Alder Hey Children's NHS
NHS Foundation Trust

Department of Pharmacy

Infliximab Information for Parents and Carers

Switching from Remicade® to Remsima® for the treatment of inflammatory bowel disease

Why have I been given this leaflet?

Your child has been receiving infusions of a brand of infliximab called **Remicade®**.

Alder Hey is now changing to use a brand of infliximab called **Remsima®**.

You will have the opportunity to discuss this with your child's consultant or nurse specialist before the change.

Why is my child going to receive a different brand of infliximab?

When infliximab was first used there was only one brand available - **Remicade®.**
The patent for **Remicade®** has now expired which means other companies can make highly similar copies of infliximab (called biosimilars). One of these biosimilars is **Remsima®**.

Remsima® is better value for money for the NHS. Therefore we are switching patients already on **Remicade®** for the treatment of inflammatory bowel disease to **Remsima®**.

What is a biosimilar?

The World Health Organization (WHO) has defined a biosimilar (also called a similar biotherapeutic product) as a drug that is similar in terms of quality, safety and efficacy (effectiveness) to the original product[1].

This means that biosimilars (such as **Remsima®**) have only very small structural differences from the original product (**Remicade®**). However this must not alter how well the medicine works, how safe it is, or how the medicine reacts with the body's immune system.

Remsima® has been shown to be as safe and as effective as **Remicade®** in clinical trials. The European Medicines Agency has authorised the use of **Remsima®** and the British Society for Paediatric Gastroenterology Hepatology and Nutrition (BSPGHAN) endorses the use of biosimilars in inflammatory bowel disease. An expert committee at Alder Hey has also approved the use of biosimilars in inflammatory bowel disease.

Remsima® is being widely prescribed in hospitals across the NHS and in Europe. Here at Alder Hey, it has been prescribed for gastroenterology patients newly started on infliximab since 2016. No unexpected problems have been observed.

What will this mean for my child?

- Your child's treatment remains unchanged because Remsima® and Remicade® contain the same active ingredient (infliximab).

[1] http://www.who.int/biologicals/areas/biological_therapeutics/BIOTHERAPEUTICS_FOR_WEB_22APRIL2010.pdf?ua=1

- The frequency of your child's infusions will remain the same – if, for example, your child receives an infliximab infusion every 8 weeks, this will not change.

- As usual, you child's condition will be assessed at each infusion visit and they will be monitored for any side-effects. If they do experience any side-effects while on **Remsima®**, please let the nurse or doctor in charge of their care know.

What will change?

- If your child usually receives their Remicade® (infliximab) over one hour, they will receive their first infusion of Remsima® (infliximab) over two hours. This is to make sure they can tolerate the infusion.

- We are monitoring patients who switch from **Remicade®** to **Remsima®** carefullythis won't mean any more tests for your child than they would usually have. Your child will have the levels of infliximab in their blood and the levels of calprotectin in their faeces (poo) checked before their first **Remsima®** (infliximab) infusion, before their fourth infusion of **Remsima®** (infliximab) and after they have been receiving **Remsima®** (infliximab) for one year.

Where can I get more information?

You can speak to the nurse or doctor in charge of your care or read the patient information leaflet available here: http://napp.co.uk/products/patients/inflammatory-conditions/

This leaflet is based on the information contained in 'Changing from Remicade® to Remsima® - My guide to changing infliximab' (NAPP)

This leaflet only gives general information. You must always discuss the individual treatment of your child with the appropriate member of staff. Do not rely on this leaflet alone for information about your child's treatment. This information can be made available in other languages and formats if requested.

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