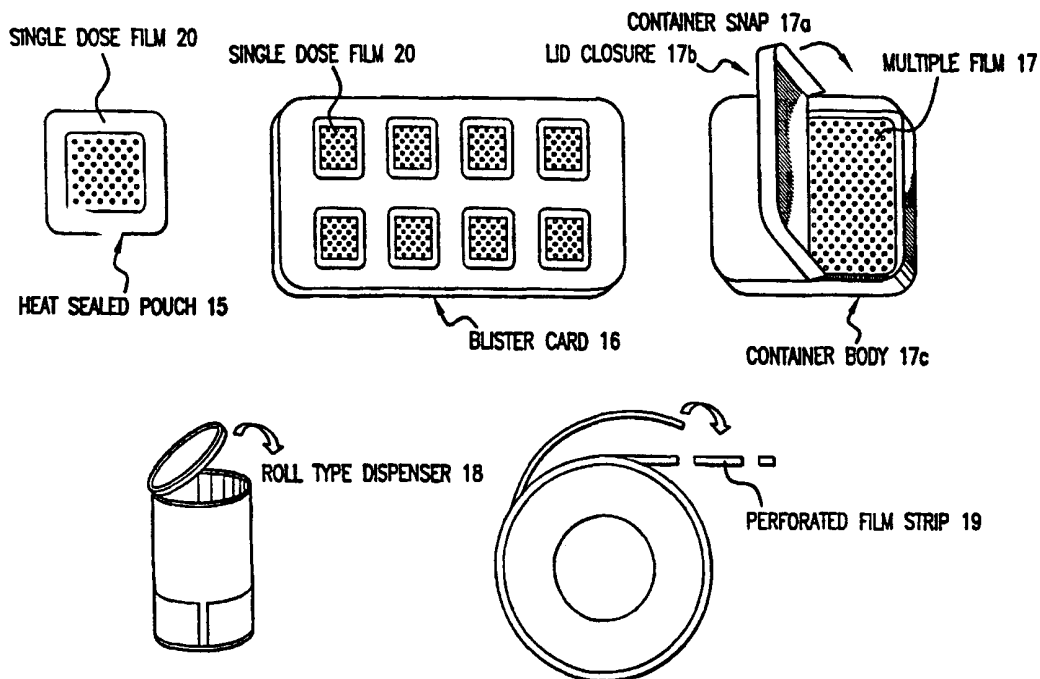




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<p>(51) International Patent Classification ⁷ : A61K 9/70, 9/00, A61P 15/10</p>	<p>A3</p>	<p>(11) International Publication Number: WO 00/42992</p> <p>(43) International Publication Date: 27 July 2000 (27.07.00)</p>
<p>(21) International Application Number: PCT/US99/31327</p> <p>(22) International Filing Date: 30 December 1999 (30.12.99)</p> <p>(30) Priority Data: 60/116,823 21 January 1999 (21.01.99) US 09/434,878 5 November 1999 (05.11.99) US</p> <p>(71) Applicant: LAVIPHARM LABORATORIES, INC. [US/US]; Suite 6, 131 Ethel Road West, Piscataway, NJ 08854 (US).</p> <p>(72) Inventors: CHEN, Li-Lan, H.; 3906 Victory Court, Edison, NJ 08817 (US). PFISTER, William, R.; 16 Saxony Lane, Robbinsville, NJ 08691 (US). RENN, Donald, W.; 4 Brew- ster Point, Glen Cove, ME 04846-0088 (US). BURANA- CHOKPAISAN, Thitiwan; 4 Stout Court, Lawrenceville, NJ 08648 (US). OSBORNE, James; Lavipharm Laboratories, Inc., Suite 6, 131 Ethel Road West, Piscataway, NJ 08854 (US). TAN, Hock, Seng; 25 Jaime Court, Old Bridge, NJ 08857 (US). TAO, Li; Lavipharm Laboratories, Inc., Suite 6, 131 Ethel Road West, Piscataway, NJ 08854 (US).</p> <p>(74) Agent: STRIMPEL, Harriet, M.; Bromberg & Sunstein LLP, 125 Summer Street, Boston, MA 02110-1618 (US).</p>		<p>(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).</p> <p>Published <i>With international search report.</i></p> <p>(88) Date of publication of the international search report: 19 October 2000 (19.10.00)</p>

(54) Title: COMPOSITIONS AND METHODS FOR MUCOSAL DELIVERY



(57) Abstract

A dosage unit comprising a water-soluble hydrocolloid and a mucosal surface-coat-forming, such film including an effective dose of active agent. In the dosage unit sildenafil citrate, nicotine, hydromorphone, oxybutynine or estradiol are used as active agents.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece			TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
BR	Brazil	IL	Israel	MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NO	Norway	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	NZ	New Zealand		
CM	Cameroon		Republic of Korea	PL	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakstan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 99/31327

A. CLASSIFICATION OF SUBJECT MATTER
 IPC 7 A61K9/70 A61K9/00 A61P15/10

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)

IPC 7 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)

WPI Data, PAJ, CHEM ABS Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 98 20862 A (LTS GMBH, DE) 22 May 1998 (1998-05-22) cited in the application claims examples page 7, line 1 - line 31 ---	1, 4, 10-21, 32, 38, 39
X	WO 91 06289 A (WATSON LABS. INC., U.S.A.) 16 May 1991 (1991-05-16) claims 1, 3, 6, 9, 20-26, 31, 32 page 10, line 24 - page 11, line 5 examples 3, 5, 10, 17 ---	1, 4, 10-13, 15, 20, 21, 23, 35, 38, 39, 43, 45, 50-52, 54

Further documents are listed in the continuation of box C.

Patent family members are listed in 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

20 July 2000

Date of mailing of the international search report

26/07/2000

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

Scarponi, U

INTERNATIONAL SEARCH REPORT

Int. Patent Application No PCT/US 99/31327

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X,P	<p>WO 99 66870 A (LAVIPHARM LABS. INC., U.S.A.) 29 December 1999 (1999-12-29)</p> <p style="margin-left: 40px;">claims 1,2,5-8,10,13-16,19,21-24,29-31 page 6, line 2 - line 31</p>	<p>1,4, 10-12, 15, 20-22, 24,34, 38,39,56</p>

INTERNATIONAL SEARCH REPORT

Information on patent family members

Int. Patent Application No PCT/US 99/31327
--

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9820862 A	22-05-1998	DE 19646392 A AU 4868297 A CZ 9901647 A EP 0936905 A HU 9904207 A NO 991921 A US 5948430 A	14-05-1998 03-06-1998 11-08-1999 25-08-1999 28-04-2000 22-04-1999 07-09-1999
WO 9106289 A	16-05-1991	DK 127691 A EP 0452334 A JP 4502913 T	28-06-1991 23-10-1991 28-05-1992
WO 9966870 A	29-12-1999	AU 4720099 A	10-01-2000