

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

Anti-D (Rho) Immunoglobulin (Monoclonal)

RHOCLONE™

100 mcg / 150 mcg / 300 mcg

(Liquid Injection)

For Intramuscular Injection only

Description :

RHOCLONE is a (Specific Subclass IgG1) Sterile Liquid Injection of Human Monoclonal Anti-rhesus Immunoglobulin (IgG1) containing antibodies to (Rho). It is derived from stable heterohybridoma cell line HG-92 and purified using protein affinity chromatography.

Composition :

Each ml contains :

Monoclonal Anti-D I.H. 100 mcg / 150 mcg / 300 mcg.

Water for Injection I.P. q.s.

Excipient & Stabilizer : Sodium Chloride I.P., Glycine I.P.

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

Indication :

RHOCLONE is indicated to prevent (Rho) 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 :

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) 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) antigens and guarantees prevention of sensitisation to these antigens. Indicated for all (Rho) negative mothers for first pregnancy. In subsequent pregnancies additional dose may be necessary to prevent subsequent sensitization.

Side effects :

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

Presentation :

One vial of **RHOCLONE** 100 mcg.

One vial of **RHOCLONE** 150 mcg.

One vial of **RHOCLONE** 300 mcg.

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) Miterrev 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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