



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

**DH Circular 62/2020**  
DH 1194/2019

2<sup>nd</sup> September 2020

**Attention All:** Consultants  
Medical Officers  
Pharmacists  
Pharmacy Technicians  
Nurses

**Re: Adalimumab 40mg Solution for Injection**

It is being brought to your attention that Adalimumab 40mg solution for injection in prefilled syringes for subcutaneous use is now available on the Government Formulary List.

Adalimumab 40mg solution for injection can be prescribed by Consultant Dermatologist, Consultant Gastroenterologist, Consultant Paediatrician and Consultant Rheumatologist as per protocol 307 attached (Annex 1).

For your attention please.

Dr Denis Vella Baldacchino  
Chief Medical Officer

## **Adalimumab 40mg Solution for Injection**

**Prescriber Criteria:** Consultant Dermatologist  
Consultant Gastroenterologist  
Consultant Paediatrician  
Consultant Rheumatologist

### **In-patient use:**

1. Inflammatory Bowel Diseases
2. Psoriasis
3. Rheumatoid Arthritis
4. Spondyloarthritis

#### **1. IBD - Crohn's Disease:**

Treatment of moderately to severely active Crohn's disease, in patients who have not responded despite a full and adequate course of therapy with a corticosteroid and/or an immunosuppressant; or who are intolerant to or have medical contraindications for such therapies.

#### ***IBD - Ulcerative Colitis:***

Treatment of moderately to severely active ulcerative colitis in patients who have had an inadequate response to conventional therapy including corticosteroids and 6-MP or AZA, or who are intolerant to or have medical contraindications for such therapies.

#### **2. Extensive Psoriasis:**

Treatment of moderate to severe plaque psoriasis in adult patients who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapy including cyclosporine, methotrexate or PUVA.

#### ***Psoriatic Arthritis:***

Treatment of active and progressive psoriatic arthritis in adults when the response to previous disease-modifying anti-rheumatic drug therapy has been inadequate.

#### **3. Rheumatoid Arthritis:**

In combination with methotrexate, for:

- the treatment of Stage II or III Rheumatoid Arthritis in patients when the response to disease-modifying anti-rheumatic drugs (DMARDs) including methotrexate has been inadequate
- the treatment of severe, active and progressive rheumatoid arthritis in patients not previously treated with methotrexate.

As monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate.

**4. *Spondyloarthritis***

Treatment of patients with severe spondyloarthritis who have had an inadequate response to, or are intolerant to conventional therapy.

**Duration of Approval:**

2 years