

For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory.

Anti Rho-D Immunoglobulin Injection (Monoclonal) **RHOCLONE™**

100 mcg / 150 mcg / 300 mcg
Freeze dried

Description :

Rhoclon is a sterile freeze dried powder of **Human Monoclonal Anti-rhesus Immunoglobulin** (IgG1) containing antibodies to Rho-D. It is derived from stable heterohybridoma cell line HG-92 and purified using protein affinity chromatography.

Composition :

Each vial contains : Monoclonal Anti Rho-D Immunoglobulin 100 mcg / 150 mcg / 300 mcg.

The Anti-D IgG secreting plasma cell has been harvested from a hyperimmunised human source, and the IgG is of 100 % human origin.

Rhoclon contains : Mannitol I.P. and Sodium Chloride I.P. as excipients and Glycine I.P. and Human Albumin I.P. as stabilizer.

Indication :

Rhoclon 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.

Administration and Dosage :

Rhoclon 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 **Rhoclon** 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 **Rhoclon** without delay.

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

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

Side effects :

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

Presentation : Combipack carton containing,

One vial of **Rhoclon** 100 mcg and one ampoule of Sterile Water for Injection I.P. 1ml.

One vial of **Rhoclon** 150 mcg and one ampoule of Sterile Water for Injection I.P. 1ml.

One vial of **Rhoclon** 300 mcg and one ampoule of Sterile Water for Injection I.P. 2ml.

Direction for Use :

Reconstitute the contents of vial with Sterile Water for Injection I.P. provided in the pack.

Storage :

Store at 2°C - 8°C. Do not freeze.

Shelf Life :

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

References :

1) Drruygina E. I. et. al, Hematologija Transfusiologija (1991), Vol : 8.

2) Miterev G. Y. et. al, Biotechnology (1993), Vol : 8.

3) Lemeneva C. N. et. al, Hematologija Transfusiologija (1992), Vol : 9 - 10.

Manufactured in India by :

BHARAT SERUMS AND VACCINES LIMITED

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