

Unintended Pregnancies Associated with Unapproved Isotretinoin Use in Japan: A 20-year Case Series from the Japan Drug Information Institute in Pregnancy

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Summary

Purpose: To investigate the characteristics and clinical profiles of unintended pregnancies among isotretinoin users in Japan.

Methods: We reviewed the medication counseling records of isotretinoin-exposed pregnant women seen at the Japan Drug Information Institute in Pregnancy (JDIIP) between October 5, 2005, and March 31, 2024. The main outcomes were the proportion of unplanned pregnancies, duration of isotretinoin exposure during pregnancy, and means of accessing isotretinoin.

Results: Of the 10,405 pregnant women seen at the JDIIP, 28 (0.27%) sought medical advice regarding isotretinoin. In 2021, 2022, 2023, and 2024 (January to March), the numbers (percentage) of patients who started medication counseling regarding isotretinoin were 3 (0.77%), 4 (1.31%), 4 (1.25%), and 4 (5.97%), respectively. All the 28 pregnancies among isotretinoin users were unplanned. Twenty-one women discontinued isotretinoin later than 2 weeks and 0 days of gestation. Sixteen women were prescribed isotretinoin by clinicians in Japan, and three by clinicians overseas. Nine women had purchased and used isotretinoin on their own. None of the patients had used oral or emergency contraceptives.

Conclusions: To prevent unplanned pregnancies during isotretinoin use in Japan, awareness should be raised among both patients and physicians regarding the teratogenic risk of isotretinoin. Additionally, guidance on contraception should be provided before prescribing isotretinoin.

Key words

Teratogenicity, Retinoids, Isotretinoin, Unintended pregnancy, Unapproved drugs, Personal importation