From the Chief Medical Officer Professor Sir Michael McBride



HSS(MD)38/2025

FOR ACTION

Chief Executives, Public Health Agency/HSC Trusts/NIAS
Chief Operating Officer, SPPG
GP Medical Advisers, SPPG
All General Practitioners and GP Locums (for onward
distribution to practice staff)
OOHs Medical Managers (for onward distribution to staff)
RQIA (for onward transmission to all independent providers
including independent hospitals)

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Our Ref: HSS(MD)38/2025 Date: 8 December 2025

PLEASE SEE ATTACHED FULL CIRCULATION LIST

Dear Colleague

MHRA DRUG SAFETY UPDATE: Mesalazine and idiopathic intracranial hypertension

The Medicines and Healthcare products Regulatory Agency (MHRA) has issued the below Drug Safety Update.

Healthcare Professionals are asked to note and action the advice for healthcare professionals, advice for healthcare professionals to provide to patients and recommendations contained within the Drug Safety Update.

Please find the link to the complete MHRA Drug Safety Update included below:

Mesalazine and idiopathic intracranial hypertension

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.

If idiopathic intracranial hypertension occurs in patients, discontinuation of mesalazine should be considered.

Reporting advice

Healthcare professionals, patients, and caregivers are asked to submit reports using the Yellow Card scheme electronically using:

- the Yellow Card website.
- the Yellow Card app; download from the Apple App Store or Google Play Store
- some clinical IT systems for healthcare professionals

When reporting suspected adverse drug reactions, please provide as much information as possible, including information about medical history, any concomitant medication, onset timing, and treatment dates.

For queries or more information, please contact info@mhra.gov.uk.

You can subscribe to the MHRA new Safety Roundup bulletin <u>here</u>. The latest MHRA Safety Roundup is available at the following link: <u>MHRA Safety Roundup</u>.

Yours sincerely

PROFESSOR SIR MICHAEL MCBRIDE Chief Medical Officer

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PROFESSOR CATHY HARRISON Chief Pharmaceutical Officer

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This letter is available on the Department of Health website at

https://www.health-ni.gov.uk/topics/professional-medical-and-environmental-health-advice/hssmd-letters-and-urgent-communications