

MINISTERU TAS-SAĦĦA



MINISTRY FOR HEALTH

Direttorat tat-Tabib Ewlieni tal-Gvern

Office of the Chief Medical Officer

DH CIRCULAR 81/2017

DH 1503/2015

4th October 2017

Attention All: Consultants
Medical Officers
Pharmacists
Pharmacy Technicians
Nurses

Re: Everolimus 5mg and 10mg Tablets and Dabrafenib 75mg Capsules

In line with Government's commitment to increase the availability of free cancer treatment, two new medicines are being introduced on the Government Formulary List.

It is being brought to your attention that Everolimus 5mg and 10mg tablets and Dabrafenib 75mg Capsules are now available **with immediate effect** for in-patient and out-patient use.

Everolimus 5mg and 10mg tablets can be prescribed by Consultant Oncologists for advanced breast cancer and advanced renal cell carcinoma, and are protocol regulated by protocol 302 (Annex 1).

Dabrafenib 75mg capsules can be prescribed by Consultant Oncologists for advanced melanoma and is protocol regulated by protocol 303 (Annex 2).

For your attention please.

Dr. Denis Vella Baldacchino
Chief Medical Officer

Everolimus 5mg and 10mg Tablets

Part A

Prescriber Criteria: Consultant Oncologist

Out-patient and In-patient use:

1. Malignant Diseases
 - Breast Cancer

To be used for the treatment of hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2) negative advanced breast cancer, in combination with exemestane, in postmenopausal women without symptomatic visceral disease after recurrence or progression following a non-steroidal aromatase inhibitor.

Duration of approval:

1 year

Part B

Prescriber Criteria: Consultant Oncologist

Out-patient and in-patient use:

1. Malignant Diseases
 - Renal Cell Carcinoma

For patients with advanced/metastatic renal cell carcinoma whose disease has progressed on or after treatment with VEGF-targeted therapy.

Duration of approval:

6 months

Dabrafenib 75mg Hard Capsules

Prescriber Criteria: Consultant Oncologist

Out-patient and In-patient use:

1. Malignant Diseases

For the treatment of adult patients with advanced (unresectable or metastatic) melanoma with a BRAF V600 mutation.

Duration of Approval:

1 year