# DAR DRUG ASSESSMENT REPORT 01 / 2019

## www.dtb.navarra.es @DTB\_Navarre dtbn **SKILARENCE<sup>®</sup>** DIMETHYL FUMARATE. FOR PSORIASIS Old tuned remedy.

It's not clear its role in the treatment of psoriasis.

### IMPORTANT THERAPEUTIC INNOVATION

MODEST THERAPEUTIC INNOVATION

SOME ADDED VALUE IN SPECI-**FIC SITUATIONS**  NO THERAPEUTIC INNOVATION

INSUFFICIENT **EVIDENCE** 

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#### WHAT IS IT?

Inmunomodulator and anti-inflammatory.

#### INDICATION

Treatment of moderate to severe plaque psoriasis in adults, who refracted or is not indicated the conventional systemic therapy.

#### **POSOLOGY AND METHOD OF ADMINISTRATION**

The dose should be individualized by efficacy (the maximum daily dose allowed is 720 mg). It must be taken with meals. Start the treatment following the next scheme.

#### **EFFECTIVENESS**

Compared with placebo: It's necessary to treat 5 patients in order to obtain a relevant clinical benefit (symptoms severity reduction in 75%) [CI 99%,(3;9)].

#### RISKS

More frequent adverse reactions: gastrointestinal, dermatologic, flushing and hematologic disorders (lymphopenia and eosinophilia). Risk of progressive multifocal leukoencephalopathy (PML): Monitoring complete blood count including lymphocyte counts (obtained prior to initiation of therapy). Consider treatment interruption in case of severe or lengthy lymphopenia. Monitoring renal and liver function tests (transaminases, alkaline phosphatase, total bilirubin) prior to treatment initiation and during treatment at intervals of 3 months. Contraindications: In severe kidney or liver injury; in pregnancy and lactation. Live vaccines should not be given.

#### PLACE IN THE THERAPEUTIC

Limited available evidence. Alternative when first-line therapy fails or intolerance.





The qualification has been assigned jointly by the New Medicines Evaluation Committees of Andalusia, Castilla y León, País Vasco, and Navarra. This information is subject to mo

#### PRESENTATIONS

Skilarence<sup>®</sup> 30 mg 42 tablets (121,3€); 120 mg 90 tablets (239,63€); 120 mg 180 tablets (436,71€).

#### **ABBREVIATIONS**

PASI (Psoriasis Area and Severity Index): it's a tool to determine psoriasis coverage and severity. PASI 75 represents the percentage of patients who have achieved a 75% or more reduction in their PASI score from baseline.

METHC	TREXATE 0	.04			
ACITRE	TIN <b>2.62</b>				
CYCLO	SPORINE 5.7	78	Calculati	on for a patient of	70kg.
DIMETH	HYL FUMAR	ATE 13.49			
etanei	RCEPT 25.0	3 **			
APREM	IILAST <b>26.06</b>	j **			
BRODA	LUMAB <b>35.7</b>	/4 **			
INFLIXI	MAB <b>36.15</b>	**			
ADALIN	IUMAB <b>37.9</b>	8 **		_	
GUSELI	KUMAB <b>40.5</b>	57 **			
IXEKIZI	JMAB <b>41.37</b>	**			
USTEK	INUMAB <b>44.</b>	87 **			
SECUK	INUMAB <b>46.</b>	08 **			