

SUMMARY

mesalazine

OSPERZO 1.5 g and 3 g,**prolonged-release granules****Initial inclusion****Original French opinion adopted by the Transparency Committee on
12 July 2023****The legally binding text is the original French opinion version****Transparency Committee's conclusions****Clinical Benefit**

- ➔ Ulcerative colitis (UC) is a chronic inflammatory bowel disease (IBD) that results in severe chronic bloody diarrhoea, progressing in flare-ups. It leads to a marked deterioration in quality of life and exposes patients to serious complications: acute colitis, dysplasia and colon cancer.
- ➔ This medicinal product is a symptomatic treatment for flare-ups and a preventive treatment for relapses.
- ➔ The efficacy/adverse effects ratio is high in view of the well-established use of mesalazine in UC.
- ➔ This is a first-line treatment in view of the therapies available (see 5.1). Other proprietary medicinal products exist containing mesalazine.

➔ Public health benefit

Considering:

- the seriousness and prevalence of ulcerative colitis, a serious and incapacitating chronic disease with high morbidity due to the frequency of acute flare-ups, its complications and recourse to surgery. It also causes a marked impairment in quality of life;
- the medical need already met by available medicinal products containing 5-ASA;
- the lack of response to the identified need: no expected additional impact on morbidity and mortality, quality of life and on the organisation of care or ease of use;

OSPERZO (mesalazine) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of OSPERZO (mesalazine) 1.5 g and 3 g prolonged-release granules is substantial in ulcerative colitis, as an initial treatment of mild to moderate flare-ups and as maintenance therapy.

The Committee issues a favourable opinion for inclusion of OSPERZO (mesalazine) 1.5 g and 3 g prolonged-release granules in both the hospital formulary list and the retail formulary list of reimbursed proprietary medicinal products approved for use in the indications and at the MA dosages.

➔ **Recommended reimbursement rate for inclusion in the retail list of reimbursed proprietary medicinal products approved for use: 65%**

Clinical Added Value

Considering:

- available data demonstrating an efficacy versus placebo as a maintenance therapy for UC;
- the lack of comparative data versus an active comparator or placebo in the initial treatment of mild to moderate flare-ups of UC;
- the absence of a demonstrated benefit on the quality of life of patients with a mild to moderate form of UC;
- the already known safety profile of medicinal products in the 5-ASA class;

the Committee deems that OSPERZO (mesalazine) 1.5 g and 3 g prolonged-release granules provides no clinical added value (CAV V) in the current care pathway for the treatment of mild to moderate ulcerative colitis in adults.