Pack Insert Date: 26-12-2012 Date: 09-06-2013* ALL Country Export (Ambernath)

(Liquid)

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) 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** 150mcg. One vial of **RHOCLONE** 300mcg.

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.

Keep out of reach of children.



Manufactured in India by :

BHARAT SERUMS AND VACCINES LIMITED

Plot No. K-27, Additional M.I.D.C. Ambernath (E) - 421 501

Size : $L \times H = 90 \times 120 \text{ mm}$.

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

Anti Rho-D Immunoglobulin Injection (Monoclonal)

RHOCLONE® 150mcg / 300mcg

(Liquid Injection)

1ml



For Intramuscular Injection only

Description :

RHOCLONE is a sterile Liquid formulation containing human monoclonal Rho-D immunoglobulin (IgG) for use in the prevention of Rh isoimmunization in Rh-negative women with Rh-positive pregnancies.

Composition:

Each ml contains:

Excipient & Stabilizer:

Sodium Chloride B.P., Glycine B.P.

RHOCLONE is manufactured from hybridoma derived from human B-cells secreting highly specific antibodies against Rho-D antigens.

Indication

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.

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, 300mcg 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 150mcg of **RHOCLONE** without delay.

Size : L x H = $90 \times 120 \text{ mm}$.

Pantone Process Black C

30% Pantone Process Black C

Paper: 40 gsm, ITC Print Paper Outline & Cutting marks not to print Artwork Code No.: IN90241E0AC

Back to Back Printing 2 Horizontal Folds