

Where immunoglobulins
come from



Patient information

bpl 

Bio Products Laboratory

a commitment for life

Primary immunodeficiency (PID)

Our body's immune system is designed to protect us against invading germs and help keep us well. A healthy immune system is made up of a team of protectors. Having PID means the immune system doesn't quite work as well as it should because it doesn't have all the parts of the protective team or some of the parts don't work properly. This is why germs keep causing illness very easily and very often.

Treatment for PID

Treating PID starts with clearing up any infections you might have right now. Then it moves on to infusing immunoglobulins on a regular basis to replace and maintain your antibody levels in the long term in order to keep you as healthy as possible.

Immunoglobulin replacement therapy.

The treatment for PID is known as immunoglobulin replacement therapy. Immunoglobulins are antibodies which are prepared from blood plasma collected from healthy donors.

You can receive your immunoglobulins by one of two routes:

- Intravenously, when a drip is given into a vein in your arm, or
- Subcutaneously, when a solution is slowly given under your skin.

Where immunoglobulins come from

Immunoglobulins are derived from human blood plasma.

Plasma-derived products are, by their very nature, susceptible to blood-borne viruses. It is the responsibility of the manufacturer of immunoglobulins to make sure that the potential for viral contamination is kept to the absolute minimum. Therefore, the safety of the immunoglobulin, and its manufacture, is extremely important.

The plasma source for immunoglobulins

The UK, European and American regulatory authorities set high standards for organisations collecting plasma used in immunoglobulin production. This ensures the highest quality donor populations and supports the highest standards of quality and safety.

Manufacturers of immunoglobulins use a variety of methods to reduce the risk of virus transmission. They include:

- virus inactivation during the production process
- carefully controlled manufacturing
- advanced plasma fractionation techniques

The BPL quality assurance process

Quality and safety are major considerations in the manufacture of immunoglobulins. It is therefore the responsibility of manufacturers of plasma products to ensure that the potential for viral contamination is kept to the absolute minimum.

With this aim, BPL has adopted the following 10 step quality assurance procedure:

1. Approved Plasma Suppliers

Plasma is collected by internationally respected and highly regulated blood or plasma collection establishments in the US.

2. Selected Donor Centres

Only a limited number of donor centres are used, and all of these are licensed by the US Food and Drug Administration (FDA).

3 Donor Screening and Deferral

US, European and industry standards are applied to donor screening. All potential donors have their identities confirmed, and have to pass interviews on lifestyle and health history. National or local donor deferral systems are in place to prevent a deferred donor from donating again.

4 Individual Donation Testing

Individual donations are tested for Anti-HCV, HBsAg and anti-HIV 1+2. All serological tests are approved by the FDA and no virus positive donations are used.

5 Minipool Testing

Even though each donation is tested using virus marker testing (see above), independent minipools (pools of samples from a relatively small number of donations) are also tested using highly sensitive nucleic acid technology (NAT). As a minimum, NAT testing is carried out for HAV, HBV, HCV, HIV and the human Parvovirus B19. Any donation which fails these tests is discarded (or destroyed).

6 A Minimum 60-day Plasma Inventory Hold

All donations are frozen and held for at least 60 days before being used to manufacture products. This allows donations from a donor who becomes ill during this period or is found to be “at risk” to be excluded from the manufacturing process.

7 Production Pool Testing

An additional series of tests for Anti HIV 1+2, HBsAg and HCV by NAT/PCR are made on pooled plasma prior to production. These tests are performed to meet further quality assurances of viral safety.

8 Fractionation

Individual donations are pooled for fractionation by well-established processes according to Good Manufacturing Practice (GMP) standards. This ensures products are manufactured to specific and consistent protocols.

9 Virus Inactivation removal

A variety of validated virus inactivation and removal procedures take place during the manufacturing process.

10 Quality Assurance for final products

Product is only released once all details have been checked and verified by persons qualified to do so (QPs). Batches are also tested by an independent laboratory, National Institute for Biological Standards and Control (NIBSC) for release in the UK.

Safety

There is no single way of measuring safety because we can only test for and take precautions against the viruses we know about. However, it has been estimated that a patient on immunoglobulin replacement therapy would need to receive over ten thousand million (10^{10}) litres of product before being exposed to single hepatitis C virus particles.¹ From this it can be concluded that the risk of viral transmission is negligible.

Reference:

1. BPL, data on file, 2000.

A Patient Information Service from:



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