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Rabies Immune Globulin (Human) (Imogam Rabies)

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In a recent clinical trial involving 16 volunteers in 4 treatment groups, two subjects reported severe headaches, one in the Imogam® Rabies – HT + placebo group and one in the Imogam® Rabies + Imovax® Rabies group, and one third of the volunteers reported moderate systemic (headache and malaise) reactions. These [28]were equally distributed among the 4 treatment groups with no significant differences between the groups.

Local adverse reactions such as tenderness, pain, soreness or stiffness of the muscles may occur at the injection site and may persist for several hours after Although not [28, 38, 39]injection. These may be treated symptomatically. Mild systemic adverse reactions to the globulin after intramuscular injection are uncommon. reported specifically for HRIG, angioneurotic edema, nephrotic syndrome, and anaphylaxis have been reported after injection of immune globulin (IG), a product similar in biochemical composition but without antirabies activity. These reactions occur so rarely that a causal relationship between IG and these reactions has not [1]been established.

Reporting of Adverse Events

The National Vaccine Injury Compensation Program, established by the National Childhood Vaccine Injury Act of 1986, requires physicians and other health-care providers who administer vaccines to maintain permanent vaccination records and to report occurrences of certain adverse events to the US Department of Health and Human Services. Reportable events include those listed in the Act for each vaccine and events specified in the package insert as contraindications to further [40, 41, 42]doses of that vaccine.

Reporting by patients, parents or guardians of all adverse events occurring after HRIG administration should be encouraged. Adverse events following treatment with HRIG should be reported by the health-care provider to the US Department of Health and Human Services (DHHS) Vaccine Adverse Event Reporting Systems (VAERS). Reporting forms and information about reporting requirements or completion of the form can be obtained from VAERS through a toll-free number [40, 41, 42]1-800-822-7967.

The health-care provider also should report these events to the Director of Scientific and Medical Affairs, Aventis Pasteur Inc., Discovery Drive, Swiftwater, PA 18370 or call 1-800-822-2463.