dupilumab (DUPIXENT[®]) in adults with atopic dermatitis

An option for very troublesome eczema after failure of ciclosporin



- Abstract -

• Atopic dermatitis (also called atopic eczema) is a chronic relapsing-remitting inflammatory skin condition. The severity of cutaneous symptoms and their impact on daily life vary greatly from one patient to another.

• The first-choice treatments for alleviating the symptoms of atopic dermatitis are non-drug measures, emollients, and topical corticosteroids during flares. For adults whose daily life is severely affected despite these measures, treatment with an oral immunosuppressant, especially *ciclosporin*, should be considered. The use of immunosuppressants is limited by their numerous and severe adverse effects.

• Dupilumab (Dupixent°, Sanofi Aventis) is a monoclonal antibody directed against the receptors for interleukins IL-4 and IL-13, which appear to be involved in the inflammatory response that occurs in atopic dermatitis. It has been authorised in the European Union for subcutaneous use in adults with moderate-to-severe atopic dermatitis, after failure of topical treatments.

 Dupilumab has not been compared with ciclosporin or other immunosuppressants.

• Clinical evaluation is mainly based on 4 doubleblind randomised trials that compared *dupilumab* with placebo for 16 to 52 weeks in a total of 2444 adults with moderate-to-severe atopic dermatitis inadequately controlled by topical treatments. One of the trials included patients who could not receive *ciclosporin* or in whom *ciclosporin* had failed.

• The proportion of "responders" (free from eczema symptoms or whose eczema was rated as minor by the investigators) was 40% to 50% in the *dupilumab* groups, versus 10% to 20% in the placebo groups. Re-emergence of symptoms was observed after *dupilumab* discontinuation.

• The main adverse effects of *dupilumab* observed in clinical trials included injection site reactions, eye disorders, oral herpes, and hypersensitivity reactions.

POSSIBLY HELPFUL

In patients with troublesome atopic dermatitis in whom topical treatments have failed, it has not been shown that *dupilumab* is at least as effective as ciclosporin or any other immunosuppressant. After failure of ciclosporin, an additional 30% of patients saw a significant improvement in their symptoms with dupilumab, as compared with placebo. Dupilumab's adverse effect profile appears to differ from that of *ciclosporin*, but in the absence of long-term data, much remains unknown about its harms. Based on the evaluation data available in late 2018, it is more prudent to only consider dupilumab therapy for patients in whom ciclosporin has failed and whose atopic dermatitis is very troublesome and greatly impacts their daily life.

DUPIXENT° - dupilumab solution for

subcutaneous injection

• 300 mg of dupilumab per pre-filled syringe

anti-interleukin-4 and 13 receptor monoclonal antibody

Indication: "moderate-to-severe atopic dermatitis in adult patients who are candidates for systemic therapy". [EU centralised procedure]

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