

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1. NAME OF THE MEDICINAL PRODUCT**

RHOCLONE -300mcg [Anti Rho-D Immunoglobulin Injection 300 mcg (Monoclonal)]

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each ml contains :

Monoclonal Anti Rho-D Immunoglobulin ..... 300 mg

Qualitative and Quantitative composition of RHOCLONE -300mcg

<b>Name of the Component</b>	<b>Specification</b>	<b>Quantity/Vial</b>	<b>Function</b>
Anti-RHO (D) immunoglobulin (Monoclonal) bulk	IH	300mcg	Active ingredient
Mannitol	BP	80.0 mg	Bulking Agent
Glycine	BP	30.0 mg	Stabilizer
Sodium Chloride	BP	17.8mg	Stabilizer
Human Albumin 20%	BP	0.005ml	Stabilizer
Sodium Hydroxide	BP	q.s	pH adjustment
Water for injection	USP	q.s	Vehicle

### **3. PHARMACEUTICAL FORM**

**Dosage form:** Freeze Dried Powder for Injection

**Description:** White to off white powdered cake.

### **4. CLINICAL PARTICULARS**

#### **4.1 Therapeutic indications**

Rhoclone is indicated to prevent Rho-D negative women from forming antibodies to foetal rhesus - positive red blood cells that may pass into the maternal blood during child birth, abortion or certain other sensitising events.

#### **4.2 Route of Administration**

Intramuscularly

#### **4.3 Posology and method of administration**

Rhoclone should always be given to rhesus negative mothers with no anti-D antibodies in

their serum and who have just delivered rhesus positive infants. A dose of 300 mcg should be given intramuscularly as soon as possible during first 3 days after delivery. In cases of abortion or termination of pregnancy, the Rh negative women should be given 150 mcg of Rhoclone within 72 hours, if the pregnancy is of 12 weeks duration or less. In cases of miscarriage in an advanced stage of pregnancy, 300 mcg should be administered.

Threatened abortion, amniocentesis carry risk of sensitisation during pregnancy. Any Rh negative women at risk of transplacental haemorrhage during pregnancy and not known to have been sensitised should be given 150 mcg of Rhoclone without delay.

Rhoclone should not be given to the infant and to Rho-D positive individuals.

Rhoclone effect in decreasing the incidence of hemolytic disease of the newborn due to Rh incompatibility has been dramatic. Rhoclone acts by eliminating the circulating Rho-D antigens and guarantees prevention of sensitisation to these antigens.

#### 4.4 **Contraindications:**

Individuals known to have had an anaphylactic or severe systemic reaction to human globulin should not receive Rhoclone or any other Anti Rho (D) Immune Globulin Injection.

#### 4.5 **Special warnings and precautions for use**

##### **Precautions**

**For intramuscular use only. Do not inject Rhoclone intravenously.**

In the case of postpartum use, the product is intended for maternal administration.

##### **Do not inject the newborn infant.**

Patients should be observed for at least 20 minutes after administration.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration.

##### **Pregnancy Category C**

Animal reproduction studies have not been conducted with **Rhoclone**. The available evidence suggests that Anti Rho (D) Immune Globulin does not harm the fetus or affect future pregnancies or the reproduction capacity of the maternal recipient.

#### 4.6 **Interaction with other medicinal products and other forms of interaction**

No drug/drug interaction studies have been conducted for Rhoclone in humans.

#### 4.7 **Effects on ability to drive and use machines**

None well documented for these groups of patients.

#### 4.8 **Undesirable effects**

No uncommon side effects detected. However local pain, fever, flushing, headache and chills may rarely occur.

### 5. **CLINICAL PHARMACOLOGY**

Pharmacotherapeutic group: Anti-RHO (D) immunoglobulin,  
ATC code: J06BB01

#### **Mechanism of Action**

**Rhoclone** Anti-RHO (D) immunoglobulin act by suppressing the immune response of Rh-negative individuals to Rh-positive red blood cells. The mechanism of action is unknown. Anti-RHO (D) immunoglobulin products are not effective in altering the course or consequences of Rh immunization once it has occurred.

### 6. **PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

- Mannitol
- Glycine
- Sodium Chloride
- Human Albumin 20%
- Sodium Hydroxide Pellets
- Water for injection

#### **6.2 Incompatibilities:**

The product is stable and there is no incompatibility amongst excipients.

#### **6.3 Shelf life :**

24 months.

#### **6.4 Special precautions for storage:**

Store at 2 °C - 8 °C. Do not freeze.

#### **6.5 Nature and contents of container:**

Combipack carton containing,

One vial of Rhoclone 300 mcg and one ampoule of Sterile Water for Injection USP 2ml.

#### **6.6 Special precautions for disposal and other handling**

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration.

#### **7. APPLICANT/MANUFACTURER:**

##### **Applicant:**

##### **Bharat Serums & Vaccines Ltd.**

3rd Floor, Liberty Tower, Plot No. K-10,  
Behind Reliable Plaza, Kalwa Industrial Estate, Airoli,  
Navi Mumbai 400708

##### **Manufactured by:**

##### **Bharat Serums and Vaccines Limited.**

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