Remsima®▼ factsheet

What is Remsima?

- Remsima (infliximab) is the first authorised biosimilar monoclonal antibody, a new-generation value-based biologic

- It is a biosimilar, which means that it has been developed to be highly similar to the reference infliximab product[1]

- Remsima is approved by the European Medicines Agency for the same disease areas as the reference infliximab:[2]
    - Rheumatoid arthritis
    - Ankylosing spondylitis
    - Crohn's disease and paediatric Crohn's disease
    - Ulcerative colitis and paediatric ulcerative colitis
    - Psoriasis
    - Psoriatic arthritis

- The dosing regimen for Remsima is also the same, as is the pharmaceutical form (powder for concentrate for solution for infusion) and strength (100 mg infliximab per vial) [2]

- Mundipharma International Limited and its network of independent associated companies have exclusive rights to market Remsima in Germany, Italy, UK, Netherlands, Belgium and Luxembourg following the expiry of the patents and Supplementary Protection Certificates protecting the reference product[3]

How does Remsima work?

- Rheumatoid arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis, psoriasis and psoriatic arthritis are all autoimmune disorders

- Autoimmune disorders are associated with excessive levels of tumour necrosis factor alpha (TNF-α) in the body, which causes an inflammatory response; depending on the disease, inflammation may appear in the digestive system, the joints, on the skin, or in several areas at once

- Remsima is a TNF-α inhibitor, which means that it reduces inflammation by blocking TNF-α[4]

What is the clinical evidence?

- The European Medicines Agency evaluated Remsima for comparability to reference infliximab based on robust comparisons of: pre-clinical data (in vitro and ex vivo biological analysis), combined with clinical efficacy data, clinical safety data and manufacturing quality studies[2]

- As part of this evaluation, two randomised, double-blind, multi-centre studies were conducted
    - The PLANETAS study was a pharmacokinetic study of 250 patients with ankylosing spondylitis[5]
    - The PLANETRA study was a phase 3 study of 606 patients with rheumatoid arthritis[6]

- Remsima is already available in a number of European countries[2] and there is a growing body of 'real world' experience

References

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3. What you need to know about biosimilar medicinal products. Consensus document, European Commission 2013 http://ec.europa.eu/enterprise/sectors/healthcare/files/docs/biosimilars_report_en.pdf Last accessed 15.12.14

4. Arthritis Research UK. The science behind the success of anti-TNF therapy. Available at: http://www.arthritisresearchuk.org/arthritis-information/arthritis-today-magazine/150-autumn-2010/success-of-anti-tnf.aspx Last accessed 15.12.14

5. Park W et al. Ann Rheum Dis 2013;72:1605-12 http://ard.bmj.com/content/72/10/1605.full Last accessed 15.12.14

6. Yoo DH et al. Ann Rheum Dis 2013;72:1613-20 http://ard.bmj.com/content/72/10/1613.full Last accessed 15.12.14