Patient Information Leaflet
ImmunoRel®, a normal human immunoglobulin 5% Solution

1. Name of Product

The product name is ImmunoRel® which is a 5% solution containing normal immunoglobulin for intravenous use.

2. Description of Product

Immunoglobulins are proteins produced by the immune system (the body's own defense system). Intravenous immunoglobulin, or IVIG for short, is a preparation of purified natural human blood plasma components.

It is usually given to patients as an intravenous infusion when it is called intravenous immunoglobulin (IVIG).

Antibodies are formed when the immune system comes into contact with foreign substances that cause infections such as viruses or bacteria. These antibodies protect us from infection.

These immunoglobulins can be extracted from donor blood and are used to treat a number of medical conditions.

The first process includes screening of the donors to make sure that they have no serious diseases which can be passed on to the patients – all are negative for hepatitis B, hepatitis C and human immunodeficiency virus (HIV). The manufacturing process includes treatment with certain chemicals that helps in eliminating any harmful viruses that rarely may be present and the same is confirmed by some tests.

There are different types of antibodies and ImmunoRel contains the most important component which is called as gamma globulin or IgG.

Maltose is used as a stabiliser in the concentration of 100g/L, which is considered as safe even for the kidneys.

3. What is in the medicine.

ImmunoRel® is available in 5% concentration solution in 50ml and 100ml preparation.

Each bottle/vial of contains:

Protein content	50 g/l
Immunoglobulin G	2.5 g/ 5 g
Stabiliser Maltose	100 g/l
IgA content	$\leq$ 80 mg/l
Immunoglobulin sub class	Normal distribution

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4. Strength of the medicine

ImmunoRel is available in 5% concentration solution in 100ml preparation (5 grams in one infusion vial of 100ml).

ImmunoRel is available in 5% concentration solution in 50ml preparation (2.5 grams in one infusion vial of 50ml).

5. What is this medicine used for.

The medicine is used for the treatment of the following condition:

An approved list of clinical conditions where immunoglobulins is indicated, is as under:
Primary Immunodeficiency (PID)
Kawasaki Syndrome
Idiopathic Thrombocytopenic Purpura
B-cell Chronic lymphocytic leukemia
Pediatric HIV 1 infection
Hemopoietic stem cell transplantation in elderly

Apart from these there are many other conditions for which the doctor will prescribe this medicine.

6. How much and how often should you use this medicine.

The dose and duration of therapy depends on the condition for which intravenous immunoglobulin will be given by the doctor to you.

The replacement dose for immunodeficiency patients is generally 400-600 mg/kg each 3-4 weeks. Assessment of dose adequacy will be made clinically and by measuring the trough IgG, which will generally be kept >7g/l.

Immunomodulation (e.g. in treatment of ITP or Kawasaki's) will require higher doses of IVIG.

In treatment of other conditions very high doses have been used.

7. When should you not take this medicine.

Intravenous immunoglobulin should not be used in patients with selective deficiency of one of the type of immunoglobulin called as immunoglobulin A (IgA). These patients possess antibody to IgA and administering IgA in these patient may trigger allergic reaction.

Immunoglobulin preparation may also not be used in patients who have a previous history of severe allergic reactions to the intravenous administration of human immunoglobulin.

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8. Undesirable effects

a) **General adverse effects:** Dose related undesirable effects including flushing, chest tightness, fever, nausea and vomiting, hypotension and flu like symptoms can be seen. These are seen more often in immune deficient patients receiving their first infusion. If the infusion is slowed or stopped it is usually possible to complete the infusion after the symptoms have resolved. Mild headaches are not uncommon and may respond to reduction in rate, or simple analgesia.
b) **Anaphylaxis:** Anaphylaxis to IVIG is rare and has been suggested to be due to anti-IgA antibodies in the recipient. If an individual has absent IgA they may make antibodies against IgA, and hence react with the small amounts of IgA in IVIG preparations. The infusion should be stopped and appropriate resuscitation commenced.
c) **Transmission of infection**: Hepatitis B has not been found to be transmitted by IVIG. To date HIV has not been transmitted by IVIG. There were several outbreaks of hepatitis subsequently identified as Hepatitis C in the late 1980's and early 1990's. Current preparations of IVIG have a manufacturing steps which inactivates hepatitis C. It is now generally, although not universally, believed that intravenous immunoglobulin is free of viral contaminants. To date there have been no cases of Creutzfeldt-Jakob disease (CJD) known to be transmitted by IVIG, however this remains a theoretical risk.
d) **Other:** cases of haemolysis, thrombosis with stroke, renal insufficiency, and alopecia in association have been reported.

9. What other medicine or food should be avoided whilst taking this medicine.

IVIG does not usually interfere with other medications. However, you must tell your doctor which medicines you are currently taking, including over-the-counter preparations and herbal remedies.

The doctor takes precaution not to mix any other drugs with the infusion bottle of IVIG or dilute with other infusible drugs. IVIG is given by a separate infusion line. No other medications or fluids should be mixed with IVIG preparations.

IVIG administration may slow the protection of live attenuated viral vaccines such as measles, mumps, rubella and varicella for at least six weeks, and possibly up to three months or long. Vaccination should be avoided during this period.

10. What should you do if you miss a dose.

Not applicable. Consult your doctor regarding the same.

11. How should you keep this medicine.

IVIG products are store refrigerated at a temperature between 2°C and 8°C and not to freeze. The medicine is warmed up to room or body temperature before use. Protect from light. Discard any remaining contents after use. Do not use after expiry date. Keep out of reach of children.

12. Signs & Symptoms of over dosage

Overdose may lead to fluid overload and hyperviscosity, particularly in the elderly and in patients with impaired renal function.

The medication is administered in hospital setup and the patients are closely monitored observed by the doctor or the nursing staff for any symptoms throughout the infusion period, and for one hour after the first infusion.

13. What to do when you have taken more than the recommended dosage.

Not applicable.

The doctors should take necessary actions based on the guidelines.

14. Name/logo of manufacturer/importer/Marketing Authorisation Holder

Manufacturer:

Reliance Life Sciences Pvt. Ltd

15. Care that should be taken when taking this medicine.

Not applicable.

The medication is administered in hospital setup and the patients are closely monitored.

In all patients, IVIG administration requires adequate hydration prior to the initiation of the infusion of IVIG, monitoring of urine output, blood urea nitrogen (BUN), monitoring of serum creatinine levels, and avoidance of concomitant use of loop diuretics.

The product is administered at the minimum concentration and infusion-rate practicable. In case of renal impairment, IVIG discontinuation is considered.

16. When should you consult your doctor.

Not applicable.

The medication is administered in hospital setup.

17. Date of Revision of PIL

Not applicable