SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the Medicinal Product

Product name

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

2. Strength:

300 mcg /Vial/1ml

3. Qualitative and Quantitative compositions

Name of the Component	Specification	Quantity/ml
Anti-RHO (D) Immunoglobulin (Monoclonal) Bulk	I.H.	300 mcg
Glycine	B.P.	22.5 mg
Sodium Chloride	B.P.	5.84 mg
Sodium Hydroxide Pelletes	B.P.	q.s.
Hydrochloric acid	B.P.	q.s.
Water for Injection	U.S.P.	q.s.

4. Pharmaceutical Form

Liquid Injection

5. Clinical Particulars

5.1 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.

5.2 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.

5.3 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.

5.4 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.

5.5 Interaction with other medicinal products and other forms of interaction

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

5.6 Use in pregnancy and lactation

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.

5.7 Effects on ability to drive and use machines

None well documented for these groups of patients.

5.8 Undesirable effects

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

5.9 Overdoses

Patients who receive Rhoclone 300 for Rh-incompatible transfusion should be monitored by clinical and laboratory means due to the risk of a hemolytic reaction

6. CLINICAL PHARMACOLOGY

6.1 Pharmaco-dynamic properties:

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.

7. Pharmaceutical Particulars

7.1 List of excipients

Glycine	B.P.
Sodium Chloride	B.P.
Sodium Hydroxide Pelletes	B.P.
Hydrochloric acid	B.P.
Water for Injection	U.S.P.

7.2 Incompatibilities:

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

7.3 Shelf life :

Sealed & Unopened containers, when stored as recommended have a shelf life of 24 months from date of manufacturing.

7.4 Special precautions for storage:

Store at 2^0C - 8^0C. Do not freeze.

7.5 Nature and contents of container:

Glass Vial USP Type-1 consisting clear colorless solution sealed with Rubber bung & Aluminum flip off seal.

8. Manufacturer (name, address, country):

Bharat Serums and Vaccines Limited

Plot No. K-27,

Anand Nagar, Additional M.I.D.C.

Ambernath (East), India.

9. Marketing authorization holder :

Bharat Serums & Vaccines Ltd.
17th Floor, Hoechst House,
Nariman Point,
Mumbai – 400 021
India.

10. Marketing authorization number :

Not Applicable

11. Date of first authorization / renewal of authorization :

Not Applicable

12. Date of revision of the text :

Not Applicable