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(來函請敍明此檔案號碼) DH DO DIMC/7-30/1
(IN REPLY PLEASE QUOTE THIS FILE REF.)

5 Dec 2025

Dear Healthcare Professionals,

Mesalazine and Idiopathic Intracranial Hypertension

Your attention is drawn to the United Kingdom Medicines and Healthcare products Regulatory Agency's (MHRA) announcement 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.

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

Advice for Healthcare Professionals:

- idiopathic intracranial hypertension (IIH) has been very rarely reported in patients receiving mesalazine
- the number of reports in the UK is very low
- 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
- 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 occurs, discontinuation of mesalazine should be considered and management of the symptoms should begin immediately
- caution is advised when prescribing for patients who have previously diagnosed or suspected IIH

Advice for Healthcare Professionals to Provide to Patients:

- there have been very rare reports of increased pressure within your 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
- tell your doctor immediately if you experience progressively more severe and recurrent headache, disturbed vision, ringing or buzzing in the ears, back pain, dizziness, or neck pain, as these could be symptoms of IIH

Background

Mesalazine

Mesalazine is an aminosalicylate and is licensed for the treatment of inflammatory bowel disease such as ulcerative colitis and Crohn's disease.

Mesalazine is currently available in the UK in the following formulations:

- Mesalazine 1g & 2g enema
- Mesalazine 1g actuation rectal foam
- Mesalazine 500mg & 1, 2g suppositories
- Mesalazine 1, 1.5, 2, 3, 4 g granules
- Mesalazine 400, 500, 800, 1000, 1200, 1600 mg tablets

Idiopathic intracranial hypertension (IIH)

The majority of patients presenting with IIH have symptoms that include the following. It should be noted that none of these symptoms alone are unique to IIH.

- a headache that is progressively more severe and frequent; the type of headache can be highly variable
- transient visual obscurations (unilateral or bilateral darkening of the vision typically lasting seconds)
- pulsatile tinnitus
- back pain
- dizziness
- neck pain
- visual blurring
- cognitive disturbances
- radicular pain
- typically horizontal diplopia

Diagnosis may be achieved through blood pressure monitoring and ophthalmology examination. However, where diagnostic uncertainty remains, experienced clinicians should be consulted, who may consider brain imaging and/or lumbar puncture.

Following diagnosis, recommendations for the management of IIH include:

1. to address the underlying cause
2. to protect the vision
3. to minimise the headache morbidity

Mesalazine and idiopathic intracranial hypertension

A 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) who 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 are very low. The MHRA has received 6 UK Yellow Card reports of increased intracranial pressure disorders associated with mesalazine. Total prescribing for mesalazine averages approximately 1.5 million items per year across all regional teams in NHS England. Additionally, the background incidence of IIH has been reported as between 1.8 and 7.8 per 100,000 population per year across Scotland, England and Wales.

New advice when prescribing mesalazine

Prior to prescribing, healthcare professionals should warn patients for signs and symptoms of idiopathic intracranial hypertension. Patients should be advised to tell their doctor immediately if they experience symptoms, including progressively more severe and recurrent headache, disturbed vision, ringing or buzzing in the ears, back pain, dizziness, or neck pain, as these could be symptoms of IIH.

Additionally, caution is advised when prescribing for patients who have previously diagnosed or suspected idiopathic intracranial hypertension.

Advice in cases of idiopathic intracranial hypertension and mesalazine

If idiopathic intracranial hypertension occurs, discontinuation of mesalazine should be considered and management of the symptoms should begin immediately.

Please refer to the following website in MHRA for details:
https://www.gov.uk/drug-safety-update/mesalazine-and-idiopathic-intracranial-hypertension

In Hong Kong, there are 23 registered pharmaceutical products containing mesalazine. All products are prescription-only medicines. So far, with regard to mesalazine, the Department of Health (DH) has received one case of adverse drug reaction report, but the case was not related to idiopathic intracranial hypertension. In light of the above MHRA's announcement, the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board of Hong Kong.

Please note that this letter serves as a means for the DH to communicate important new safety information about registered pharmaceutical products with healthcare professionals in Hong Kong and is not intended to serve as guidelines or to replace professional clinical judgement. Healthcare professionals are advised to balance the risk of possible adverse effects against the benefit of treatment.

Please report any adverse events caused by drugs to the Clinical Trials and Pharmacovigilance Unit of the DH (tel. no.: 2319 2920, fax: 2319 6319 or email: adr@dh.gov.hk). For details, please refer to the website at Drug Office under "ADR Reporting": http://www.drugoffice.gov.hk/adr.html. You may wish to visit the Drug Office's website for subscription and browsing of "Drug News" which is a monthly digest of drug safety news and information issued by Drug Office.

Yours faithfully,

(Clive CHAN)
for Assistant Director (Drug)