

Safety Alert

11-2023

Darzalex

EDA performs label update to include the following:

4. Possible side effects

Rare (may affect up to 1 in 1000 people):

- severe allergic reaction which may include a swollen face, lips, mouth, tongue or throat, difficulty swallowing or breathing or an itchy rash (hives). See section 2.
- eye pain
- blurred vision

Common (may affect up to 1 in 10 people):

- COVID-19.

Background:

DARZALEX is a cancer medicine that contains the active substance daratumumab. It belongs to a group of medicines called “monoclonal antibodies”. Monoclonal antibodies are proteins that have been designed to recognise and attach to specific targets in the body. Daratumumab has been designed to attach to specific cancer cells in your body, so that your immune system can destroy the cancer cells.

References:

EMA:

https://www.ema.europa.eu/en/documents/product-information/darzalex-epar-product-information_en.pdf