

Consumer Update

Feb 2022

Upadacitinib and risk of diverticulitis

EDA performs label update to include the following:

Special warnings and precautions for use Diverticulitis

Events of diverticulitis have been reported in clinical trials and from post-marketing sources.

Diverticulitis may cause gastrointestinal perforation. Upadacitinib should be used with caution in patients with diverticular disease and especially in patients chronically treated with concomitant medications associated with an increased risk of diverticulitis: nonsteroidal anti-inflammatory drugs, corticosteroids, and opioids. Patients presenting with new onset abdominal signs and symptoms should be evaluated promptly for early identification of diverticulitis to prevent gastrointestinal perforation.

Table 2. Adverse reactions

System Organ Class	Very common	Common	Uncommon
Infections and infestations	Upper respiratory tract infections	Bronchitisa,b Herpes zoster Herpes simplexa Folliculitis Influenza	Pneumonia Oral candidiasis Diverticulitis

Background:

Therapeutic indications

Rheumatoid arthritis

Psoriatic arthritis

Ankylosing spondylitis

Atopic dermatitis

References: AEMPS (Click here)