

Drug Alert

CLASS 3 MEDICINES RECALL Action Within 5 Days

Date: 26th January 2021 Our Ref: MDR017-01/2021

Dear Healthcare Professional,

Farmarosib SRL

Bromazepam Arena 3mg tablets (Bromazepam)

(AA1161/00201)

Batch Number	Expiry Date	Pack Size	First Distributed
1240520	27 th May 2023	x 40 tablets	18 th June 2020

Following a notification received from a retail pharmacy, a decision was taken to recall Bromazepam Arena 3mg tablets with batch number 1240520.

The reason for this recall is that missing tablets (30 tablets instead of 40) were found in a considerable number of the packs received by the pharmacist within the retail pharmacy.

This recall has been classified as a Class III recall down to pharmacy level and will be under the supervision of the Medicines Authority. Patients will be supplied with an alternative batch of the product.

Yours faithfully

Muriel Giglio Senior Medicines Inspector Malta Medicines Authority

Medicines Authority Distribution Licensing Authority Superintendent of Public Health