



MINISTRY for ENERGY and HEALTH
15, PALAZZO CASTELLANIA, MERCHANTS STREET, VALLETTA, MALTA

DH CIRCULAR No. 58/2015
DH 660/2015

12th February 2015

Attention All: Consultants
Medical Doctors
Pharmacists
Pharmacy Technicians
Nurses

Re: Mesalazine 400mg Modified Release Tablets

Mesalazine is an anti-inflammatory drug structurally related to the salicylates and active in inflammatory bowel disease; it is considered to be the active moiety of sulfasalazine. Mesalazine is thought to act locally on the inflamed intestinal tissue, rather than systemically.

Mesalazine 400mg MR tablets are indicated in:

- Ulcerative Colitis - for the treatment of mild to moderate acute exacerbations; and for the maintenance of remission.
- Crohn's ileo-colitis - for the maintenance of remission.

Patients suffering from Inflammatory Bowel Disease are entitled to Mesalazine 400mg MR tablets. Consultant Gastroenterologists, Consultant Surgeons and Consultant Paediatricians can prescribe Mesalazine 400mg MR tablets.

Kindly note that currently, **two** formulations of mesalazine 400mg Modified Release tablets are available on the Government Formulary List:

1. Mesalazine 400mg Modified Release Tablets -
A formulation which releases its active ingredient in the terminal ileum and colon. It is currently available as Pentacol® 400mg MR tablets.
2. Mesalazine 400mg Modified Release Tablets (Active ingredient released at pH ≥ 7) -
A formulation which releases its active ingredient in the terminal ileum and colon at pH equal to or above 7. This item will be protocol regulated as per protocol 124 (Annex I) and it is to be reserved for patients in whom Pentacol® is ineffective, and require a formulation that its active ingredient is released at pH ≥ 7 . Examples include: Asacol®, Ipocol® and Octasa®.

These formulations should not be confused with Mesalazine (Pentasa®) 500mg Slow Release Tablets, which is a formulation that provides a time-dependent release of mesalazine.

For your attention please.

Dr. Denis Vella Baldacchino
Chief Medical Officer

Mesalazine 400mg Slow Release Tablets (Active Ingredient Released at pH \geq 7)

Prescriber Criteria: Consultant Gastroenterologist
Consultant Paediatrician
Consultant Surgeon

Out-patient and In-patient Use:

1. Inflammatory Bowel Disease

To be reserved for patients in whom Pentacol® is ineffective and require a formulation that its active ingredient is released at pH \geq 7.

Duration of Approval:

1 year