



## SAFETY ALERT

DRAP SAFETY ALERT NO. 61

### Safety Alert of Risk of Idiopathic Intracranial Hypertension with Mesalazine

Date: 30<sup>th</sup> of January, 2026

#### Target Audience.

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

#### Background.

The HPRA of Ireland, through a Drug Safety Newsletter in June 2025, announced that the product information for mesalazine is updated to include the risk of idiopathic intracranial hypertension (pseudotumor cerebri). The EMA's PRAC recommendations are based on a review of available data on benign intracranial hypertension from the literature and spontaneous reports, including, in some cases, a close temporal relationship, a positive de-challenge and/or re-challenge. If idiopathic intracranial hypertension occurs, discontinuation of mesalazine should be considered.

The MHRA-UK, on 4<sup>th</sup> of December 2025, through a Drug Safety Update, also informed that idiopathic intracranial hypertension (IIH) has been very rarely reported in patients treated with mesalazine. Following a recent review, warnings for idiopathic intracranial hypertension are being added to the product information for all mesalazine products. The recent European review of safety data for mesalazine identified an association between mesalazine and idiopathic intracranial hypertension following very rare reports of this event. Consequently, recommendations have been made to update the product information for mesalazine products to contain warnings for idiopathic intracranial hypertension. The benefit-risk balance remains unchanged in the approved indications.

The findings of this review were considered by the UK's independent Pharmacovigilance Expert Advisory Committee (PEAG) of the Commission on Human Medicines (CHM), which agreed with the recommendations and advised that the MHRA inform healthcare professionals and patients of the possibility of idiopathic intracranial hypertension with mesalazine. The number of reports of intracranial hypertension and mesalazine received in the UK and identified through the European review is very low. The MHRA has received 6 UK Yellow Card reports of increased intracranial pressure disorders associated with mesalazine





### Action in Pakistan.

The case was discussed in the 6<sup>th</sup> meeting of the Pharmacovigilance Risk Assessment Expert Committee (PRAEC) held on 31<sup>st</sup> of December, 2025 which decided as per Rule 10 (1) (h) (iv) of Pharmacovigilance Rules, 2022 that registration holders are required to include information regarding the risk of idiopathic intracranial hypertension in the Warnings and Precautions section and also list this risk with a frequency of “not known” in the Adverse Drug Reactions (ADRs) section of the SmPC/label for all mesalazine-containing medicine in Pakistan in line with MHRA-UK decision.

### Therapeutic Good Affected.

**Name:** Mesalazine (5-aminosalicylic acid) is an intestinal anti-inflammatory agent indicated for the treatment of mild to moderate ulcerative colitis, both in the acute phase and in the prevention of recurrence, treatment of Crohn’s disease, both in the acute (active) phase and for the prevention of recurrence, as long as the disease is restricted to the colon.

### Advice for Healthcare Professionals.

Healthcare professionals are informed that idiopathic intracranial hypertension (IIH) has been very rarely reported in patients receiving mesalazine. Patients using any form of mesalazine should be warned to look for signs and symptoms of IIH, including severe or recurrent headache, visual disturbances or tinnitus. Healthcare professionals should remain vigilant of signs and symptoms of IIH in patients taking mesalazine and act promptly with a multidisciplinary approach, involving clinicians managing the patient’s mesalazine as well as neurology, neurosurgery and ophthalmology teams as appropriate. If symptoms of IIH occur, discontinuation of mesalazine should be considered, and management of the symptoms should begin immediately. Caution is also advised when prescribing for patients who have previously diagnosed or suspected IIH.

### Advice for patients.

Patients are informed that there have been very rare reports of increased pressure within the skull, known as idiopathic intracranial hypertension (IIH), in some patients receiving mesalazine. IIH is not normally life-threatening; however, in rare cases can cause serious vision problems, which must be monitored and treated where possible. Patients are advised to tell their doctor immediately if they experience progressively more severe and recurrent headaches, disturbed vision, ringing or buzzing in the ears, back pain, dizziness, or neck pain, as these could be symptoms of IIH.





### **Guidelines for reporting Adverse Drug Reactions (ADRs).**

Healthcare professionals and patients are requested to report any adverse drug reaction/ event with Mesalazine and/or any other medicines 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 6<sup>th</sup> meeting of the Pharmacovigilance Risk Assessment Expert Committee \(PRAEC\), DRAP.](#)
- [MHRA-UK: Drug Safety Update of Mesalazine and Idiopathic Intracranial Hypertension](#)
- [EMA-PRAC: Minutes of meeting on 30 September - 03 October 2024](#)

