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(54) Title: METHOD FOR TREATMENT OF ROSACEA INCLUDING PATIENT REPORTED OUTCOMES THEREOF

(57) Abstract: A regimen is described for the therapeutic treatment of rosacea including topically applying to the skin of a subject in need of the treatment a pharmaceutical composition. The pharmaceutical composition includes about 1% w/w to about 10% w/w benzoyl peroxide as an active ingredient, and a pharmaceutically acceptable carrier or excipient. The benzoyl peroxide is the only active ingredient in said pharmaceutical composition, and the pharmaceutical composition is applied once daily for a period of at least about 2 weeks, about 4 weeks, about 8 weeks or about 12 weeks. A decrease in Patient Assessment of Papulopustular Rosacea Signs and Symptoms (PAPSS) is at least about 40% after treatment with the pharmaceutical composition for about 4 weeks, and a decrease in Patient Assessment of Papulopustular Rosacea Impacts (PAPI) is from about 60% to about 70% after treatment with the pharmaceutical composition for at least about 8 weeks.



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INTERNATIONAL SEARCH REPORT

International application No.

PCT/IB 20/00126

A. CLASSIFICATION OF SUBJECT MATTER

IPC - A61K 31/4164; A61K 31/4174; A61K 31/7048 (2020.01)

CPC - A61J 9/06; A61K 31/4164; A61K 31/4174; A61K 31/7048

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

See Search History document

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

See Search History document

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2018 / 0147165 A1 (Sol-Gel Technologies Ltd) 31 May 2018 (31.05.2020), Abstract, para [00188], para [0018], para [0019], para [0043], para [0046], para [00195], para [0035], and entire document	1-7, 18-22, 35-39, 48-50, 59-61, 70-72
A	WO 2014/083557 A1 (Sol-Gel Technologies Ltd) 5 June 2014 (05.06.2014) Abstract; pg 3 para 1- pg 22 para 4	1-7, 18-22, 35-39, 48-50, 59-61, 70-72
A	DE 202011100767 U1 (Walter Dubiel) 19 December 2011 (19.12.2011) Abstract	1-7, 18-22, 35-39, 48-50, 59-61, 70-72
A	US 2009/0306172 A1 (Chang et al) 10 December 2009 (10.12.2009) Abstract, para [0010]-[0031]	1-7, 18-22, 35-39, 48-50, 59-61, 70-72
A	US 2012/0064135 A1 (Levin et al) 15 March 2012 (15.03.2012) Abstract; para [0036]-[0052]	1-7, 18-22, 35-39, 48-50, 59-61, 70-72

 Further documents are listed in the continuation of Box C.
 See patent family annex.

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"D" document cited by the applicant in the international application	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"E" earlier application or patent but published on or after the international filing date	"&" document member of the same patent family
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/IB 20/00126

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. Claims Nos.: 8-17, 23-34, 40-47, 51-58, 62-69, 73-80
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- No protest accompanied the payment of additional search fees.