

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

Human Normal Immunoglobulin I.P.  
(Human Gammaglobulin)  
***BHARGLOB***

**Manufactured from human plasma,  
Negative for HBsAg, HIV-1,2 and HCV antibodies**

**Description :**

**BHARGLOB** is a sterile non-pyrogenic solution of immunoglobulins active against pathogens normally occurring in the population. **BHARGLOB** is prepared from the plasma of healthy volunteers. Each unit of plasma is stringently screened for the presence of Hepatitis B virus using third generation tests. **BHARGLOB** is non-reactive for Hepatitis B virus Antigen. Individual donations have been screened for HIV and HCV antibodies by ELISA and found to be non-reactive.

Pooled plasma is fractionated using COHNS fractionation methods to obtain a concentrate of immunoglobulins which are mainly IgG. The IgG immunoglobulins are intact monomers with a normal biological half life and no anticomplementary activity.

Sophisticated techniques ensure the absence of aggregates, oligomers and fragments which are responsible for the instability, ineffectiveness of the product and inadvertent sensitisation to human proteins. Thiomersal (0.01%) is added as preservative.

**Indications :**

**BHARGLOB** (1) may therefore be considered in the following cases : For PROPHYLAXIS in healthy subjects who have had no opportunity of gaining immunity by natural means or by active immunisation and who are at risk for e.g. following exposure to infective Hepatitis, mumps, measles, poliomyelitis, varicella, rubella, oral herpetiform lesions especially in communes of infants, mentally retarded children or aged. Persons at risk include non-immune pregnant woman and post operative cases. (2) For SUBSTITUTION in cases of congenital or acquired agammaglobulinemia or hypogammaglobulinemia, where the normal response to an immunogenic stimulus is impaired. Such cases marked by an abnormal susceptibility to infection (especially recurrent infections of the GI and respiratory tracts) include preterm infants, geriatric patients, disorders associated with protein loss (nephrotic syndrome), systemic infections and iatrogenic antibody deficiency syndromes (due to steroid or cytotoxic therapy).

(3) For THERAPY in patients suffering from generalised infections including hepatitis, mumps, measles, varicella, bronchial asthma and allergic manifestations combined with bronchial infections.

**Effects :**

- Provides immediate passive immunity.
- Maximum plasma levels are attained within 48 hours.
- Provides protection for longer period of time as it has a biological half life of 23 days.
- Does not interfere with the normal immune mechanism.
- No risk of anaphylaxis.

**Side effects :**

Local pain, Fever, Flushing, Headache may occur.

**DOSAGE CHART FOR 10% & 16.5% SOLUTION OF BHARGLOB**

INDICATION	DOSAGE		PROPHYLAXIS	ADMINISTRATION DOSAGE		THERAPEUTIC FREQUENCY
	10%	16.5%		10%	16.5%	
Measles	0.6ml	0.3ml	Within first 6 days after exposure	0.8ml	0.5ml	
Hepatitis A	0.03ml	0.02ml	within 14 days	0.6ml	0.4ml	
Hepatitis B	0.06ml	0.05ml	As soon as possible	0.6ml	0.4ml	Should be repeated after 1 month
Poliomyelitis	0.3ml	0.2ml	within 5-7 days			
Rubella	0.3ml	0.2ml	within 5 days			
Mumps	0.3ml	0.2ml	within 24 hours			
Varicella	0.3ml	0.2ml	within 3 days			
Oral Herpetiform lesions	0.2ml	0.1ml	As soon as possible	0.2ml	0.1ml	Every week
Hypogammaglo - bulinemia or Agammaglobulinemia				Initial dose of 1.8ml followed by 5ml	Initial dose of 1.3ml followed by 0.4ml	Every 3 to 4 week
Herpes Zoster				Initial dose of 10ml followed by 5ml	Initial dose of 7ml followed by 3.5ml	Every week
Bacterial infections				0.6ml	0.4ml	To be repeated if necessary with antibiotic therapy
Pertussis		0.2ml	0.3ml		0.6ml	0.4ml
Bronchial asthma				0.3ml to 0.5ml	0.2ml to 0.4ml	Repeated after 4 weeks
Allergic manifestation combined with bronchial infections				0.1ml	0.6ml	To be repeated every week

Note : Dosage is indicated in ml. per kg. body weight

**Mode of administration :**

**BHARGLOB** is given as an intramuscular injection only.

**Presentation :**

10% solution in vials of 1ml / 2ml and 16.5% solution in vials of 1ml / 2ml.

**Storage :**

Store at 2<sup>0</sup>C - 8<sup>0</sup>C. Do not freeze. Protect from light.

**Shelf Life :**

Sealed & Unopened containers, when stored as recommended have a shelf life of 36 months from date of manufacturing.

**Caution :**

Do not use if the solution is cloudy or turbid.

**References :**

1. Nydegger, U.E.et al (1984) : Antibiotic Immunosuppression and its treatment with Human IgG preparations Vox Sang 47:92.
2. IUIS/WHO Notice on appropriate uses of human IgG in clinical practice. clin. Exptal Immunol 52:417-(1983).
3. Nydegger, U.E.et al (1984) : Antibiotic Immunosuppression and its treatment with Human IgG human serum against opportunistic infections. Kelo J. Med 29:169.
4. Indian Pharmacopoeia (1996), Volume I p 391.
5. Steihm E.R. (1979) : Std and specific human immune serum globulin as therapeutic agents. Pediatrics 63:301.
6. Smith G. N. et al (1972) : Uptake of IgG after i.m. and subcutaneous injection, Lancet 1:120.

Manufactured in India by :

**BHARAT SERUMS AND VACCINES LIMITED**

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