

EFFECTIVENESS AND SAFETY OF APREMILAST IN A THIRD-LEVEL HOSPITAL

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1. Background and importance

Apremilast is indicated for the treatment of Psoriatic arthritis (PA) alone or in combination with disease-modifying antirheumatic drugs (DMARD), and the treatment of moderate to severe plaque psoriasis (PP) in adult patients who failed to respond or have a contraindication, or are intolerant to DMARD or other systemic therapy, including biological.

According to de EMA, reasons for discontinuation are the lack of response at 24 weeks, diarrhea and nausea.

2. Aim and objectives

The aim of the study was to assess the effectiveness and safety of apremilast in patients with PA or PP.

3. Materials and methods

Retrospective study with patients who started apremilast between June 2016 and February 2021 and their evolution was followed until August 2021.

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|---------------------|---|--|
| Collected variables | <ul style="list-style-type: none"> • Demographics  • Previous treatment • Clinics | <ul style="list-style-type: none"> • Biological • Non-biological • Topical • Phototherapy • DMARD |
|---------------------|---|--|

Efficacy and safety were analyzed based on the general subjective assessment of the physician. Data were obtained from medical records and analysis was performed using Microsoft Excel[®]

4. Results

| Demographic characteristics (PA) | | Demographic characteristics (PP) | |
|----------------------------------|---|----------------------------------|-------------------------|
| Variable | Result | Variable | Result |
| N | 38 patients | N | 9 patients |
| Sex (women), n | 13 | Sex (women), n | 6 |
| Median age | 53,5 (22-82) | Median age | 46 (28-70) |
| Previous treatment | 16 non-biological 11 biological 9 topical 2 phototherapy | Previous treatment | 8 DMARD 1 biological |

Effectiveness at 6 months

| Variable | Result |
|---------------------|--|
| Satisfactory answer | 24 patients (19 PA y 5 PP) |
| Response type PA | 8 full whitening 11 partial whitening |
| Response type PP | 4 moderate disappearance of pain 1 mild disappearance of pain |

At the end of follow up, 8 patients (7 PP and 1 PA) continued with apremilast, with a median of 21 (8,6-30,9) months.

Seguridad

| Variable | Result |
|--|--|
| Interruption | 39 patients (31 PA y 8 PP) |
| Duration of treatment of those who interrupted | PA: 3,4 months (0,5-24,8) PP: 6,2 months (4,3-10,8) |
| Adverse effects (patients) | Lack of response (16), loss of efficacy (14), vomiting (3), diarrhea (4), headache (1), exitus (1) |

5. Conclusion and relevance

- Apremilast has been effective in half of patients at 6 months, but less than a quarter remain on treatment.
- Regarding safety profile, 8 patients discontinued due to adverse events, being the gastrointestinal adverse event the most common.