

FDA approves first pill to treat moderate-to-severe Crohn's disease

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Patients with Crohn's disease have a new treatment option, following

U.S. Food and Drug Administration approval of a pill called Rinvoq (upadacitinib).

Rinvoq is meant to treat adults with moderately to severely active Crohn's disease who have not had success with TNF ([tumor necrosis factor](#)) blockers. The daily pill is the first oral treatment for this group of patients.

Crohn's is a chronic inflammatory bowel disease. It causes inflammation in any part of the digestive tract, typically affecting the [small intestine](#) and the beginning of the large intestine. Common symptoms include diarrhea, cramping, stomach pain and weight loss.

The [medication](#) was previously approved for several other conditions, including eczema, [rheumatoid arthritis](#), [psoriatic arthritis](#) and [ulcerative colitis](#), according to the website of pharmaceutical company AbbVie.

Researchers evaluated its safety and effectiveness in two randomized trials in 857 patients with the disease. Participants received either 45 mg of Rinvoq or a placebo daily for 12 weeks.

More patients treated with the medication achieved remission than those treated with the placebo, the [FDA](#) said in a news release. Also, more people treated with the medication had improvement in intestinal inflammation, which was assessed with a colonoscopy.

The FDA also assessed Rinvoq as a maintenance treatment, evaluating 343 patients who had responded to the 12 weeks of medication. This group received 15 mg or 30 mg once daily or a placebo for a year. More of those on the maintenance treatment achieved remission and reduced intestinal inflammation than those on the placebo.

Side effects of the medication were upper respiratory tract infections,

anemia, fever, acne, herpes zoster and headache.

The drug is not recommended for use with other Janus kinase (JAK) inhibitors, biological therapies for Crohn's disease or with strong immunosuppressants including azathioprine and cyclosporine.

Among the risks are serious infections, death, cancer, major adverse cardiovascular events and thrombosis (blood clot).

Patients should take 45 mg of Rinvoq once daily for 12 weeks and then start a 15 mg maintenance dose. A higher 30 mg maintenance dose can be considered for [patients](#) with refractory, severe or extensive Crohn's disease, according to the FDA.

More information: The U.S. National Institutes of Health has more on [Crohn's disease](#).

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