

Drug Alert

CLASS 2 MEDICINES RECALL

Action Within 48 Hours

Date: 27th December 2018

Our Ref: MDR 9-12/18

Dear Healthcare Professional,

(Neofarma Pharmaceuticals Ltd.)

Voltaren 50mg tablets (diclofenac sodium)

PI908/00201A

Diovan 80mg tablets (valsartan)

PI908/05001A

Diovan 160mg tablets (valsartan)

PI908/05002A

Voltaren 50mg tablets

Batch Number	Expiry Date	Pack Size	First Distributed
KO543	March 2020	x 20 tablets	19th September 2017
KA761	July 2020	x 20 tablets	19 th December 2017
KA853	July 2020	x 20 tablets	17 th April 2018
KC532	September 2020	x 20 tablets	20 th March 2018
KD142	October 2020	x 20 tablets	12 th June 2018
KE342	December 2020	x 20 tablets	12 th June 2018
KF586	March 2021	x 20 tablets	2 nd October 2018

Diovan 80mg tablets

Batch Number	Expiry Date	Pack Size	First Distributed
BAX20	January 2021	x 28 tablets	20 th November 2018
BT850	March 2020	x 28 tablets	20 th October 2017
BU456	April 2020	x 28 tablets	27 th February 2018

Diovan 160mg tablets

Batch Number	Expiry Date	Pack Size	First Distributed
BC895	January 2019	x 28 tablets	2 nd August 2016
BE720	February 2019	x 28 tablets	14 th March 2018
BE721	March 2019	x 28 tablets	28 th February 2017
BK822	August 2019	x 28 tablets	25 th April 2017
BU362	April 2020	x 28 tablets	17 th March 2018

Under the supervision of the Medicines Authority, the licensed wholesale dealer Neopharma Pharmaceuticals Ltd. is initialising a recall of the above product batches. The reason for this recall is that the patient information leaflet and label of the packs are not in line with the current PI conditions. The products will be recalled from the market, up to pharmacy level, and will be repackaged with the correct PIL and label. Please note that this recall is strictly related to repackaging.

Yours faithfully

Muriel Giglio
Senior Medicines Inspector