

Formulation – IG products mostly come as solutions, but some come in a ‘freeze-dried’ form and need to be reconstituted according to the manufacturer’s instructions.

Are all products equally effective?

All IG products have to obtain a marketing approval licence from the European Medicines Agency to prove that they have the right amount of specified protective antibodies in them and are effective. The licence states what the IG product can be used for.

What side effects occur when switching?

Common side effects experienced when switching IG product include headaches, chills and tiredness. Some patients may experience mild forms of these symptoms initially. Rarely do patients have more significant side effects when products are switched.

You will be supervised at your treatment centre to monitor any side effects you may experience and to ensure that you can tolerate the product. During this infusion you will be given advice, guidance and any training required for your new product.

Please keep a diary of any reactions you may have when using the new product.

How will the switching process be managed?

The need to switch from your existing IG product to another should ideally be discussed at your next routine appointment. The actual switch would then occur at the next routine appointment after that. To avoid extra visits, some centres may contact you in advance and provide verbal and/or written information on switching and then switch at your next appointment if you are in agreement. For hospitals that have many patients, the process of switching may take six months depending on the centre’s capacity.

About Primary Immunodeficiency UK

Primary Immunodeficiency UK (PID UK) is a national organisation supporting individuals and families affected by primary immunodeficiencies (PIDs).

We are the UK national member of the International Patient Organisation for Primary Immunodeficiencies (IPOPI), an association of national patient organisations dedicated to improving awareness, access to early diagnosis and optimal treatments for PID patients worldwide.

Our website at www.piduk.org provides useful information on a range of conditions and topics, and explains the work we do to ensure the voice of PID patients is heard.

If we can be of any help, please contact us at hello@piduk.org or on **0800 987 8986**, where you can leave a message. Visit www.piduk.org for further information.

Support us by becoming a member of PID UK. It’s free and easy to do via our website at www.piduk.org/register or just get in touch with us. Members get monthly newsletters.

PID UK is reliant on voluntary donations. To make a donation, please go to www.piduk.org/donate



Switching immunoglobulin products

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This leaflet helps answer some of the questions patients, parents and carers may have about switching immunoglobulin products.

Switching immunoglobulin products

We understand that having to switch immunoglobulin (IG) products can cause anxiety among people who are dependent on IG treatment as a lifelong therapy. This leaflet aims to reassure you and help guide you through the switching process.

You should be involved in the decision to switch IG products, and any changes to your treatment should always be carried out under the supervision of your immunology team.

Why you may be asked to change your IG product

There are three reasons:

1. Some products are being withdrawn by a company and replaced by an alternative. For example, Shire's Subcuvia 16% will be replaced with Cuvitru 20%.
2. A company may no longer be able to provide certain products due to supply issues.
3. The NHS has decided to fund only a selected number of products owing to their lower cost.

What questions should I ask?

Here is a list of questions that we recommend you ask your immunology team:

- Why am I being asked to switch?
- Is the switch for a clinical reason?
- Will the new IG product work as well as my existing IG product?
- Will I have side effects and how will these be monitored?
- Will my infusions take longer?
- What happens if I do have new side effects? Can I switch back to my old IG product?
- Am I likely to have to switch again anytime soon?
- Do I have to change?
- Will my treatment be changed in future to limit my dose or will there be another change?

What should I expect if I have to switch products?

A medical or nursing member of your immunology team will discuss with you the issues surrounding switching your IG products. Please share with them any concerns or anxieties that you have about the switching process. Your doctors and nurses should be acting as your advocate during this process. If you are uncomfortable with being asked to change products, your centre should respect your decision.

Ask what the change will mean for you (see the previous list). Your team will make decisions about which product is most suitable for you based on clinical need.

When you switch to a new IG product your treatment centre should arrange for the first infusion to be administered at the clinic. This is so that your clinical team can monitor how well you tolerate the new product. As soon as you and your clinical team are confident that the new product is right for you, you will be able to return to your normal pattern of infusions. Under no circumstances should switching occur without medical supervision and oversight.

Is switching compulsory?

Patients on a product that is no longer available will have no choice but to switch to an alternative product. The immunology team looking after you will discuss the options available to you.

In other circumstances where, for example, the NHS is restricting access to certain products, the ultimate decision about which treatment is most appropriate for you rests with your clinical team. They should discuss the options available to you during your routine clinic visit. Acting as your advocates, your doctors and nurses should ensure your wishes are taken into account in making any switching decision and you should be given the time you need to consider the switch proposed. Remember, if you are uncomfortable with being asked to change products, your centre should respect your decision.

Please ensure that your doctor knows about any allergies you have, especially if you have ever had a severe reaction to any IG product.

Are all IG products the same?

Products are not identical. Whether a particular IG product is right for you or not can depend on its ingredients and formulation.

Some of the key differences are related to:

Plasma pool and source – IG products are made from blood donations, and several thousand blood donations are pooled in the manufacturing process. For these reasons there is always a risk of catching an infection from one of the blood donors. The risk is very small owing to the careful screening of donors and the extensive procedures that are used to eliminate pathogens. However, companies producing IG products use different donor pools and it is considered good practice to minimise risk even further by not switching patients to products derived from a different donor pool.

Infusion volume – formulations with a larger fluid volume should be avoided in patients who have to limit their fluid intake (e.g. because of heart failure, high blood pressure or kidney disease) and in infants.

IG concentration – the concentration of IG in products varies between 3% and 20%. Higher concentrations can be useful when higher doses need to be given. However, high concentrations of IG should be avoided in patients at risk of cardiovascular disease.

Immunoglobulin A level – this should be as low as possible for patients with any history of severe hypersensitivity reactions, including anaphylaxis.

Stabilisers – these ingredients (most often sugars) are added to ensure that the IG remains dissolved in the infusion solution. The type and concentration of stabilisers in IG products can affect how suitable they are for certain patients.