Upadacol/Ubicid

The drug should be sold by retail under prescription of Gastroenterologist Only

Abbreviated Prescribing information for Upadacol/Ubicid [Upadacitinib Extended -Release Tablets 45 mg]

[Please refer the complete prescribing information available at www.torrentpharma.com]

WARNING: SERIOUS INFECTIONS, MORTALITY, MALIGNANCY, MAJOR ADVERSE CARDIOVASCULAR EVENTS (MACE), and THROMBOSIS

- Increased risk of serious bacterial, fungal, viral, and opportunistic infections leading to hospitalization or death, including tuberculosis (TB). Interrupt treatment with Upadacitinib if serious infection occurs until the infection is controlled. Test for latent TB before and during therapy; treat latent TB prior to use. Monitor all patients for active TB during treatment, even patients with initial negative, latent TB test.
- Higher rate of all-cause mortality, including sudden cardiovascular death with another Janus kinase (JAK) inhibitor vs. tumor necrosis factor (TNF) blockers in rheumatoid arthritis (RA) patients.
- Malignancies have occurred in patients treated with Upadacitinib. Higher rate of lymphomas and lung cancers with another JAK inhibitor vs. TNF blockers in RA patients.
- Higher rate of MACE (defined as cardiovascular death, myocardial infarction, and stroke) with another JAK inhibitor vs. TNF blockers in RA patients. Thrombosis has occurred in patients treated with Upadacitinib. Increased incidence of pulmonary embolism, venous and arterial thrombosis with another JAK inhibitor vs. TNF blockers.

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: Upadacitinib is a selective and reversible Janus kinase (JAK) inhibitor. JAKs are intracellular enzymes that transmit cytokine or growth factor signals involved in a broad range of cellular processes including inflammatory responses, hematopoiesis, and immune surveillance.

INDICATIONS: Upadacitinib is indicated for the treatment of adults with moderately to severely active ulcerative colitis who have had an inadequate response or intolerance to one or more TNF blockers.

DOSAGE AND ADMINISTRATION: The recommended induction dose of upadacitinib is 45 mg once daily for 8 weeks. For patients who do not achieve adequate therapeutic benefit by week 8, upadacitinib 45 mg once daily may be continued for an additional 8-week period. The recommended maintenance dose of upadacitinib is 15 mg or 30 mg once daily based on individual patient presentation.

CONTRAINDICATION: • Hypersensitivity to the active substance or to any of the excipients. • Active tuberculosis (TB) or active serious infections. • Severe hepatic impairment. • Pregnancy

WARNINGS & PRECAUTIONS: Upadacitinib should only be used in patients 65 years and older if no suitable treatment alternatives are available. Upadacitinib should not be initiated in patients with an active, serious infection, including localised infections. Upadacitinib therapy should be interrupted if a patient develops a serious or opportunistic infection. Upadacitinib should not be given to patients with active TB. Screening for viral hepatitis and monitoring for reactivation should be performed before starting and during therapy with Upadacitinib. Prior to initiating upadacitinib treatment, it is recommended that patients be brought up to date with all immunisations. Lymphoma and malignancies have been reported in patients receiving JAK inhibitors, including Upadacitinib. NMSCs have been reported in patients treated with Upadacitinib. Upadacitinib should be used with caution in patients who may be at risk for gastrointestinal perforation (e.g., patients with diverticular disease, a history of

diverticulitis, or who are taking nonsteroidal anti-inflammatory drugs (NSAIDs), corticosteroids, or opioids). If increases in ALT or AST are observed during routine patient management and drug-induced liver injury is suspected, upadacitinib therapy should be interrupted until this diagnosis is excluded. In patients with known VTE risk factors other than cardiovascular or malignancy risk factors, upadacitinib should be used with caution. Patients should be advised to promptly seek medical care in case they experience symptoms suggestive of retinal vein occlusion. If a clinically significant hypersensitivity reaction occurs, treatment with upadacitinib must be discontinued and appropriate therapy must be instituted. Dose adjustment of anti-diabetic medicinal products may be necessary if hypoglycaemia occurs. Patients should be instructed to contact their healthcare professional if medication residue is observed repeatedly. Upadacitinib monotherapy should not be used for the treatment of acute relapses of giant cell arteritis as efficacy in this setting has not been established.

DRUG INTERACTIONS: Upadacitinib exposure is increased when co-administered with strong CYP3A4 inhibitors (such as ketoconazole, itraconazole, posaconazole, voriconazole, clarithromycin, and grapefruit juice). Upadacitinib exposure is decreased when co-administered with strong CYP3A4 inducers (such as rifampin and phenytoin), which may lead to reduced therapeutic effect.

ADVERSE REACTIONS: Upper respiratory tract infections (URTI), acne, bronchitis, herpes zoster, herpes simplex, folliculitis, influenza, urinary tract infection, pneumonia, oral candidiasis, non-melanoma skin cancer, anaemia, neutropenia, lymphopenia, urticaria,, hypercholesterolaemia, hyperlipidaemia, headache, dizziness, vertigo, cough, abdominal pain, nausea, rash, fatigue, pyrexia, peripheral oedema, increased blood CPK, ALT, AST, weight gain, diverticulitis, sepsis, serious hypersensitivity reactions, hypertriglyceridaemia, and gastrointestinal perforation.

MARKETED BY:

TORRENT PHARMA

Torrent Pharmaceuticals Limited.

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(Additional information is available on request)