



## **PRODUCTS WITH ADDITIONAL RISK MINIMIZATION MEASURES (RMM)**

### **Etanercept (Enbrel)**

#### ***Introduction***

Etanercept (Enbrel) is indicated for the underlisted:

- Rheumatoid arthritis
- Psoriatic arthritis
- Ankylosing spondylitis
- Non-radiographic axial spondylarthritis
- Plaque psoriasis
- Juvenile idiopathic arthritis

#### ***Safety Concern:***

Congestive heart failure in adult subjects is an identified important risk.

#### ***Additional Risk Minimization Measure (aRMM)***

Patient card to be distributed to patient by etanercept prescribing physicians aimed at reducing the risk of serious infections and congestive heart failure and ensuring the traceability of Enbrel drug product.

The card will provide the following important safety information to the patients:

- That Etanercept treatment may increase the risk of infection and congestive heart failure in adults.
- Signs or symptoms of these safety concerns and when to seek attention from a healthcare professional.
- Instructions to record the brand name and batch number of the medication to ensure traceability.
- Contact details of the Prescriber.

EMBREL PATIENT CARD -

[http://fdaghana.gov.gh/img/NEAR%20Enbrel\\_Patient%20Card%20July%202021%20Final%20Version.pdf](http://fdaghana.gov.gh/img/NEAR%20Enbrel_Patient%20Card%20July%202021%20Final%20Version.pdf)