Similar effect may be expected with co-administration of 9 to 6 mg.

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at increased risk of death. Analyses of 17 placebo-controlled trials (modal duration of 10 weeks), 16 how supplied.

Changes that may increase cardiovascular/cerebrovascular risk. These metabolic changes include:

- Hyperglycemia and diabetes mellitus
- Dyslipidemia
- Weight Gain

Metabolic Changes (Hyperglycemia and diabetes mellitus, Dyslipidemia, and Weight Gain)

Site Packaging Development

including symptoms of aggression towards others, deliberate self-injuriousness, temper

manic or mixed episodes associated with Bipolar I Disorder. Efficacy was established in one

5.14 Body Temperature Regulation

Disruption of body temperature regulation has been attributed to antipsychotic agents. Both

5.10 Potential for Cognitive and Motor Impairment

Pathological mechanism has been identified to explain this finding, and no consistent pattern for

higher incidence of mortality was observed in patients treated with furosemide plus risperidone

for extended periods should periodically re-evaluate the long-term risks and

5.12 Carcinogenesis, Mutagenesis, Impairment of Fertility

changes that may increase cardiovascular/cerebrovascular risk. These metabolic changes

Psychosis: Risperidone is not approved for use in patients with dementia-related

5.6 Dementia-Related Psychosis

Effective treatment regimens for uncomplicated NMS.

Table 4. Change in Random Lipids from Seven Placebo-Controlled, 3-to 8-Week, Fixed- or Flexible-Dose

\[
\begin{array}{ll}
\text{Placebo} & \text{Risperidone} \\
-0.2 mg/dL at Week 24 (n=103); & \text{c) fasting HDL of +0.4 mg/dL at Week 24 (n=103); and (d) Fasting\n\end{array}
\]

Table 5. Change in Fasting Lipids from Three Placebo-Controlled, 3- to 6-Week, Fixed-Dose

\[
\begin{array}{ll}
\text{Placebo} & \text{Risperidone} \\
\text{Non-fasting triglycerides of } & -0.2 mg/dL at Week 24 (n=103); (c) fasting HDL of +0.4 mg/dL at Week 24 (n=103); and (d) Fasting
\end{array}
\]

Table 10 lists the adverse reactions reported in 2% or more of risperidone-treated adult patients

Table 12. Adverse Reactions in ≥5% of Risperidone-Treated Pediatric Patients (and greater

- Abdominal pain
- Stomach discomfort
- Dyspepsia
- Diarrhea
- Salivary hypersecretion
- Constipation
- Tachycardia
- Fatigue

5.4 Tardive Dyskinesia

To report SUSPECTED ADVERSE REACTIONS, contact Jubilant Cadista Pharmaceuticals Inc.

References

1.2 Bipolar Mania

11.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

1 - Treatment for patients with depression associated with Bipolar I Disorder

2.4 Dosing in Patients with Severe Renal or Hepatic Impairment

the dose to achieve the optimal balance of efficacy and safety. The physician who elects to use

26.1.2 How Supplied/Storage and Handling

16.1 How Supplied

DOSAGE AND ADMINISTRATION

Warnings and Precautions (5.8) 02/2017

5.13 Body Temperature Regulation

Disruption of body temperature regulation may be attributed to antipsychotic agents.

5.12 Carcinogenesis, Mutagenesis, Impairment of Fertility

Effective treatment regimens for uncomplicated NMS.

Table 4. Change in Random Lipids from Seven Placebo-Controlled, 3-to 8-Week, Fixed- or Flexible-Dose

\[
\begin{array}{ll}
\text{Placebo} & \text{Risperidone} \\
-0.2 mg/dL at Week 24 (n=103); & \text{c) fasting HDL of +0.4 mg/dL at Week 24 (n=103); and (d) Fasting
\end{array}
\]

Table 5. Change in Fasting Lipids from Three Placebo-Controlled, 3- to 6-Week, Fixed-Dose

\[
\begin{array}{ll}
\text{Placebo} & \text{Risperidone} \\
\text{Non-fasting triglycerides of } & -0.2 mg/dL at Week 24 (n=103); (c) fasting HDL of +0.4 mg/dL at Week 24 (n=103); and (d) Fasting
\end{array}
\]
Comparing 4 fixed doses of risperidone (2, 6, 10, and 16 mg/day), including (1) a Parkinsonism

Two methods were used to measure extrapyramidal symptoms (EPS) in an 8-week trial

risk for extrapyramidal and/or withdrawal symptoms following

Risperidone may antagonize the effects of levodopa and dopamine agonists.

effects of other therapeutic agents with this potential.

Repeated oral doses of risperidone (3 mg twice daily) did not affect the exposure (AUC) or peak

not needed

dosing.

dosing.

peak plasma concentrations of risperidone occurred at about 1 hour. Peak concentrations of

placebo, as measured by significant reduction of total YMRS score. The efficacy on the primary

change from baseline in the total YMRS score.


mood, speech, increased activity, sexual interest, language/thought disorder, thought content,

mannerisms, and insight) in a range from 0 (no manic features) to 60 (maximum score). The

mood, speech, increased activity, sexual interest, language/thought disorder, thought content,

mannerisms, and insight) in a range from 0 (no manic features) to 60 (maximum score). The

mood, speech, increased activity, sexual interest, language/thought disorder, thought content,

mannerisms, and insight) in a range from 0 (no manic features) to 60 (maximum score). The

mood, speech, increased activity, sexual interest, language/thought disorder, thought content,

mannerisms, and insight) in a range from 0 (no manic features) to 60 (maximum score). The

mood, speech, increased activity, sexual interest, language/thought disorder, thought content,

mannerisms, and insight) in a range from 0 (no manic features) to 60 (maximum score). The

mood, speech, increased activity, sexual interest, language/thought disorder, thought content,

mannerisms, and insight) in a range from 0 (no manic features) to 60 (maximum score). The

mood, speech, increased activity, sexual interest, language/thought disorder, thought content,

mannerisms, and insight) in a range from 0 (no manic features) to 60 (maximum score). The

mood, speech, increased activity, sexual interest, language/thought disorder, thought content,

mannerisms, and insight) in a range from 0 (no manic features) to 60 (maximum score). The

mood, speech, increased activity, sexual interest, language/thought disorder, thought content,

mannerisms, and insight) in a range from 0 (no manic features) to 60 (maximum score). The

mood, speech, increased activity, sexual interest, language/thought disorder, thought content,

mannerisms, and insight) in a range from 0 (no manic features) to 60 (maximum score). The

mood, speech, increased activity, sexual interest, language/thought disorder, thought content,

mannerisms, and insight) in a range from 0 (no manic features) to 60 (maximum score). The

mood, speech, increased activity, sexual interest, language/thought disorder, thought content,

mannerisms, and insight) in a range from 0 (no manic features) to 60 (maximum score). The

mood, speech, increased activity, sexual interest, language/thought disorder, thought content,

mannerisms, and insight) in a range from 0 (no manic features) to 60 (maximum score). The

mood, speech, increased activity, sexual interest, language/thought disorder, thought content,

mannerisms, and insight) in a range from 0 (no manic features) to 60 (maximum score). The

mood, speech, increased activity, sexual interest, language/thought disorder, thought content,

mannerisms, and insight) in a range from 0 (no manic features) to 60 (maximum score). The

mood, speech, increased activity, sexual interest, language/thought disorder, thought content,

mannerisms, and insight) in a range from 0 (no manic features) to 60 (maximum score). The

mood, speech, increased activity, sexual interest, language/thought disorder, thought content,