**PRESCRIBING INFORMATION**

(Please refer to the Summary of Product Characteristics before prescribing) **Rhophylac®** (human anti-D immunoglobulin) 300mcg (1500 IU)/2ml pre-filled syringe for injection.

**Indications**

Prevention of Rh(D) isoimmunisation in Rh(D) negative women. Treatment of Rh(D) negative adults, children and adolescents (0-18 years) after incompatible transfusions of Rh(D) positive blood or other products containing red blood cells. **Dosage and administration**

**Prevention of Rh(D) isoimmunisation in Rh(D) negative women:**

- **Planned antepartum prophylaxis:** 300mcg (1500 IU) by intravenous (IV) or intramuscular (IM) injection between 28 and 30 weeks of gestation.
- **Antepartum prophylaxis following complications of pregnancy:** 300mcg as soon as possible and within 72 hours and repeated at 6-12 week intervals throughout the pregnancy if necessary. **Postpartum prophylaxis:** 300mcg (1500 IU) by IV or IM. If given IV a minimum dose of 200 mcg (1000 IU) may be sufficient provided large foeto-maternal haemorrhage (FMH) can be excluded. Administer as soon as possible within 72 hours of delivery. If more than 72 hours have elapsed, do not withhold but administer as soon as possible. If a large FMH is suspected, its extent should be determined and additional doses given. **Overweight patients:** In patients with a BMI ≥30 intravenous administration should be considered.

**Incompatible transfusions:** 20mcg (100 IU) per 2 ml of transfused Rh(D)-positive blood or per 1 ml of red blood cell concentrate. The IV route is recommended. A maximum dose of 3000mcg (15,000 IU) is sufficient even if more than 300 ml of Rh(D)-positive blood or 150ml erythrocyte concentrate was infused. **Contraindications**

Hypersensitivity to the active substance, any of the excipients or to human immunoglobulins. The intramuscular route in severe thrombocytopenia or other disorders of haemostasis. **Special warnings and special precautions for use**

Rhophylac should not be given to the newborn infant. It is not intended for use in Rh(D) positive individuals or those already immunised to Rh(D) antigen. Allergic or anaphylactic type reactions can occur and warrant immediate discontinuation. Contains low levels of IgA. Individuals deficient in IgA have the potential for developing IgA antibodies and anaphylaxis. Monitor patients treated with very large doses for incompatible transfusions because of the risk of a haemolytic reaction. There have been reports that IM administration of Rhophylac in patients with a BMI ≥30 is associated with an increased risk of lack of effect. Therefore, in patients with a BMI ≥30 IV administration should be considered. Contains up to 11.5 mg (0.5 mmol) sodium per syringe. Despite standard measures to prevent infections resulting from the use of medicinal products prepared from human blood or plasma, the possibility of transmitting infective agents cannot be totally excluded. The measures taken are considered effective for enveloped viruses such as HIV, HBV and HCV but may be of limited value against non-enveloped viruses such as HAV and parvovirus B19. The transitory rise of the various passively transferred antibodies in the patient’s blood may result in misleading positive results in serological testing. Efficacy of live vaccine immunisation may be impaired if given in close proximity to anti-D administration.

**Undesirable effects**

Hypersensitivity, anaphylactic shock, headache, tachycardia, hypotension, dyspnoea, nausea, vomiting, skin reaction, erythema, pruritus, arthralgia, fever, malaise, chills, injection site reaction. Severe intravascular haemolysis in Rh(D) positive primary immune thrombocytopenia (ITP) patients. Haemolysis resulting in death has been reported. **Marketing Authorisation Number:** PL 15036/0019 **Further information is available from:** CSL Behring UK Limited, Haywards Heath, West Sussex, RH16 1AH **Legal Category:** POM **Basic NHS Price:** £46.50 **Date text last revised:** 1 May 2018.

Adverse events should be reported. Reporting forms and information can be found at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard).

Adverse events should also be reported to CSL Behring UK Ltd. on 01444 447 405

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