



Consumer/Patient Information Leaflet

Brand Name: Gamma IV

[Normal Immunoglobulin for Intravenous use B.P. (Human)]

For Intravenous usage

What's in your injectable medicine?

The name of your medicine is Gamma IV [Normal Immunoglobulin for Intravenous use B.P. (Human)] containing Immunoglobulin G as active ingredient. It contains the active ingredient of 0.05 g / ml in each vial of Gamma IV.

(Kindly refer to Pack insert for more pharmacological / usage details)

What is Human Normal Immunoglobulin?

Normal immunoglobulin is an extract of human (donor) blood which contains antibodies to diseases. Immunoglobulin from blood donated by a wide cross-section of population is likely to contain antibodies to most common diseases. Antibodies are produced by the immune system when the body is exposed to foreign organisms. These antibodies are specific to the infecting organism, for example the measles virus, and their first function is to help the body recognise and kill the foreign organisms. The antibodies formed remain in the blood and recognise and attack any future infection with the same organism. Donated blood contains antibodies to diseases to which the general population has been exposed, either through vaccination or actual infection. Normal immunoglobulin therefore contains antibodies to most common diseases. These include hepatitis A, measles, mumps, and German measles (rubella). Normal immunoglobulin is used when immediate protection from a disease is needed, for example to prevent disease in unvaccinated people who have been exposed to an infectious disease, to prevent infection following burns injuries and to reduce the number and severity of infections in people with antibody deficiency syndromes. In these syndromes (agammaglobulinaemia, hypogammaglobulinaemia, dysgammaglobulinaemia) the body is unable to produce antibodies. Normal immunoglobulin does not stimulate the body to produce its own antibodies and therefore the effect is not long-lasting. It diminishes progressively over 3-4 weeks. Continued protection requires repeated injections.



What conditions does this medication treat?

Gamma IV [Normal Immunoglobulin for Intravenous use B.P. (Human)] is indicated in the treatment of primary immunodeficiency states in which severe impairment of antibody forming capacity has been shown. Gamma I.V. is especially useful when high levels or rapid elevations of circulating antibodies are desired or when intramuscular injections are contraindicatory.

Gamma IV is indicated for following conditions:

1. Primary Immunodeficiency (PID)
2. Kawasaki syndrome
3. Idiopathic Thrombocytopenic Purpura (ITP)
4. Bone Marrow Transplantation
5. Chronic B-cell Lymphocytic Leukemia
6. Pediatric HIV-1 Infection
7. Guillain-Barre syndrome (GBS)

How does Gamma IV work?

Human normal immunoglobulin contains mainly immunoglobulin G (IgG) with a broad spectrum of antibodies against infectious agents.

Human normal immunoglobulin contains the IgG antibodies present in the normal population. It is usually prepared from pooled plasma from not fewer than 1000 donations. It has a distribution of immunoglobulin G subclasses closely proportional to that in native human plasma. Adequate doses of this medicinal product may restore abnormally low immunoglobulin G levels to the normal range. The mechanism of action in indications other than replacement therapy is not fully elucidated, but includes immunomodulatory effects.

Primary Humoral Immunodeficiency:

Gamma I.V. supplies a broad spectrum of opsonic and neutralizing IgG antibodies for the prevention or attenuation of wide variety of infectious diseases. As Gamma I.V. is administered intravenously, essentially 100% of the infused IgG antibodies are immediately available in the recipient circulation. 30% of the infused IgG disappeared from the circulation in first 24 hours. A further decline to about 40% of the peak level is observed during first week. The in-vivo half-life of Gamma I.V. equals or exceeds the three week half-life reported in the literature.



Idiopathic Thrombocytopenic Purpura: (ITP)

Gamma I.V. has been shown to be effective in ITP. The mechanism of action has not been fully elucidated.

Bone Marrow Transplantation:

Gamma I.V. has been shown to be effective in bone marrow transplant patients 20 years of age in the first 100 days post - transplant for the prevention of systemic and local infections, interstitial pneumonia of infectious and idiopathic etiologies. In patients with limited or compromised acid-base compensatory mechanisms, consideration should be given to the effect of the additional acid load Gamma I.V. may present.

What is the most important information I should know about Gamma IV – 0.5?

Gamma IV is given as an Intravenous Injection.

Before using this medication, tells your doctor if:

- you are pregnant, planning to become pregnant or are breast-feeding
- you are taking any prescription or non-prescription medicine, herbal preparation, or dietary supplement
- you are allergic to any other medications or substances.

Ask your health care provider if Gamma I.V. may interact with other medicines that you take. Check with your health care provider before you start, stop, or change the dose of any medicine.

How should I use Gamma IV ?

Use Gamma IV exactly as directed by your Physician.

What happens if I miss a dose?

Contact your doctor if you miss a dose of Gamma IV.

What should I avoid while using Gamma IV?

Follow your doctor's instructions about any restrictions on food, beverages, or activity.



How will Gamma IV be given to you?

Gamma IV should be administered only Intravenously; as the intramuscular and subcutaneous routes have not been evaluated.

How to store the Medicine?

Store the product at 2⁰C - 8⁰C. Protect from light. Do not freeze

The product license/ authorization holder is:

BHARAT SERUMS AND VACCINES LIMITED

Plot no K-27, Jambivili village, Anand Nagar, Additional M.I.D.C,
Ambernath (East) Maharashtra State



Manufactured in India by:

BHARAT SERUMS AND VACCINES LIMITED

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

This is only a summary of the Gamma IV (Normal Immunoglobulin for Intravenous use B.P.). If you have any questions after reading this leaflet then please ask your doctor who has access to additional information or refer to the pack insert.