Pharmacokinetics:
The pharmacokinetic properties of the new drug were evaluated in a randomized, double-blind, placebo-controlled study. The drug was administered as a single oral dose to healthy volunteers. The pharmacokinetic parameters, including maximum plasma concentration (Cmax) and area under the curve (AUC), were calculated and compared to those of the placebo group.

Pharmacodynamics:
The drug showed a dose-dependent effect on the target parameter. The effect was evaluated by measuring the change in the target parameter after drug administration. The results indicated a significant improvement in the target parameter compared to the placebo group.

Adverse Events:
The most common adverse events observed were mild gastrointestinal symptoms, headache, and dizziness. These events were reported in approximately 10% of the participants in both the drug and placebo groups. No serious adverse events were reported.

Conclusion:
The new drug demonstrated a promising profile in the study. Further clinical trials are recommended to confirm the safety and efficacy of the drug in different populations.

ZYPREXA (Olanzapine) Japanese Label Changes

Dear St. Michael

Sandys Regulating Hills Association

300 wycliff st, melbourne, victoria 3018

Dear Sir/Madam,

I refer to your reply dated 26 April 2002 to our letter dated 18 April 2002 regarding the Japanese Label

ZYPREXA (Olanzapine) Japanese Label Changes

Dear Sir/Madam,

Sandys Regulating Hills Association

300 wycliff st, melbourne, victoria 3018

Dear Sir/Madam,

I refer to your reply dated 26 April 2002 to our letter dated 18 April 2002 regarding the Japanese Label

ZYPREXA (Olanzapine) Japanese Label Changes

Dear Sir/Madam,

Sandys Regulating Hills Association

300 wycliff st, melbourne, victoria 3018

Dear Sir/Madam,

I refer to your reply dated 26 April 2002 to our letter dated 18 April 2002 regarding the Japanese Label

ZYPREXA (Olanzapine) Japanese Label Changes

Dear Sir/Madam,

Sandys Regulating Hills Association

300 wycliff st, melbourne, victoria 3018

Dear Sir/Madam,

I refer to your reply dated 26 April 2002 to our letter dated 18 April 2002 regarding the Japanese Label

ZYPREXA (Olanzapine) Japanese Label Changes

Dear Sir/Madam,

Sandys Regulating Hills Association

300 wycliff st, melbourne, victoria 3018

Dear Sir/Madam,

I refer to your reply dated 26 April 2002 to our letter dated 18 April 2002 regarding the Japanese Label

ZYPREXA (Olanzapine) Japanese Label Changes

Dear Sir/Madam,

Sandys Regulating Hills Association

300 wycliff st, melbourne, victoria 3018

Dear Sir/Madam,

I refer to your reply dated 26 April 2002 to our letter dated 18 April 2002 regarding the Japanese Label

ZYPREXA (Olanzapine) Japanese Label Changes

Dear Sir/Madam,

Sandys Regulating Hills Association

300 wycliff st, melbourne, victoria 3018

Dear Sir/Madam,

I refer to your reply dated 26 April 2002 to our letter dated 18 April 2002 regarding the Japanese Label

ZYPREXA (Olanzapine) Japanese Label Changes

Dear Sir/Madam,

Sandys Regulating Hills Association

300 wycliff st, melbourne, victoria 3018

Dear Sir/Madam,

I refer to your reply dated 26 April 2002 to our letter dated 18 April 2002 regarding the Japanese Label

ZYPREXA (Olanzapine) Japanese Label Changes

Dear Sir/Madam,

Sandys Regulating Hills Association

300 wycliff st, melbourne, victoria 3018

Dear Sir/Madam,

I refer to your reply dated 26 April 2002 to our letter dated 18 April 2002 regarding the Japanese Label

ZYPREXA (Olanzapine) Japanese Label Changes

Dear Sir/Madam,

Sandys Regulating Hills Association

300 wycliff st, melbourne, victoria 3018

Dear Sir/Madam,

I refer to your reply dated 26 April 2002 to our letter dated 18 April 2002 regarding the Japanese Label

ZYPREXA (Olanzapine) Japanese Label Changes

Dear Sir/Madam,

Sandys Regulating Hills Association

300 wycliff st, melbourne, victoria 3018

Dear Sir/Madam,

I refer to your reply dated 26 April 2002 to our letter dated 18 April 2002 regarding the Japanese Label

ZYPREXA (Olanzapine) Japanese Label Changes

Dear Sir/Madam,

Sandys Regulating Hills Association

300 wycliff st, melbourne, victoria 3018

Dear Sir/Madam,

I refer to your reply dated 26 April 2002 to our letter dated 18 April 2002 regarding the Japanese Label

ZYPREXA (Olanzapine) Japanese Label Changes

Dear Sir/Madam,

Sandys Regulating Hills Association

300 wycliff st, melbourne, victoria 3018

Dear Sir/Madam,

I refer to your reply dated 26 April 2002 to our letter dated 18 April 2002 regarding the Japanese Label

ZYPREXA (Olanzapine) Japanese Label Changes

Dear Sir/Madam,

Sandys Regulating Hills Association

300 wycliff st, melbourne, victoria 3018

Dear Sir/Madam,

I refer to your reply dated 26 April 2002 to our letter dated 18 April 2002 regarding the Japanese Label

ZYPREXA (Olanzapine) Japanese Label Changes

Dear Sir/Madam,

Sandys Regulating Hills Association

300 wycliff st, melbourne, victoria 3018

Dear Sir/Madam,

I refer to your reply dated 26 April 2002 to our letter dated 18 April 2002 regarding the Japanese Label

ZYPREXA (Olanzapine) Japanese Label Changes

Dear Sir/Madam,

Sandys Regulating Hills Association

300 wycliff st, melbourne, victoria 3018

Dear Sir/Madam,

I refer to your reply dated 26 April 2002 to our letter dated 18 April 2002 regarding the Japanese Label

ZYPREXA (Olanzapine) Japanese Label Changes

Dear Sir/Madam,

Sandys Regulating Hills Association

300 wycliff st, melbourne, victoria 3018

Dear Sir/Madam,

I refer to your reply dated 26 April 2002 to our letter dated 18 April 2002 regarding the Japanese Label

ZYPREXA (Olanzapine) Japanese Label Changes

Dear Sir/Madam,

Sandys Regulating Hills Association

300 wycliff st, melbourne, victoria 3018

Dear Sir/Madam,

I refer to your reply dated 26 April 2002 to our letter dated 18 April 2002 regarding the Japanese Label

ZYPREXA (Olanzapine) Japanese Label Changes

Dear Sir/Madam,

Sandys Regulating Hills Association

300 wycliff st, melbourne, victoria 3018

Dear Sir/Madam,

I refer to your reply dated 26 April 2002 to our letter dated 18 April 2002 regarding the Japanese Label

ZYPREXA (Olanzapine) Japanese Label Changes

Dear Sir/Madam,

Sandys Regulating Hills Association

300 wycliff st, melbourne, victoria 3018

Dear Sir/Madam,

I refer to your reply dated 26 April 2002 to our letter dated 18 April 2002 regarding the Japanese Label

ZYPREXA (Olanzapine) Japanese Label Changes

Dear Sir/Madam,

Sandys Regulating Hills Association

300 wycliff st, melbourne, victoria 3018

Dear Sir/Madam,

I refer to your reply dated 26 April 2002 to our letter dated 18 April 2002 regarding the Japanese Label

ZYPREXA (Olanzapine) Japanese Label Changes

Dear Sir/Madam,

Sandys Regulating Hills Association

300 wycliff st, melbourne, victoria 3018

Dear Sir/Madam,

I refer to your reply dated 26 April 2002 to our letter dated 18 April 2002 regarding the Japanese Label

ZYPREXA (Olanzapine) Japanese Label Changes

Dear Sir/Madam,

Sandys Regulating Hills Association

300 wycliff st, melbourne, victoria 3018

Dear Sir/Madam,

I refer to your reply dated 26 April 2002 to our letter dated 18 April 2002 regarding the Japanese Label

ZYPREXA (Olanzapine) Japanese Label Changes

Dear Sir/Madam,

Sandys Regulating Hills Association

300 wycliff st, melbourne, victoria 3018

Dear Sir/Madam,

I refer to your reply dated 26 April 2002 to our letter dated 18 April 2002 regarding the Japanese Label

ZYPREXA (Olanzapine) Japanese Label Changes

Dear Sir/Madam,

Sandys Regulating Hills Association

300 wycliff st, melbourne, victoria 3018

Dear Sir/Madam,
10 May 2002

Drug Safety Evaluation Branch
Clinical Evaluation Unit
Dr. Janice Fenta

Your Majesty

Head of Clinical Evaluation Unit, Dr. Philip Chippman on (02) 6232 8113.

If you wish to discuss this issue, please do not hesitate to contact either myself on (02) 6232 8356 or the

By 14 June 2002, Therapeutic Goods Act 1989, 10 include the required information. Such a notification should be submitted
in the Australian PMS database. Please ensure a safety notification pursuant to Section 37(4) of the
For use as Section 4 „Undesirable effects of the EL¼.SPC provided in your response shall be included.