

STOP THE INVASION

# TOFAHENZ

Tofacitinib 5 mg Tablets

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## Tofacitinib 5 mg Tablets

### Background

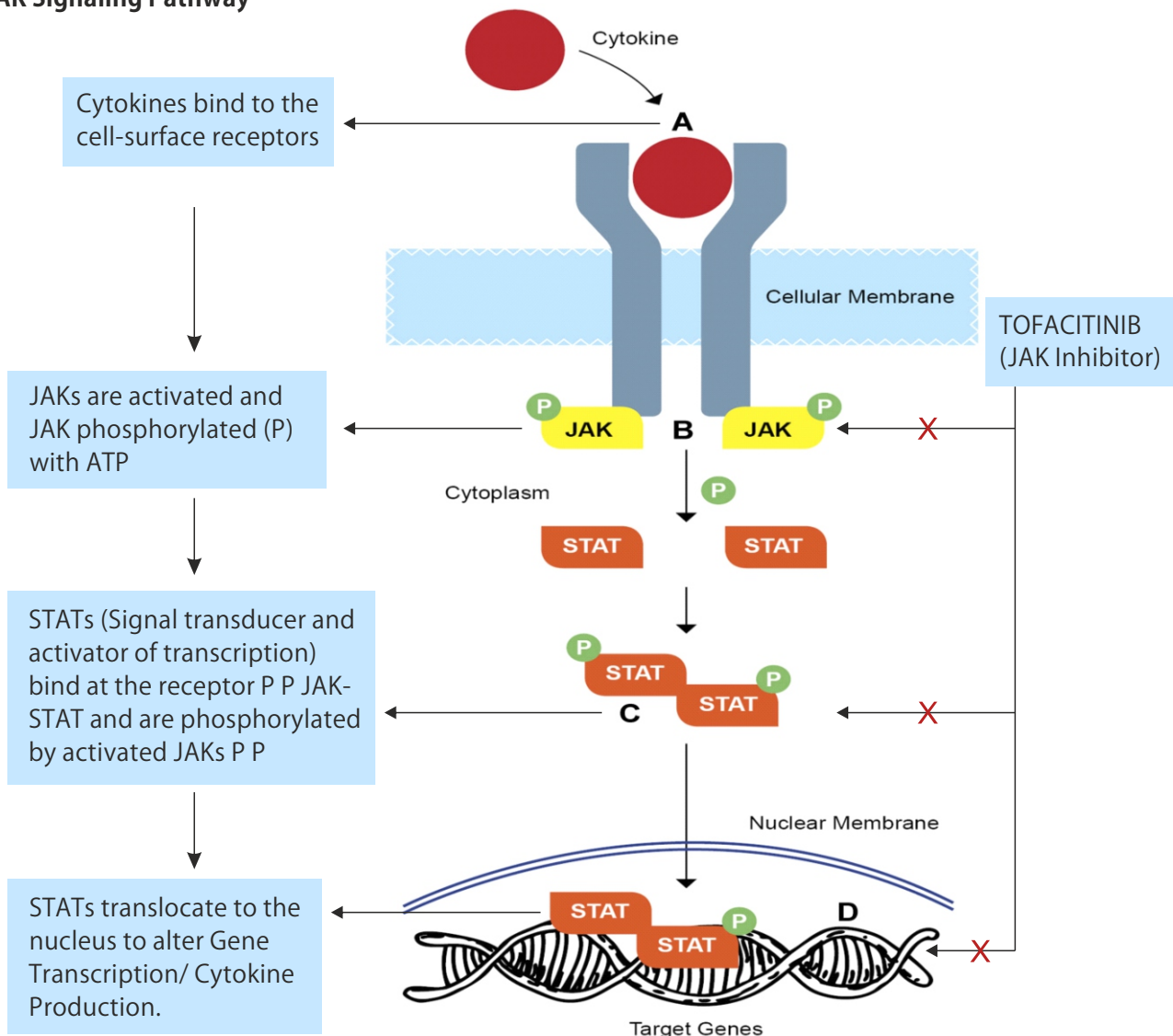
Ulcerative Colitis (UC) is an idiopathic immune-mediated inflammatory bowel disease of the colon, most commonly afflicting adults aged 30 - 40 years and resulting in disability. The overall incidence and prevalence of UC is reported to be 1.2–20.3 and 7.6–245 cases per 100,000 persons/year respectively.<sup>1</sup>

### Janus Kinase (JAKs)

Janus kinases (JAKs) are a pivotal family of protein tyrosine kinase (PTK). They are receptor-associated intracellular tyrosine kinase proteins that play a pivotal role in cytokine receptor signaling. The JAKs family comprises JAK1, JAK2, JAK3 and TYK2.<sup>2</sup>

### Role of JAK Signaling and Inhibition Pathway in Ulcerative Colitis<sup>3</sup>

#### JAK Signaling Pathway



## Clinical Evidence<sup>4</sup>

### Tofacitinib as Induction and Maintenance Therapy for Ulcerative Colitis

**Aim :** To evaluate the efficacy of tofacitinib as induction and maintenance therapy in Ulcerative colitis.

#### Study design :

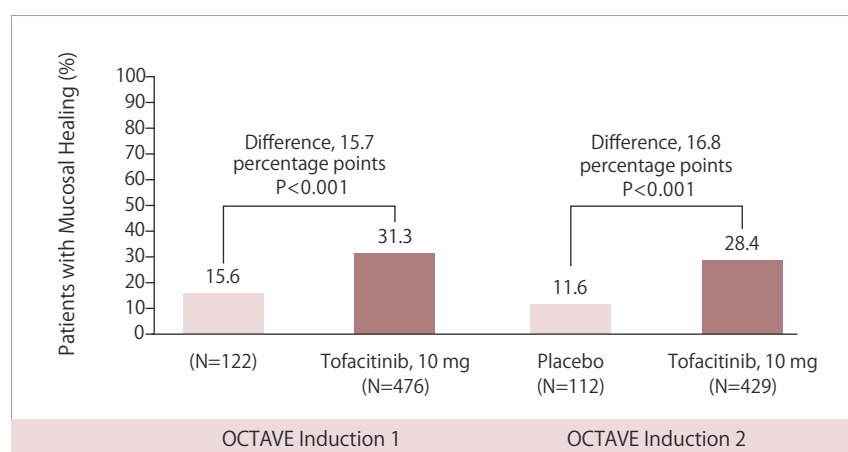
A. Total no of patients : 1732

B. Dose and Duration :

- 1) OCTAVE Induction 1 and 2 (8 weeks) (Induction therapy 10 mg BID)
- 2) OCTAVE Sustain (52 weeks) (Maintenance therapy either 5 mg or 10 mg BID)

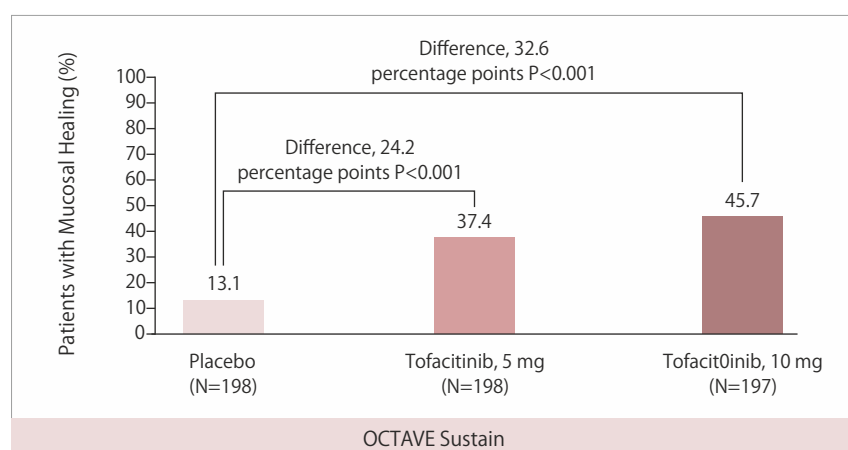
#### Study Outcomes (Result) :

A. Mucosal Healing in OCTAVE INDUCTION 1 and OCTAVE INDUCTION 2 :



At week 8 Tofacitinib 10 mg group shows significant improvement in mucosal healing as compared to placebo in both OCTAVE Induction 1 and 2 trial [p = < 0.001]

A. Mucosal Healing in OCTAVE SUSTAIN :



At week 52 Tofacitinib 5 mg and 10 mg group shows significant improvement in mucosal healing as compared to placebo in the OCTAVE Sustain trial [p = < 0.001].

#### Conclusion :

Tofacitinib, a novel JAK inhibitor, is more effective as induction and maintenance therapy in moderately to severely active Ulcerative colitis than placebo.

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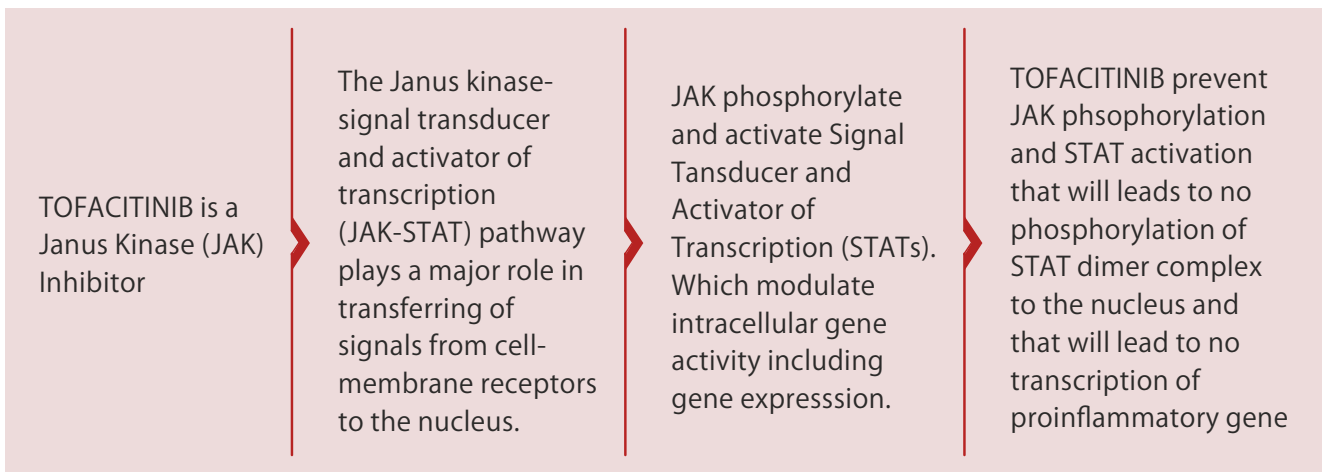
### Description

Each film coated tablet contains Tofacitinib Citrate equivalent to Tofacitinib 5 mg.

### Indication

It is indicated in the treatment of Ulcerative Colitis.

### Mechanism of Action



### Key Features

- 1.Tofacitinib is an oral small molecule pan-Janus kinase (JAK) inhibitor.
- 2.Tofacitinib inhibits JAK1 and JAK3 with 5–100 fold selectivity over JAK2
- 3.Tofahenz can reduce symptoms, including rectal bleeding and stool frequency, in as early as 2 weeks.
- 4.Tofahenz can improve the appearance of the intestinal lining.
- 5.Tofahenz can provide long lasting steroid-free remission.

### Dosage

The recommended dose is 10 mg twice a day for 8 weeks followed by 5 mg twice a day.

References : 1. Drug Design, Development and Therapy 2019;13 4091–4105 | 2. Disease-a-Month Volume 65, Issue 12, December 2019,100851  
3. Seif et al. Cell Communication and Signaling (2017) 15:23 | 4. The New England Journal of Medicine, MAY,2017

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