WinRho® SDF Intravenous

[Rh_0 (D) Immune Globulin (Human)]

THE FIRST I/V ANTI-D IMMUNE GLOBULIN PRODUCT IN THE WORLD LICENSED FOR THE TREATMENT OF ITP

US FDA WinRho SDF™ APPROVED

Efficacy:

- Simple mechanism of action
- Clinical response rates of up to 90% across all subgroups
- Childhood and adult chronic ITP
- Childhood acute ITP
- Adult and childhood ITP secondary to HIV infection
- Excellent long-term maintenace therapy in chronic ITP
- WinRho SDF™ administered as a single indicated dose of 50 - 75 mcg/kg body weight

Convenient:

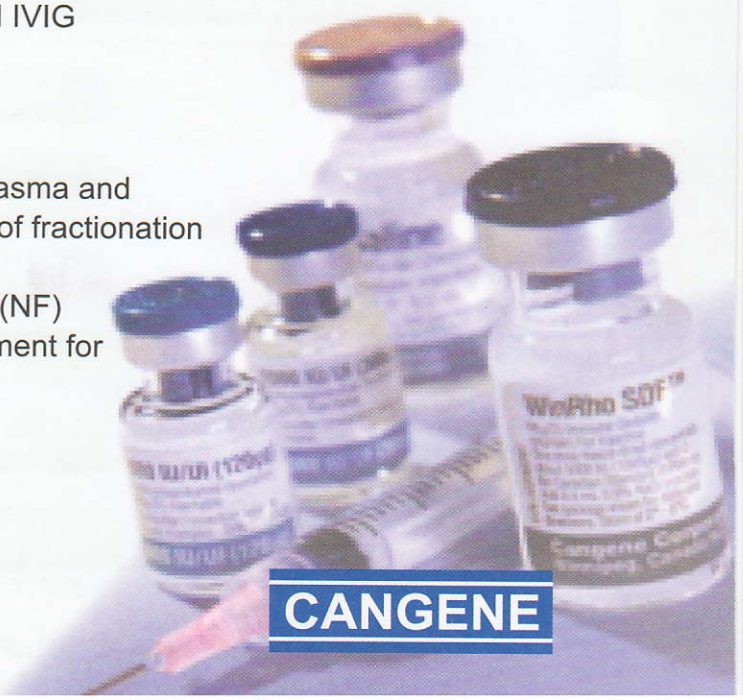
- Faster administration than standard IVIG- initial dose may be given as a single dose over 3-5 minutes.
- *Can be administered in out patient department / clinic*
- Lower fluid load administered to the patient in comparison to standard IVIG
- *WinRho SDF™ is available in two convenient packaging* formats 300 mcg (1500 IU) & 1000 mcg (5000 IU)

Cost Effectiveness :

- Shorter infusion time
- Lower total treatment costs compared to standard IVIG

Safety:

- Low incidence of adverse events.
- Twice PCR Tested: First PCR Test on individual plasma and second PCR Test on Plasma pool before the start of fractionation for the absence of HIV, HCV & HBV,
- Validated Viral inactivation by use of nanofiltration (NF) process added to the solvent detergent (SD) treatment for an extra measure of safety.



Paviour

An ISO 9001-2008 Certified Company

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ITP Treatment Algorithm in Adult

" Ibrahim N. Nakhoul, MD, Peter Kozuch, MD, Mala Varma, MD :
Clinical Advances in Hematology & Oncology Volume 4, Issue 2 February 2006 "

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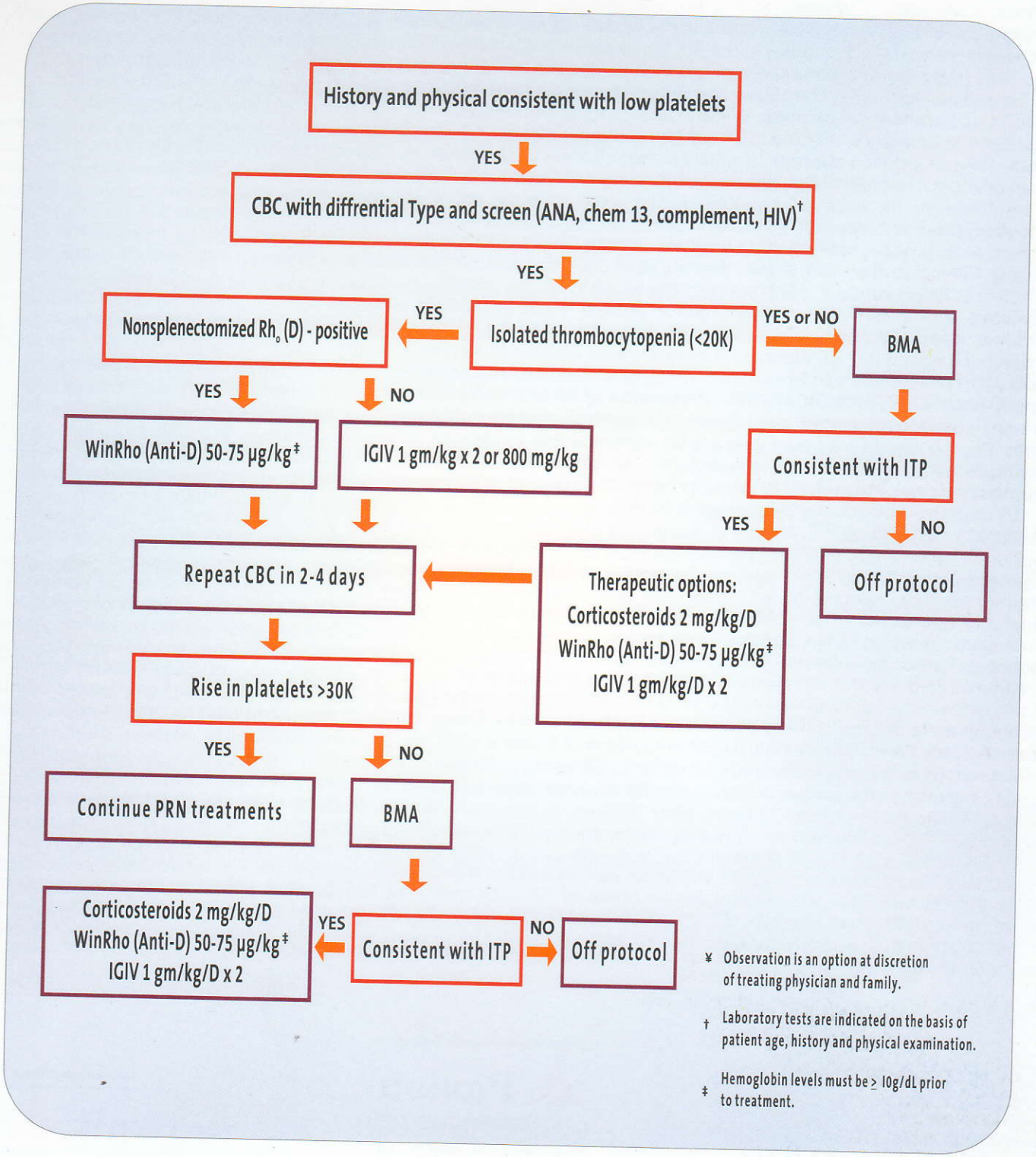
CHLA Algorithm for Diagnosis and Initial Treatment of ITP in Children



¥ Observation is an option at discretion of treating physician and family.

† Laboratory tests are indicated on the basis of patient age, history and physical examination.

‡ Hemoglobin levels must be ≥ 10g/dL prior to treatment.

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December 3-7 2006, Anaheim Orange County, CA, USA

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BASIC INFORMATION

WinRho SDF™ Rh_0 (D) Immune Globulin (Human) For Injection (Schedule D Drug) 1500 IU (300 mcg) and 5000 IU (1000 mcg) Powder for injection: Passive Immunizing Agent Standard:In-house standard against WHO 1st Reference Preparation 1976 (WinRho SDF™ immunoglobulin, human) **INDICATION AND CLINICAL USE : *Pregnancy and other obstetric Conditions :*** WinRho SDF™, Rh_0 (D) Immune Globulin (Human) is recommended for prevention of Rh immunization of Rh_0 (D) negative women at risk of developing Rh antibodies. Rh_0 (D) Immune Globulin (Human) prevents the development of Rh antibodies in the Rh_0 (D) negative and previously not sensitized mother carrying a Rh_0 (D) positive fetus, thus preventin the occurrence of haemolytic disease in the fetus or the newborn. The administration of WinRho SDF™ to women satisfying the above conditions should be done at about 28 weeks gestation when the child's father is either Rh_0 (D) positive or unknown. WinRho SDF™ should be administered within 72 hours after delivery if the baby is Rh_0 (D) positive or unknown. WinRho SDF™ administration is also recommended in these same women within 72 hours after spontaneous or induced abortion, amniocentesis, chorion villus sampling, ruptured tubal pregnancy, abdominal trauma or transplacental haemorrhage, unless the blood type of the fetus or father are confirmed to be Rh_0 (D) negative. It should be administered as soon as possible in the case of maternal bleeding due to threatened abortion. ***Immune Thrombocytopenic Purpura (ITP)*** WinRho SDF™, Rh_0 (D) Immune Globulin (Human) is recommended in the treatment of destructive thrombocytopenia of an immune etiology in situations where platelet counts must be increased to control bleeding. Clinical studies have shown that the peak platelet counts occur about seven days after IV anti- Rh_0 (D) treatment. The effect is not curative but is transient; platelet counts are usually elevated from several days to several weeks. For individuals with chronic ITP, a maintenance dosage is recommended with the dosage schedule determined on an individual basis. WinRho SDF™, Rh_0 (D) Immune Globulin (Human), is recommended for the treatment of nonsplenectomized Rh_0 (D) positive 1) children with chronic or acute ITP, 2) adults with chronic ITP, or 3) children and adults with ITP secondary to HIV infection in clinical situations requiring an increase in platelet count to prevent excessive haemorrhage. **CONTRAINDICATIONS : *Prevention of Rh Immunization :*** When Winrho SDF™, Rh_0 (D) Immune Globulin (Human) is used to prevent Rh alloimmununization, it should not be administered to: Rh_0 (D) positive individuals including babies; Rh_0 (D) negative women who are Rh immunized as evidenced by standard manual Rh antibody screening tests. Individuals with a history of anaphylactic or other severe systemic reaction of immune globulins. ***Immune Thrombocytopenic Purpura (ITP)*** When WinRho SDF™ is used to treat patients with ITP, it should not be administered to: Rh_0 (D) negative individuals, Splenectomized individuals, Individuals with known hypersensitivity to plasma products. **WARNINGS :** WinRho SDF™, Rh_0 (D) Immune Globulin (Human) contains trace quantities of IgA. Although WinRho has been used successfully to treat selected IgA deficient individuals, the physician must weight the potential benefit of treatment with WinRho SDF™ against the potential for hypersensitivity reactions. Individuals deficient in IgA have a potential for development of IgA antibodies and anaphylactic reactions after administration of blood components containing IgA: Burks et al. (1986) have reported that as little as 15 mcg IgA/ml of blood product has elicited an anaphylactic reaction in IgA deficient individuals. Individuals known to have had an anaphylactic or severe systemic reaction to human globulin should not receive WinRho SDF™ or any other Immune Globulin (Human). WinRho SDF™ must be administered via the intravenous route for the treatment of ITP as its efficacy has not been established by the intramuscular or subcutaneous routes. WinRho SDF™ should not be administered to Rh_0 (D) negative or splenectomized individuals as its efficacy in these patients has not been demonstrated. **DOSAGE AND ADMINISTRATION : *Pregnancy and other obstetric Condition :*** A 1500 IU (300mcg) dose of WinRho SDF™ Rh_0 (D) Immune Globulin (Human) should be given by intravenous or intramuscular administration at 28 weeks gestation of WinRho SDF™ Rh_0 (D) Immune Globulin (Human) should be given by intravenous or intramuscular administration as soon after delivery of a confirmed Rh_0 (D) positive baby as possible and no later than 72 hours after delivery. In the event that Rh status of the baby is not know at 72 hours. WinRho SDF™ should be administered to the mother at 72 hours after delivery. If more than 72 hours have elapsed. WinRho SDF™ should not be withheld but administered as soon as possible up to 28 days after delivery. In the case of threatened abortion. WinRho SDF™ should be administered as soon as possible. ***Immune Thrombocybocytopenic Purpura (ITP) :*** WinRho SDF™ is recommended with Doses of 50 - 75 mcg / kg body weight should be given by intravenous administration. **INJECTION :** Parenteral products such as WinRho SDF™ , Rh_0 (D) Immune Globulin (Human) should be inspected for Particulate matter and discoloration prior to administration. Use product within four hours of reconstitution. Aseptically administer the product intravenously in suitable vein with rate of injection of 1,500 IU (300 µg)/5 to 15 seconds .

(For additional information see package insert)

Manufactured by:

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Paviour

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