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KG, KM, KN, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV,  
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For two-letter codes and other abbreviations, refer to the "Guid-  
ance Notes on Codes and Abbreviations" appearing at the begin-  
ning of each regular issue of the PCT Gazette.

(54) Title: ORAL DOSAGE FORMS COMPRISING PROGESTERONE AND METHODS OF MAKING AND USING THE  
SAME

(57) Abstract: The present invention relates to an oral pharmaceutical dosage form comprising micronized progesterone, an edible oil, an absorbing disintegrant, and a hydrophilic excipient. Particularly, the invention relates to a pharmaceutical dosage form wherein the dosage form is in a powder form and is contained in a pharmaceutically acceptable capsule. The present invention is also directed toward methods of making the dosage form, methods of using the dosage form, and kits comprising the dosage form.



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# INTERNATIONAL SEARCH REPORT

International application No  
PCT/US2006/020609

<b>A. CLASSIFICATION OF SUBJECT MATTER</b> INV. A61K9/48                      A61K9/16                      A61K31/57		
According to International Patent Classification (IPC) or to both national classification and IPC		
<b>B. FIELDS SEARCHED</b> Minimum documentation searched (classification system followed by classification symbols) A61K		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practical, search terms used) EPO-Internal, BIOSIS, EMBASE		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	FR 2 851 918 A (GALENIX INNOVATIONS) 10 September 2004 (2004-09-10) claims 1-27; example 1 -----	1-48
A	WO 91/18613 A (RESEARCH CORP. TECH., INC.) 12 December 1991 (1991-12-12) claims 1-95; example 5 -----	1-48
A	US 5 620 705 A (L. DONG ET AL.) 15 April 1997 (1997-04-15) cited in the application claims 1,2; figures 1-5; example 1 -----	1
A	US 4 963 540 A (W. MAXSON ET AL.) 16 October 1990 (1990-10-16) cited in the application the whole document -----	1
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input checked="" type="checkbox"/> See patent family annex.		
* Special categories of cited documents :		
*A* document defining the general state of the art which is not considered to be of particular relevance *E* earlier document but published on or after the international filing date *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	*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 *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 *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. *&* document member of the same patent family	
Date of the actual completion of the international search	Date of mailing of the international search report	
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Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Authorized officer  GLIKMAN, J	

**FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210**

Continuation of Box II.1

Although claims 28-43 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.

The subject-matter of claims 49-56 merely relates to the presentation of information and is excluded from patentability according to Rules 39 and 67 PCT, see PCT Guidelines 9.11.

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US2006/020609

## Box 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.: 28-43 (in part), 49-56  
because they relate to subject matter not required to be searched by this Authority, namely:  
see FURTHER INFORMATION sheet PCT/ISA/210
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.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box 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 an additional fee, this Authority did not invite payment of any additional fee.
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.
- No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No PCT/US2006/020609
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