

## **Executive Summary of Actual Use Study**

This was a four-week, open-label, single-arm, multi-center actual use (AU) trial to evaluate self-selection and self-administration (use) of Plan B in an OTC-like setting. This study was conducted in five family planning clinic settings across five states and five pharmacy stores in the state of Washington. A total of 585 subjects ages 14-44 years were enrolled from family planning clinics (94%) and pharmacy stores (6%) in the United States.

The results suggest that the study population:

- 1) correctly self-selected and use Plan B in an OTC setting
- 2) demonstrated most of the incorrect use due to not taking the 2<sup>nd</sup> pill at 12 hours after the first pill (correct rate was 67.8%). Eighty-nine percent of subjects took the second pill  $12.5 \pm 3.2$  hours after the first
- 3) decreased “At least one sex act without contraception” from 60% (before study) to 20% (during study)
- 4) increased condom use from 79% (before study) to 90% (during study)
- 5) decreased withdrawal contraception from 27.6% (before study) to 10.1% (during study)
- 6) had more women switch from a “less effective” contraception method to a “more effective” contraception method during the four-week study
- 7) did not generate new safety signals
- 8) had similar self selection and contraceptive use across demographics
- 9) had similar self-selection and contraceptive use whether or not experienced with prior emergency contraception use before study

Limitation of this study included:

- 1) The majority of subjects were recruited from family planning clinics, which may limit generalization of results to an OTC population.
- 2) Subjects were observed for only four weeks and therefore results may not predict long term use patterns
- 3) Only five percent (n=29) of subjects were ages 14-16 years old. Due to the small sample size, conclusions regarding this demographic is limited
- 4) Subjects were only allowed to purchase one package of Plan B and were only allowed additional purchases after undergoing a re-enrollment process. This did not closely represent an OTC environment
- 5) Some concepts that demonstrated low comprehension in the labeling comprehension study were not addressed by the actual use study

## **Summary of the Results of Actual Use of Low Comprehension Concepts From Label Comprehension Study**

Certain components of the proposed label demonstrated low comprehension in the label comprehension study. These components are listed below and underlined. The results of the actual use study that are relevant to these issues follows each of these components.

1. Plan B is not for regular use for contraception: Routine contraception and effective contraception use was not affected during the study
2. Take the first tablet as soon as possible after intercourse: Over ninety percent of subjects in the actual use study demonstrated dosing within 72 hours. However, the actual use study did not evaluate whether subjects understood that the sooner the first pill is taken after unprotected intercourse, the more effective it is
3. Take the second tablet 12 hours after the first one: Sixty-eight percent of subjects took the second dose 12 hours after the first and 89% of subjects took the second pill  $12.5 \pm 3.2$  hours after the first
4. Do not use Plan B if you have unexplained vaginal bleeding: This was not evaluated by the study. One percent of subjects that used Plan B reported “unexplained vaginal bleeding” when taking this product. This study did not determine the number of women who chose not to use the product because of unexplained vaginal bleeding. Consequently, the one percent with vaginal bleeding in the study can not be used to assess the understanding of this concept
5. The label comprehension study indicated lower comprehension of the label in low literacy and less educated populations. The study did not do literacy assessments. The study demonstrated that overall *incorrect use, contraindicated use, adverse events and adverse behaviors* were not increased in subjects age 14-16 or those with less than a high school education. The small sample size of both subgroups limits conclusions