Case: 1:16-cv-00651 Document #: 178 Filed: 12/19/18 Page 1 of 5 PageID #:6162

00/10) AO 120 (D

AO 120 (Rev. 08/10)			-
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DECISION/JUDGEMENT

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US008242158B1

(12) United States Patent

Roychowdhury et al.

(54) **DEXMEDETOMIDINE PREMIX** FORMULATION

- (75) Inventors: Priyanka Roychowdhury, San Rafael, CA (US); Robert A. Cedergren, Libertyville, IL (US)
- (73) Assignee: Hospira, Inc., Lake Forest, IL (US)
- (*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.
- (21) Appl. No.: 13/343,672
- (22) Filed: Jan. 4, 2012
- (51) Int. Cl. *A61K 31/164* (2006.01)
- See application file for complete search history.

(56) **References Cited**

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(10) Patent No.: US 8,242,158 B1 (45) Date of Patent: Aug. 14, 2012

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Primary Examiner — James D Anderson Assistant Examiner — Gregg Polansky (74) Attorney, Agent, or Firm — Baker Botts LLP

(57) **ABSTRACT**

docs/nda/99/21-038_Precedex.cfm>.

The presently disclosed subject matter relates to pharmaceutical compositions comprising dexmedetomidine or a pharmaceutically acceptable salt thereof wherein the composition is formulated as a liquid for parenteral administration to a subject, and wherein the composition is disposed within a sealed container as a premixture. The pharmaceutical compositions can be used, for example, in perioperative care of a patient or for sedation.

4 Claims, No Drawings

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US008338470B1

(12) United States Patent

Roychowdhury et al.

(54) **DEXMEDETOMIDINE PREMIX** FORMULATION

- (75) Inventors: Priyanka Roychowdhury, San Rafael, CA (US); Robert A. Cedergren, Libertyville, IL (US)
- (73) Assignee: Hospira, Inc., Lake Forest, IL (US)
- (*) 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.

- (21) Appl. No.: 13/541,524
- (22) Filed: Jul. 3, 2012

Related U.S. Application Data

- (63) Continuation of application No. 13/343,672, filed on Jan. 4, 2012, now Pat. No. 8,242,158.
- (51) Int. Cl. A61K 31/164 (2006.01)
- (52) U.S. Cl. 514/396; 514/816
- (58) Field of Classification Search None See application file for complete search history.

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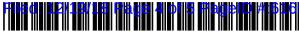
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Primary Examiner - Jeffrey S. Lundgren Assistant Examiner — Gregg Polansky (74) Attorney, Agent, or Firm - Baker Botts LLP

ABSTRACT (57)

The presently disclosed subject matter relates to pharmaceutical compositions comprising dexmedetomidine or a pharmaceutically acceptable salt thereof wherein the composition is formulated as a liquid for parenteral administration to a subject, and wherein the composition is disposed within a sealed container as a premixture. The pharmaceutical compositions can be used, for example, in perioperative care of a patient or for sedation.

7 Claims, No Drawings



US008455527B1

(12) United States Patent

Roychowdhury et al.

(54) METHODS OF TREATMENT USING A DEXMEDETOMIDINE PREMIX FORMULATION

- (71) Applicant: Hospira, Inc., Lake Forest, IL (US)
- (72) Inventors: Priyanka Roychowdhury, Foster City, CA (US); Robert A. Cedergren, Libertyville, IL (US)
- (73) Assignee: Hospira, Inc., Lake Forest, IL (US)
- (*) 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.

- (21) Appl. No.: 13/678,148
- (22) Filed: Nov. 15, 2012

Related U.S. Application Data

- (63) Continuation of application No. 13/541,524, filed on Jul. 3, 2012, now Pat. No. 8,338,470, which is a continuation of application No. 13/343,672, filed on Jan. 4, 2012, now Pat. No. 8,242,158.
- (51) Int. Cl.
- *A61K 31/164* (2006.01) (52) U.S. Cl.
- (58) Field of Classification Search None

See application file for complete search history.

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(45) **Date of Patent:** *Jun. 4, 2013

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Venn et al., "Pharmacokinetics of dexmedetomidine infusions for sedation of postoperative patients requiring intensive care." British Journal of Anaesthesia, 2002, vol. 88(5), pp. 669-675.

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Primary Examiner — Jeffrey S. Lundgren

Assistant Examiner — Gregg Polansky

(74) Attorney, Agent, or Firm - Baker Botts, L.L.P.

(57) ABSTRACT

The presently disclosed subject matter relates to pharmaceutical compositions comprising dexmedetomidine or a pharmaceutically acceptable salt thereof wherein the composition is formulated as a liquid for parenteral administration to a subject, and wherein the composition is disposed within a sealed container as a premixture. The pharmaceutical compositions can be used, for example, in perioperative care of a patient or for sedation.

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US008648106B2

(12) United States Patent

Roychowdhury et al.

(54) DEXMEDETOMIDINE PREMIX FORMULATION

- (71) Applicant: Hospira, Inc., Lake Forest, IL (US)
- (72) Inventors: Priyanka Roychowdhury, Foster City, CA (US); Robert A. Cedergren, Libertyville, IL (US)
- (73) Assignee: Hospira, Inc., Lake Forest, IL (US)
- (*) 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.

- (21) Appl. No.: 13/867,861
- (22) Filed: Apr. 22, 2013

(65) **Prior Publication Data**

US 2013/0237576 A1 Sep. 12, 2013

Related U.S. Application Data

- (63) Continuation of application No. 13/678,260, filed on Nov. 15, 2012, now Pat. No. 8,436,033, which is a continuation of application No. 13/541,524, filed on Jul. 3, 2012, now Pat. No. 8,338,470, which is a continuation of application No. 13/343,672, filed on Jan. 4, 2012, now Pat. No. 8,242,158.
- (51) Int. Cl. *A61K 31/164*

	C07D 233/56	(2006.01)
(52)	U.S. Cl.	

USPC **514/396**; 514/816; 548/346.1

(2006.01)

(58) Field of Classification Search None

See application file for complete search history.

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(10) Patent No.: US 8,648,106 B2

(45) **Date of Patent: *Feb. 11, 2014**

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Primary Examiner — Savitha Rao Assistant Examiner — Gregg Polansky (74) Attorney, Agent, or Firm — Baker Botts LLP

(57) ABSTRACT

The presently disclosed subject matter relates to pharmaceutical compositions comprising dexmedetomidine or a pharmaceutically acceptable salt thereof wherein the composition is formulated as a liquid for parenteral administration to a subject, and wherein the composition is disposed within a sealed container as a premixture. The pharmaceutical compositions can be used, for example, in perioperative care of a patient or for sedation.

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