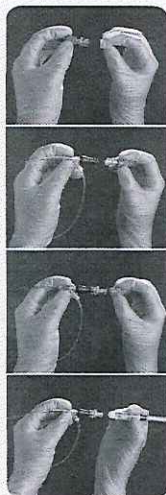


## Instructions for using the SAFSITE® Needle-free IV System

As an alternative to intramuscular administration for the suppression of Rh isoimmunization, Rhophylac® can be administered intravenously. This method of administration removes the risk of accidental needlesticks for both patients and healthcare workers. The Rhophylac syringe is compatible with most IV systems. However, if an adaptor is required, the SAFSITE Needle-free IV System is recommended.



### Working with the SAFSITE Needle-free IV System is easy.

According to the instructions of the IV system manufacturer, close the clamp above the port and/or reset the pump, swab the top of the port per hospital protocol, then follow these simple instructions:

1. **Remove the clear cap** from the SAFSITE Valve and attach it to the IV port by turning the valve clockwise.
2. **Remove the blue end cap** from the SAFSITE Valve and discard. Be careful not to touch the opening of the SAFSITE Valve. Alcohol swabbing is not necessary.
3. **Gently remove the white cap** from the Rhophylac prefilled syringe and attach it to the SAFSITE Valve by turning the syringe until it is firmly seated on the valve.
4. When you have finished administering Rhophylac, remove the SAFSITE Valve from the IV port, discard the valve with the Rhophylac syringe still attached, then open the IV clamp and/or restart the pump.

### B. Braun is the manufacturer of the SAFSITE Valve

- Customer service: 1.800.BBRAUN2 (1.800.227.2862) • Product no. 415068
- For any questions on the SAFSITE Valve, please call Braun Customer Service.

See reverse side for full Important Safety Information, and accompanying full prescribing information for Rhophylac.



**Rhophylac®**  
Rh<sub>0</sub>(D) Immune Globulin  
Intravenous (Human)

For intravenous or intramuscular injection.

### Important Safety Information

Rhophylac is indicated for suppression of rhesus (Rh) isoimmunization in:

- **Pregnancy and obstetric conditions** in non-sensitized, Rh<sub>0</sub>(D)-negative women with an Rh-incompatible pregnancy, including routine antepartum and postpartum Rh prophylaxis and Rh prophylaxis in cases of obstetric complications, invasive procedures during pregnancy, or obstetric manipulative procedures.
- **Incompatible transfusions** in Rh<sub>0</sub>(D)-negative individuals transfused with blood components containing Rh<sub>0</sub>(D)-positive red blood cells.

For suppression of Rh isoimmunization, Rhophylac can be administered IM or IV.

Rhophylac is indicated to raise platelet counts in Rh<sub>0</sub>(D)-positive, non-splenectomized adult patients with chronic immune thrombocytopenic purpura (ITP). For the treatment of ITP, Rhophylac must be administered IV.

**WARNING: This warning does not apply to Rh<sub>0</sub>(D)-negative patients treated for the suppression of Rh isoimmunization.** Intravascular hemolysis leading to death has been reported in Rh<sub>0</sub>(D)-positive patients treated for immune thrombocytopenic purpura (ITP) with Rh<sub>0</sub>(D) Immune Globulin Intravenous (Human) products. Intravascular hemolysis can lead to clinically compromising anemia and multi-system organ failure, including acute respiratory distress syndrome (ARDS). Serious complications, including severe anemia, acute renal insufficiency, renal failure, and disseminated intravascular coagulation (DIC), have also been reported. Closely monitor patients treated for ITP with Rhophylac in a healthcare setting for at least 8 hours after administration. See full prescribing information for complete boxed warning.

Rhophylac is contraindicated in individuals with known anaphylactic or severe systemic reaction to human immune globulin products.

Allergic or hypersensitivity reactions may occur with Rhophylac; early signs of hypersensitivity include generalized urticaria, chest tightness, wheezing, hypotension, and anaphylaxis. Individuals with selective IgA deficiency can develop antibodies to IgA and may develop severe hypersensitivity and anaphylactic reactions. For these individuals, weigh the expected benefits of treatment against the potential risks.

Rhophylac is derived from human plasma. The risk of transmission of infectious agents, including viruses and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent, cannot be completely eliminated.

**Suppression of Rh Isoimmunization:** For postpartum use following an Rh-incompatible pregnancy, Rhophylac should not be given to the newborn infant.

The most common adverse reactions in the suppression of Rh isoimmunization with Rhophylac are nausea, dizziness, headache, injection-site pain, and malaise.

**Immune Thrombocytopenic Purpura:** The most serious adverse reactions in patients receiving Rh<sub>0</sub>(D) immune globulin have been observed in the treatment of ITP. ITP patients being treated with Rhophylac should be monitored for signs and symptoms of intravascular hemolysis, including back pain, shaking chills, fever, and hemoglobinuria. Potentially serious complications of intravascular hemolysis include clinically compromising anemia, acute renal insufficiency, and, very rarely, disseminated intravascular coagulation, and death.

The most common adverse reactions observed in the treatment of ITP are chills, pyrexia/increased body temperature, and headache. Mild extravascular hemolysis has also been observed. In patients with preexisting anemia, weigh the benefits of Rhophylac against the potential risk of increasing the severity of the anemia.

Immunoglobulin administration may transiently interfere with the immune response to live virus vaccines, such as measles, mumps and rubella.

Please see accompanying full prescribing information for Rhophylac.

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