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(12) **United States Patent**
Calderari et al.

(10) **Patent No.:** **US 8,729,094 B2**
(45) **Date of Patent:** ***May 20, 2014**

- (54) **LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON**
- (71) Applicants: **Helsinn Healthcare SA**, Lugano (CH); **Roche Palo Alto LLC**, Palo Alto, CA (US); **Simone Macciocchi**, Melide (CH); **Giulio Macciocchi**, Breganzona (CH)
- (72) Inventors: **Giorgio Calderari**, Rancate (CH); **Daniele Bonadeo**, Casalzuigno (IT); **Roberta Cannella**, Varese (IT); **Alberto Macciocchi**, Melide (CH); **Andrew Mikszal**, Palo Alto, CA (US); **Thomas Malefyt**, Carmel Valley, CA (US); **Kathleen M Lee**, Palo Alto, CA (US)
- (73) Assignees: **Helsinn Healthcare SA**, Pambio-Noranco (CH); **Roche Palo Alto LLC**, Palo Alto, CA (US)

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

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(65) **Prior Publication Data**
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Related U.S. Application Data

(63) Continuation of application No. 13/901,437, filed on May 23, 2013, now Pat. No. 8,598,219, which is a continuation-in-part of application No. 13/087,012, filed on Apr. 14, 2011, now Pat. No. 8,518,981, which is a continuation of application No. 11/186,311, filed on Jul. 21, 2005, now Pat. No. 7,947,724, which is a continuation of application No. PCT/EP2004/000888, filed on Jan. 30, 2004.

(60) Provisional application No. 60/444,351, filed on Jan. 30, 2003.

(51) **Int. Cl.**
A61K 47/00 (2006.01)

(52) **U.S. Cl.**
USPC **514/296**

(58) **Field of Classification Search**
USPC 514/296
See application file for complete search history.

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(74) *Attorney, Agent, or Firm* — Clark G. Sullivan; Troutman Sanders LLP

(57) **ABSTRACT**

The present invention relates to shelf-stable liquid formulations of palonosetron for reducing chemotherapy and radiotherapy induced emesis with palonosetron. The formulations are particularly suitable for oral liquid formulations.

Dr. Reddy's Laboratories, Ltd., et al.
v.
Helsinn Healthcare S.A., et al.





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The present invention relates to shelf-stable liquid formulations of palonosetron for reducing chemotherapy and radiotherapy induced emesis with palonosetron. The formulations are particularly useful in the preparation of intravenous and oral liquid medicaments.

30 Claims, No Drawings

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