

Safety Alert

Jan. 2026

Ibrutinib – risk of uveitis

EDA performs label update to include the following:

Undesirable effects

Eye disorders

Uncommon :Uveitis

Background:

Uveitis is the clinical term for inflammation of the **uvea**, the middle layer of the eye. Because this layer is highly vascular (rich in blood vessels), inflammation here can quickly affect other vital structures like the retina and optic nerve, making it one of the leading causes of preventable blindness worldwide.

Uveitis symptoms often vary depending on which part of the eye is inflamed. While some cases are sudden and painful, others can be "silent" and only involve gradual vision changes.

Common Symptoms

- Blurred or cloudy vision
- Floaters
- Photophobia
- Eye Redness
- Eye Pain
- Vision Loss

Therapeutic Indication

It is used to treat the following blood cancers in adults:

- Mantle cell lymphoma (MCL), a type of cancer affecting the lymph nodes, when the disease has come back or has not responded to treatment.
- Chronic lymphocytic leukaemia (CLL) a type of cancer affecting white blood cells called lymphocytes that also involves the lymph nodes. it is used in patients who have not previously been treated for CLL or when the disease has come back or has not responded to treatment.
- Waldenström's macroglobulinaemia (WM), a type of cancer affecting white blood cells called lymphocytes. It is used in patients who have not previously been treated for WM or when the disease has come back or has not responded to treatment or in patients for whom chemotherapy given together with an antibody is not a suitable therapy.

Reference

EMA ([click Here](#))