

## Safety Alert

01-2024

### IDACIO

EDA performs label update to include the following:

1. **What Idacio is and what it is used for**

Ulcerative colitis in adults and children

Ulcerative colitis is an inflammatory disease of the ~~bowe~~large intestine.

Idacio is used to treat moderate to severe ulcerative colitis in adults and children aged 6 to 17 years . If you have ulcerative colitis you ~~will~~may first be given other medicines. If these medicines do not work well enough, you will be given Idacio to reduce the signs and symptoms of your disease.

3. **How to use Idacio**

Children and adolescents from 6 to 17 years of age weighing 40 kg or more	Initial dose of 160 mg (as four 40 mg injections in one day or two 40 mg injections per day for two consecutive days), followed by 80 mg (as two 40 mg injections in one day) two weeks later.  Thereafter, the usual dose is 80 mg every other week.	Patients who turn 18 years of age while on 80 mg every other week, should continue their prescribed dose.
Children and adolescents from 6 to 17 years of age weighing less than 40 kg	Initial dose of 80 mg (as two 40 mg injections in one day), followed by 40 mg (as one 40 mg injection) two weeks later.  Thereafter, the usual dose is 40 mg every other week.	Patients who turn 18 years of age while on 40 mg every other week, should continue their prescribed dose.

4. **Possible side effects**

weight gain (for most patients, the weight gain was small).

**Background:**

Idacio is intended for the treatment of the following inflammatory diseases:

- rheumatoid arthritis,
- polyarticular juvenile idiopathic arthritis,
- enthesitis-related arthritis,
- ankylosing spondylitis,
- axial spondyloarthritis without radiographic evidence of ankylosing spondylitis,
- psoriatic arthritis,
- psoriasis,
- hidradenitis suppurativa,
- Crohn's disease,
- ulcerative colitis and
- non-infectious uveitis

**References:**

[https://www.ema.europa.eu/en/documents/product-information/idacio-epar-product-information\\_en.pdf](https://www.ema.europa.eu/en/documents/product-information/idacio-epar-product-information_en.pdf)