

The case for intravenous immunoglobulin



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Intravenous immunoglobulins

- **Availability**

Preparations available in India - I

Indigenous

Manufacturer	Product
Bharat Serum	<i>Ivigama</i>
VHB Pharma	<i>Iviglob</i>
Claris	<i>Norglobin</i>
Synergy	<i>MeGlob</i>
Nirlife Healthcare	<i>IVIG</i>

Preparations available in India - II

Indigenous

Manufacturer	Product
Intas	<i>Globucel</i>
Reliance	<i>Immunorel</i>

Preparations available in India – III FDA / EMEA approved

Manufacturer	Product
Biotest	<i>Intratect</i> <i>Intraglobin - X</i> <i>Pentaglobin - X</i>
Bharat Serum/ Talecris	<i>Gamunex</i>
Baxter	<i>Kiovig</i> <i>Gammagard - X</i>
Novartis	<i>Sandoglobulin - X</i>
Octapharma	<i>Octagam - X</i>
Alpha	<i>Venoglobulin - X</i>

Intravenous immunoglobulins

- **Cost of product**

Cost of IVIg in India

	Indigenous preparations	FDA/EMEA approved preparations
Cost per 5 grams	<i>INR 7,500</i> <i>(US \$ 138)</i>	<i>INR 25,000</i> <i>(US \$ 462)</i>

Intravenous immunoglobulins

- **Advantages**

Easy administration of large doses

Good tolerance

Proven efficacy

Intravenous immunoglobulins

- **Problems**

Poor venous access

Need for frequent hospital visits

Systemic adverse reactions

Intravenous immunoglobulins

- **Adverse reactions**

Adverse reactions - IVIg

During infusion - minor

- Fever
- Myalgia / Arthralgia
- Bronchospasm
- Chills

Adverse reactions - IVIg

During infusion - major

- Anaphylactoid (occ. anaphylactic) reactions
- Hypotension
- Myocardial infarction
- Thrombosis
- Stroke

Adverse reactions - IVIg

Within 24-48 hours

- Headache, vomiting
- Aseptic meningitis (esp. in children with
rheumatic diseases)
- Hyperviscosity syndrome

Adverse events - IVIg

Long term

- All blood products carry inherent **risks of transfer of infectious agents**
- *'Absolute safety'* is an unattainable goal
- Risk, however, may be so low as to be virtually non-existent

Long term safety of IVIg ppns.

- Enveloped and non-enveloped viruses
- Risk of HCV: the 1983 scare
- Health of the donor
- Donor screening : HCV, HBV, HIV
 - *PCR rather than ELISA*

Safety of the product

- Plasma from screened donors
- Donations are serologically tested
- PCR tested mini-pools

Steps for viral reduction

Production step	Mechanism of action
1. Ethanol precipitation	Removal of enveloped and non-enveloped viruses
2. Octanoic acid/calcium acetate treatment	Inactivation of enveloped and non-enveloped viruses
3. Solvent/detergent treatment	Inactivation of enveloped viruses
4. 20 nm virus filtration	Exclusion of enveloped and non-enveloped viruses > 20 nm in size

Intravenous immunoglobulins

- Available preparations are very safe

Intravenous immunoglobulins

- **Ease of administration – the Indian setting**

Government hospitals

Private hospitals / clinics

At home

Our experience with IVIg in India

- First entered the Indian market in 1991
- Indigenous brands have been marketed since mid-1990s
- Products are easily available

Our experience with IVIg in India

- Efficacy as replacement therapy
- Efficacy as immunomodulatory agents

- Side-effects
- Safety profile: long-term

