

DIPARTIMENT TAS-SAHHÀ



DEPARTMENT OF HEALTH

MALTA

L-Uffiċċju tal-Uffiċjal Mediku Ewlieni

Office of the Chief Medical Officer

DH CIRCULAR No.106/2014

DH 1419/2014

25 March 2014

Attention All: Consultants
Medical Officers
Pharmacists
Pharmacy Technicians
Nurses

Re: Fingolimod 0.5mg Capsules

Fingolimod 0.5mg capsules have been recommended by the Government Formulary List Advisory Committee for introduction onto the Government Formulary List.

Fingolimod capsules are protocol-regulated with protocol number 70 (attached) and can be prescribed by Consultant Neurologists.

Fingolimod is a sphingosine 1-phosphate receptor modulator to be used as a single disease modifying therapy in highly active relapsing remitting multiple sclerosis for adult patient groups as per protocol.

Fingolimod 0.5mg capsules have been procured and are now available for use.

For your attention please

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A/Chief Medical Officer

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Version 03

Nov 11

Fingolimod 0.5mg Capsules

Prescriber Criteria: Consultant Neurologist

Out-patient and In-patient use:

1. Multiple Sclerosis

Single disease modifying therapy in highly active relapsing remitting multiple sclerosis for the following adult patient groups:

- Patients with high disease activity despite treatment with a beta-interferon.

These patients may be defined as those who have failed to respond to a full and adequate course (normally at least one year of treatment) of beta-interferon. Patients should have had at least 1 relapse in the previous year while on therapy, and have at least 9 T2-hyperintense lesions in cranial MRI or at least 1 Gadolinium-enhancing lesion. A “non-responder” could also be defined as a patient with an unchanged or increased relapse rate or ongoing severe relapses, as compared to the previous year.

or

- Patients with rapidly evolving severe relapsing remitting multiple sclerosis defined by 2 or more disabling relapses in one year, and with 1 or more Gadolinium enhancing lesions on brain MRI or a significant increase in T2 lesion load as compared to a previous recent MRI.

Duration of Approval:

1 year