



OFFICE of the DEPUTY PRIME MINISTER
MINISTRY for HEALTH
15, PALAZZO CASTELLANIA, MERCHANTS STREET, VALLETTA, MALTA

DH CIRCULAR No. 96/2017
DH 1373/2017

21st November 2017

Attention All: Consultants
Medical Officers
Pharmacists
Pharmacy Technicians
Nurses

Re: Biosimilar Etanercept 50mg Pre-Filled Pen

Etanercept is a biological drug that treats autoimmune diseases by inhibiting tumour necrosis factor (TNF). Etanercept 50mg pre-filled pens are listed on the Government Formulary and can be prescribed by Consultant Rheumatologists for Stage II or III Rheumatoid Arthritis as per protocol 66.

Apart from the original etanercept preparation Enbrel[®], the biosimilar Benepali[®] has now also been procured. There will therefore be two brands of etanercept 50mg pre-filled pens available within the Government Health Services. These will be dispensed as follows:

- Newly diagnosed patients with Stage II or III Rheumatoid Arthritis eligible for treatment with etanercept as per protocol 66 (Annex 1) will be provided with the biosimilar Benepali[®].
- Patients who are already on the originator etanercept Enbrel[®] will continue to be provided with Enbrel[®] unless the Consultant Rheumatologist decides to switch to biosimilar Benepali[®].

Prescriptions and MAS permits are to include the brand name and dispensing is to be done according to the brand name stated on the MAS permit.

For your attention please.

Dr. Denis Vella Baldacchino
Chief Medical Officer

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Etanercept 25mg and 50mg Injections

Prescriber Criteria: Consultant Rheumatologist

Out-patient and In-patient use:

1. Rheumatoid Arthritis

For patients with Stage II or III Rheumatoid Arthritis

- not responding to other traditional disease modifying anti-rheumatic drugs
OR
- who have experienced allergies or other side effects to other traditional disease modifying anti-rheumatic drugs
OR
- when such therapies are contra-indicated (eg. methotrexate being contra-indicated in patients with liver disease or cyclosporine A being contra-indicated in patients with hypertension).

Duration of Approval:

1 year

Kindly note that the brand Benepali® will be provided to any newly started patient on Etanercept 50mg Injection and for those patients whom the Consultant decides to switch over from Enbrel®.