

Safety Alert

Nov. 2025

Mesalazine – Risk of idiopathic intracranial hypertension

EDA performs label update to include the following:

Special warning and precaution for use

Idiopathic intracranial hypertension

Idiopathic intracranial hypertension (pseudotumor cerebri) has been reported in patients receiving mesalazine. Patients should be warned for signs and symptoms of idiopathic intracranial hypertension, including severe or recurrent headache, visual disturbances or tinnitus. If idiopathic intracranial hypertension occurs, discontinuation of mesalazine should be considered.

Undesirable Effects

Nervous System Disorder:

Idiopathic intracranial hypertension :Unknown

Background:

Idiopathic Intracranial Hypertension (IIH) is a neurological disorder characterized by increased pressure inside the skull (intracranial pressure) for an unknown reason.

The symptoms of IIH are caused by the elevated pressure on the brain and the optic nerve:

Headache: The most common symptom, often severe, constant, and can be worse in the morning or when bending down.

Vision Changes: These are the most dangerous symptoms and require immediate attention:

Transient Visual Obscurations (TVOs): Brief episodes of darkened or "greyed out" vision, lasting only seconds, often triggered by coughing or bending over.

Peripheral (Side) Vision Loss: Can be progressive and often goes unnoticed until advanced.

Blurred or Double Vision (Diplopia): Often caused by pressure on the sixth cranial nerve (abducens nerve).

Pulsatile Tinnitus: A whooshing or rhythmic sound in the ears that pulses in sync with the heartbeat.

Nausea, Vomiting, and Dizziness.

Neck, Shoulder, or Back Pain.

Therapeutic Indication

- Ulcerative Colitis (UC)
- Crohn's Disease (CD)

Reference

EMA ([click Here](#))