induration, warmth, pruritus, rash	rare

There have been spontaneous reports of severe intravascular haemolysis when anti-D has been administered intravenously to Rh(D) positive patients with primary immune thrombocytopenia (ITP). Haemolysis resulting in death has been reported. The exact frequency of this adverse event is not known.

[...]