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adverse effects on the breastfed infant from Octagam 10% liquid or from the underlying milk, the effects of Octagam 10% on the breastfed child, and the effects of Octagam 10% on the mother’s reproductive capacity. Immune globulins cross the placenta from maternal circulation respectively. 

Immune Globulin Intravenous (Human), Octagam, is a solvent/detergent (SD)-treated, sterile preparation of highly purified immunoglobulin G (IgG) derived from large pools of human plasma. Octagam is a solution for infusion to be administered intravenously. This preparation contains approximately 100 mg of protein per mL (10%) of which not less than 5% is normal human immunoglobulin G. Octagam contains not more than 3% aggregates by size exclusion and not more than 3% fragments. On average, the product contains 106 g/L of IgG and even lower amounts of IgM. 

The product is manufactured by the cold ethanol fractionation process followed by ultrafiltration and chromatography. The manufacturing process includes treatment with an organic S/D mixture composed of tri-n-butyl phosphate (TNBP) and Triton X-100 (Octoxynol).

The safety and effectiveness of Octagam 10% has not been established in pediatric patients with chronic ITP and/or thrombocytopenia. The use of Octagam 10% in pediatric patients is recommended only in the presence of failed response to other therapies. 

Reactions No. of Subjects (% of Subjects [n=116])

<table>
<thead>
<tr>
<th>Reaction</th>
<th>No. of Subjects</th>
<th>(%) of Subjects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headache</td>
<td>25 (22)</td>
<td></td>
</tr>
<tr>
<td>Pruritus</td>
<td>17 (15)</td>
<td></td>
</tr>
<tr>
<td>Heart Rate Decreased</td>
<td>18 (15)</td>
<td></td>
</tr>
</tbody>
</table>

One subject experienced a serious adverse reaction (headache).

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

No data are available to indicate the presence or absence of drug-associated risk. Animal reproduction studies have not been conducted with Octagam 10%. It is not known whether Octagam 10% can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Immune globulins cross the placenta from maternal circulation increasing after 30 weeks of gestation. Octagam 10% should be given to pregnant women only if it is clearly needed. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2.4% and 15.0%, respectively.

8.2 Lactation

No data are available to assess the presence or absence of Octagam 10% in breast milk. The effects of Octagam 10% on the breastfed child, and the effects of Octagam 10% on the mother’s reproductive capacity are unknown. 

9 CLINICAL PHARMACOLOGY

9.1 Mechanism of Action

The mechanism of action of immunoglobulin in the treatment of chronic ITP has not been fully elucidated.

9.2 Pharmacokinetics

Pharmacokinetic studies with Octagam 10% have not been performed in patients with chronic ITP.

9.3 NON-CLINICAL TOXICOLOGY

9.3.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

No studies were conducted on carcinogen or mutagenicity, or impairment of fertility with Octagam 10%.

9.3.2 Animal Toxicology and/or Pharmacology

No studies were conducted on pharmacology and pharmacodynamics with Octagam 10% in animals.

A variety of single-dose toxicity studies were performed for Octagam 10% and Octagam alone or in combination: the lowest toxic dose of ITP and Octagam in rats was 1000 mg/kg TNF alpha 10% (10), 1 g/kg TNF alpha 10% (11), 1.5 g/kg TNF alpha 10% (12) and 2 g/kg TNF alpha 10% (13). The lowest toxic dose for rats was 60 mg/kg TNF alpha 10% (10), 100 mg/kg Octagam 10% (11), 150 mg/kg Octagam 10% (12) and 200 mg/kg Octagam 10% (13). The lowest toxic dose for dogs was 50 mg/kg TNF alpha 10% (10), 250 mg/kg Octagam 10% (11), 500 mg/kg Octagam 10% (12) and 1000 mg/kg Octagam 10% (13). 

15 REFERENCES