Itraconazole contaminated with rilmazafone in Japan: A retrospective analysis using the Japanese Adverse Drug Event Report database

*Drugs – Real World Outcomes*

Supplementary Information

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**Suppl Table 1** Number of CNS-depression related ADR reports associated with ITCZ in each time period (based on report date)

| Number of ADRs reported | –2019 4th quarter (–2020/3) | 2020 1st quarter (2020/4–6) | 2020 2nd quarter (2020/7–9) | 2020 3rd quarter (2020/10–12) | 2020 4th quarter (2021/1–3) | 2021 1st quarter (2021/4–6) |
|-------------------------|-----------------------------|-----------------------------|-----------------------------|-----------------------------|-----------------------------|-----------------------------|
| Somnolence (n=185)      | 5 (0.1%)                    | 0 (0%)                      | 0 (0%)                      | 102 (21.9%)                 | 77 (18.0%)                  | 1 (1.2%)                    |
| Amnesia (n=9)           | 0 (0%)                      | 0 (0%)                      | 0 (0%)                      | 4 (0.9%)                    | 5 (1.2%)                    | 0 (0%)                      |
| Dizziness (n=130)       | 12 (0.1%)                   | 0 (0%)                      | 0 (0%)                      | 59 (12.7%)                  | 59 (13.8%)                  | 0 (0%)                      |
| Memory impairment (n=36) | 2 (0.0%)                    | 0 (0%)                      | 0 (0%)                      | 27 (5.8%)                   | 7 (1.6%)                    | 0 (0%)                      |
| Altered state of consciousness (n=72) | 20 (0.2%) | 1 (1.2%) | 0 (0%) | 33 (7.1%) | 17 (4.0%) | 1 (1.2%) |
| Loss of consciousness (n=28) | 12 (0.1%) | 0 (0%) | 0 (0%) | 14 (3.0%) | 2 (0.5%) | 0 (0%) |
| Falls (n=69)            | 3 (0.0%)                    | 0 (0%)                      | 0 (0%)                      | 20 (4.3%)                   | 46 (10.8%)                  | 0 (0%)                      |
| Depressed level of consciousness (n=14) | 8 (0.1%) | 0 (0%) | 0 (0%) | 5 (1.1%) | 0 (0%) | 1 (1.2%) |
| Traffic Accidents (n=4) | 3 (0.0%)                    | 0 (0%)                      | 0 (0%)                      | 0 (0%)                      | 1 (0.2%)                    | 0 (0%)                      |

ADR: adverse drug reaction, CNS: central nervous system, ITCZ: Itraconazole