



DIRECTORATE FOR PHARMACEUTICAL POLICY AND MONITORING
Strategy and Sustainability Division
Ministry for Social Policy

12/10/2009

DH Circular No.252/2009
DH 3983/2009

Attention all Consultants
Medical Officers
Pharmacists
Nursing Officers

Re : Zoledronic Acid preparations

Kindly note that there are **two** parenteral preparations of zoledronic acid available on the Government Formulary for different clinical indications, in line with the SPCs for both products. Zoledronic acid 50mg injections (Aclasta®) for the treatment of Paget's Disease can be prescribed by Consultant Rheumatologists as per protocol number 229, whilst zoledronic acid 4mg injections (Zometa®) prescribed by Consultants, will be reserved for oncology patients suffering from malignant hypercalcaemia, bone secondaries and myeloma with osteolysis as per protocol number 228.

The zoledronic acid preparations will in part, replace the use of disodium pamidronate injections for the above mentioned indications. Hence the protocol for pamidronate has also been amended.

The protocols are hereby attached for ease of reference.

For your attention please.

Regards,

Dr N Azzopardi Muscat
Director General SS

Pamidronate 15mg vials

Part A

Prescriber criteria : Consultants

Clinical Indications :

- Non-malignant hypercalcaemia due to hyperparathyroidism.
- Osteoporosis secondary to a schedule V condition (unlicensed indication).

Conditions qualifying patients for drug :

Patients suffering from one of the above mentioned conditions.

Duration of approval : 1 year.

Part B

Prescriber criteria : Consultant diabetologist and endocrinologist

Indications: Acute Charcot's joints as a complication of Diabetes mellitus

Conditions qualifying patients for treatment : Patients with above mentioned disease

Investigations required prior to starting treatment : Foot X-Ray, bone scan

Treatment evaluation / Clinical parameters : Collagen cross links; foot warmth

Frequency of review : To be approved for cycles of 6 months per foot

Zoledronic acid 4mg vials

Prescriber Criteria : Consultants

Clinical Indications : Oncology patients with -

- Malignant hypercalcaemia and widespread malignant bone deposit
- Extensive bone secondaries who do not respond to endocrine or cytotoxic therapy, or to localised radiotherapy
- Myeloma with extensive generalised osteolysis

Condition qualifying patients for drug : Patients suffering from one of the above mentioned conditions

Duration of Approval : 1 year

Zoledronic acid 5mg vials

Prescriber Criteria : Consultant Rheumatologist

Clinical Indications : Paget's Disease

Duration of Approval : 1 year