



SAFETY ALERT

DRAP SAFETY ALERT NO. 60

Safety Alert of Risk of Sacroiliitis with Isotretinoin

Date: 30th of January, 2026.

Target Audience.

- Provincial Health Departments/Provincial PV Centres;
- Manufacturers and importers of Isotretinoin; and
- Healthcare Professionals
- Patients

Background.

Health Canada, through its Newsletter Infowatch (March 2025) informed about its assessment of the potential risk of Sacroiliitis with Isotretinoin. The safety review found a possible link between isotretinoin and the risk of sacroiliitis. It was informed that Health Canada will work with the manufacturers to update the product safety information in the Canadian product monograph (CPM) for isotretinoin-containing products to include the risk. Sacroiliitis, inflammation of the sacroiliac joints (where the spine connects to the pelvis), usually results in pain.

Health Canada reviewed 24 international cases of sacroiliitis in patients taking isotretinoin. Of those 24 cases, 23 were found to be possibly linked to the use of isotretinoin, and 1 was unlikely to be linked. The average age was 20 years in cases where the age was provided. No deaths were reported among the 24 cases reviewed. Health Canada also reviewed 18 articles published in the scientific literature. While the studies supported a link between the risk of sacroiliitis and the use of isotretinoin, they did not identify a clear biological mechanism to explain how isotretinoin use could lead to sacroiliitis. In both the cases reviewed and the scientific literature, sacroiliitis improved after discontinuation of isotretinoin and appropriate treatment.

Action in Pakistan.

The case was discussed in the 6th meeting of the Pharmacovigilance Risk Assessment Expert Committee (PRAEC) held on 31st of December, 2025 which decided as per Rule 10 (1) (h) (iv) of Pharmacovigilance Rules, 2022 that registration holders of isotretinoin-containing medicines are required to include information on the risk of sacroiliitis in the Adverse Drug Reactions and Warnings and Precautions sections of the SmPC/label, in line with the Health Canada Product Monograph.

Therapeutic Good Affected.

Name: Isotretinoin is a prescription drug used for the treatment of severe forms of acne in patients 12 years of age and older, when the acne fails to respond to other treatments.





Advice for Healthcare Professionals and Patients.

Healthcare professionals and patients are informed that Isotretinoin may be associated with sacroiliitis (inflammation of pelvic joints). Patients are advised to contact their doctor if they develop persistent lower back, hip, or buttock pain, especially pain worse at night or with rest and not stop treatment without medical advice.

Guidelines for reporting Adverse Drug Reactions (ADRs).

Healthcare professionals and patients are requested to report any adverse drug reaction with Isotretinoin and/or any other medicine to the National Pharmacovigilance Centre (NPC), Drug Regulatory Authority of Pakistan (DRAP), through the [Med Vigilance E-Reporting System \(E-forms\)](#) available on the DRAP website. Similarly, adverse events and adverse drug reactions can also be reported through the VigiMobile App by scanning the following QR code, which can also be downloaded (add to home screen) in the mobile:



References.

- [Minutes of the 6th meeting of the Pharmacovigilance Risk Assessment Expert Committee \(PRAEC\), DRAP.](#)
- [Health Canada: Summary Safety Review - Isotretinoin - Assessing the Potential Risk of Sacroiliitis](#)
- [Health Canada: Health Product InfoWatch: March 2025.](#)

