

## Safety Alert

01-2024

### Remicade

EDA performs label update to include the following:

#### 2. What you need to know before you use Remicade

##### Warnings and precautions

If you received Remicade while you were pregnant, your baby may also be at higher risk for getting an infection as a result of receiving a live vaccine during the first year of life. It is important that you tell your baby's doctors and other healthcare professionals about your Remicade use so they can decide when your baby should receive any vaccine, including live vaccines such as the BCG vaccine (used to prevent tuberculosis).

#### 4. Possible side effects

##### Uncommon: may affect up to 1 in 100 people

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

#### Background:

Remicade belongs to a group of medicines called 'TNF blockers'. It is used in adults for the following inflammatory diseases:

- Rheumatoid arthritis
- Psoriatic arthritis
- Ankylosing spondylitis (Bechterew's disease)
- Psoriasis.

Remicade is also used in adults and children 6 years of age or older for:

- Crohn's disease
- Ulcerative colitis.

#### References:

EMA:

<https://www.ema.europa.eu/en/documents/product-information/remicade-epar-product->