

(19)



(11)

EP 2 402 012 A3

(12)

EUROPEAN PATENT APPLICATION

(88) Date of publication A3:
29.02.2012 Bulletin 2012/09

(51) Int Cl.:
A61K 31/4545^(2006.01) **A61K 9/00**^(2006.01)
A61K 9/08^(2006.01) **A61K 47/10**^(2006.01)
A61P 11/02^(2006.01) **A61P 11/04**^(2006.01)
A61P 37/08^(2006.01) **G01N 30/02**^(2006.01)

(43) Date of publication A2:
04.01.2012 Bulletin 2012/01

(21) Application number: **11172101.5**

(22) Date of filing: **30.06.2011**

(84) Designated Contracting States:
**AL AT BE BG CH CY CZ DE DK EE ES FI FR GB
GR HR HU IE IS IT LI LT LU LV MC MK MT NL NO
PL PT RO RS SE SI SK SM TR**
Designated Extension States:
BA ME

(72) Inventors:
• **Suriol Ferrer, M Montserrat**
E-08018 Barcelona (ES)
• **Morlesin Capdevila, M Silvia**
E-08020 Barcelona (ES)

(30) Priority: **16.07.2010 US 364992 P**
30.06.2010 EP 10382184

(74) Representative: **ABG Patentes, S.L.**
Avenida de Burgos 16D
Edificio Euromor
28036 Madrid (ES)

(71) Applicant: **J. Uriach y Compania S.A.**
08184 Palau-solità i Plegamans
(Barcelona) (ES)

(54) **Liquid formulations of rupatadine fumarate**

(57) The present invention provides cyclodextrin-free aqueous liquid formulations of rupatadine fumarate, useful for the treatment of allergic rhinitis and urticaria. Said formulations comprise rupatadine fumarate, one or

more cosolvents and one or more pH regulating agents wherein the composition has a pH between 4 and 6.5.

EP 2 402 012 A3



Europäisches
Patentamt
European
Patent Office
Office européen
des brevets

EUROPEAN SEARCH REPORT

Application Number
EP 11 17 2101

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
X,D	ES 2 087 818 A1 (URIACH & CIA SA J [ES]) 16 July 1996 (1996-07-16) * abstract; claims * * page 7, lines 20-40 * -----	1-6,9, 12,13	INV. A61K31/4545 A61K9/00 A61K9/08 A61K47/10 A61P11/02 A61P11/04 A61P37/08 G01N30/02
A	WO 2006/131737 A2 (BIOLIPOX AB [SE]; PERESWETOFF-MORATH LENA [SE]; CARLSSON ANDERS [SE]) 14 December 2006 (2006-12-14) * abstract; claims 1-8 * * page 66, lines 22-33 * -----	1-14	
A,D	EP 0 577 957 A1 (URIACH & CIA SA J [ES]) 12 January 1994 (1994-01-12) * claims; compound 4 * * page 12, lines 35-41 * -----	1-14	
A,D	DATABASE WPI Week 201031 Thomson Scientific, London, GB; AN 2010-D58323 XP002604402, -& CN 101 669 926 A (DONGGUAN TAILI BIOTECH CO LTD) 17 March 2010 (2010-03-17) * abstract * -& CN 101 669 926 A (DONGYING TAILI BIOLOG ENGINEER) 17 March 2010 (2010-03-17) * abstract * -----	1-14	TECHNICAL FIELDS SEARCHED (IPC) A61K G01N
X,P	DATABASE WPI Week 201111 Thomson Scientific, London, GB; AN 2011-B22141 XP002658722, -& CN 101 926 762 A (UNIV SOUTHEAST) 29 December 2010 (2010-12-29) * abstract * -----	1-14	
----- The present search report has been drawn up for all claims -----			
Place of search Munich		Date of completion of the search 13 September 2011	Examiner Madalinska, K
CATEGORY OF CITED DOCUMENTS X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons ----- & : member of the same patent family, corresponding document	

2

EPO FORM 1503 03.82 (P04C01)



Application Number

EP 11 17 2101

CLAIMS INCURRING FEES

The present European patent application comprised at the time of filing claims for which payment was due.

- Only part of the claims have been paid within the prescribed time limit. The present European search report has been drawn up for those claims for which no payment was due and for those claims for which claims fees have been paid, namely claim(s):
- No claims fees have been paid within the prescribed time limit. The present European search report has been drawn up for those claims for which no payment was due.

LACK OF UNITY OF INVENTION

The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

see sheet B

- All further search fees have been paid within the fixed time limit. The present European search report has been drawn up for all claims.
- As all searchable claims could be searched without effort justifying an additional fee, the Search Division did not invite payment of any additional fee.
- Only part of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the inventions in respect of which search fees have been paid, namely claims:
- None of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the invention first mentioned in the claims, namely claims:
- 1-14
- The present supplementary European search report has been drawn up for those parts of the European patent application which relate to the invention first mentioned in the claims (Rule 164 (1) EPC).



**LACK OF UNITY OF INVENTION
SHEET B**

Application Number
EP 11 17 2101

The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

1. claims: 1-14

A cyclodextrin-free liquid pharmaceutical composition comprising rupatadine fumarate

2. claims: 15, 16

The HPLC method of assessing the purity of a composition comprising rupatadine fumarate using as marker compound of formula II

ANNEX TO THE EUROPEAN SEARCH REPORT
ON EUROPEAN PATENT APPLICATION NO.

EP 11 17 2101

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

13-09-2011

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
ES 2087818 A1	16-07-1996	ES 2087818 A1 NO 944487 A	16-07-1996 26-05-1995
-----	-----	-----	-----
WO 2006131737 A2	14-12-2006	AU 2006256518 A1 CA 2608631 A1 EP 1888033 A2 JP 2008542438 A KR 20080016621 A US 2009220583 A1 WO 2006131737 A2	14-12-2006 14-12-2006 20-02-2008 27-11-2008 21-02-2008 03-09-2009 14-12-2006
-----	-----	-----	-----
EP 0577957 A1	12-01-1994	AT 124939 T CA 2096318 A1 DE 69300255 D1 DE 69300255 T2 DE 122008000031 I1 DK 0577957 T3 EP 0577957 A1 ES 2042421 A1 ES 2076817 T3 HK 1006169 A1 JP 2730612 B2 JP 6087856 A LU 91121 A9 NL 300384 I1 US 5407941 A	15-07-1995 23-11-1993 17-08-1995 04-01-1996 02-10-2008 04-12-1995 12-01-1994 01-12-1993 01-11-1995 12-02-1999 25-03-1998 29-03-1994 03-01-2005 02-06-2009 18-04-1995
-----	-----	-----	-----
CN 101669926 A	17-03-2010	NONE	
-----	-----	-----	-----
CN 101669926 A	17-03-2010	NONE	
-----	-----	-----	-----
CN 101926762 A	29-12-2010	NONE	
-----	-----	-----	-----