

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

**"FOR IMMUNOTHERAPY OF ALLERGIC DISORDERS"**

## **HISTOGLOB<sup>®</sup>**

**Manufactured from human plasma,  
Negative for HBsAg, HIV-1, 2 and HCV-RNA by PCR**

### **Composition :**

Each ml contains :

Human Normal Immunoglobulin I.P. .... 12 mg  
Histamine Dihydrochloride B.P. .... 0.15 mcg  
Sodium Thiosulphate I.P. .... 32 mg  
Water for Injection I.P. .... q.s.

Excipients : Stabilizer : Maltose ..... 7%

Preservative : Benzyl Alcohol ..... 1%

### **Description :**

HISTOGLOB is a sterile preparation of Histamine dihydrochloride coupled to active protein fraction extracted from human blood (gammaglobulin) in strictly defined proportions. This conjugate is capable of eliciting an immunological response in the human body with the production of highly potent antihistaminic antibodies. Gammaglobulin used in HISTOGLOB is tested negative for HBsAg, HIV-1,2, antibodies and HCV-RNA by PCR. HISTOGLOB is subjected to rigid stability tests, electrophoretic analysis and repeated immunological checks in laboratory animals to ensure purity and safety.

### **Pharmacological Action :**

Symptoms of allergy are caused by a sudden release of various chemical factors, amongst which Histamine is predominant.

In allergic conditions, IgE antibodies are produced which bind to mast cells and / or circulating basophils. In the presence of the allergen an antigen-antigen-antibody reaction occurs leading to degranulation of the mast cells and / or basophils and subsequent capillary permeability and contraction of smooth muscle which in turn give to several distressing symptoms in the individual.

The anti-histamine antibodies formed by the administration of HISTOGLOB neutralise the Histamine so released and effectively eliminate allergic reactions.

HISTOGLOB is a systemic treatment against allergic conditions, but not a remedy for allergic attacks. HISTOGLOB usually leads to the progressive subsidence of allergic conditions within four weeks from the end of treatment. The duration of this protection may vary from patient to patient and may last several months.

### **Indications :**

HISTOGLOB is a basic treatment for allergic conditions. It is therefore recommended for all allergic complaints whatever their symptoms or cause.

### **HISTOGLOB is recommended for the following indications :**

1. Respiratory system : Allergic rhinitis; hay fever, bronchial asthma; asthmatic bronchitis, chronic bronchitis; spasmodic tracheitis.
2. Cutaneous : Eczema, urticaria, generalised skin allergies.
3. Nervous system : Migraine.
4. Gynaecological : Premenstrual syndrome (PMS) of allergic aetiology.

HISTOGLOB may also be used prophylactically with children (where there is a family history of allergy) who are about to undergo an adenoidectomy or tonsillectomy.

**Contra-Indications :**

It is advisable to avoid HISTOGLOB treatment during pregnancy or during menstruation. DO NOT ADMINISTER HISTOGLOB DURING AN ACUTE ALLERGIC ATTACK.

**Side Effects :**

HISTOGLOB is normally well tolerated even by children and infants. However, in very rare cases an exacerbation of the clinical symptoms is observed after the 1st and 2nd injection. This is only of a transient nature and is usually a sign that the system is responding favourably to the medication. HISTOGLOB must always be given subcutaneously.

**Precautions :**

HISTOGLOB is thermolabile, hence store the product at recommended temperature of 20C - 80C.

Always treat any existing superinfection before beginning HISTOGLOB treatment. Never start treatment during an acute allergic attack, specially an acute asthmatic attack. In such cases the usual specific remedy must be used first. If an acute attack occur after an injection of HISTOGLOB treatment, this should be viewed as a positive sign. Discontinue HISTOGLOB treatment until symptomatic treatment has alleviated the acute attack, and then continue the HISTOGLOB regime.

In small doses, corticoid therapy is compatible with HISTOGLOB treatment. In many cases the doses of corticoids can be gradually reduced, or even stopped. HISTOGLOB is not contra-indicated with desensitization treatment. In a good number of cases a combined treatment appears to reinforce the effects. It is important to remember that results may only be evident 3 to 4 weeks after the end of treatment.

**Dosage & administration :**

**Dosage in general :**

Adults : 3 injections each of 1 ml at intervals of 4 days.

Children : 3 injections each of 1 ml at intervals of 8 days.

The course may be repeated after one month. In chronic allergic cases, booster dose may be given 3 and 6 months after the first injection.

**Dosage for seasonal allergies :**

(Hay fever, asthma, chronic bronchitis etc.). Give the first 6 injections at intervals of 4 days, 3 months before seasonal manifestations are expected.

**Dosage for premenstrual syndrome :**

At the time of each menstrual cycle, one injection to be given on each day of the 6th, 13th and 20th day. Then one injection every 20th day of all following cycles until menopause, if required.

**Dosage for adenoidectomy and tonsillectomy :**

A series of 3 injections 6 weeks before the operation, followed by a new series 4 weeks after the operation.

For allergic migraines, chronic urticaria, atopic eczema, a series of 16 injections, without interruption at 2-days intervals may be given.

**Administration :**

The contents of each vial is required to be administered by subcutaneous route only.

**Storage :**

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

**Presentation :**

Blister pack containing 3 vials of HISTOGLOB.

Manufactured in India by :

**BHARAT SERUMS AND VACCINES LIMITED**

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