

## Drug Alert

### CLASS 2 MEDICINES RECALL UP TO WHOLESALE DEALER AND PHARMACY

Action Within 48 hours

Date:30/9/2021

Our Ref: MDR24-09/2021

Dear Healthcare Professional,

**Pfizer Hellas S.A.**

**Distributor: Vivian Corporation Ltd.**

**Champix 0.5mg and 1 mg film coated tablets      MA number: EU/1/06/36**

**(Varenicline tartrate)**

Further to the recommendation of the CHMP, dated 16 September 2021, and the Maltese Medicines Authority request, Pfizer is recalling all product lots with N-nitroso-varenicline (NNV) levels above the EMA determined acceptable intake (AI).

The recall is a Class 2 recall up to wholesale dealer and pharmacy level. It is being conducted by the distributor, Vivian Corporation Ltd. under the supervision of the Malta Medicines Authority.

The recall is for the following Champix (varenicline tartrate) 0.5 mg and 1 mg film coated tablets lots currently within expiry on the Maltese market:

Product Name	Batch Number	Expiry Date	Pack Size	First Distributed
Champix 0.5mg/1mg	00021535	06-2022	x11/x14 tablets	18 <sup>th</sup> March 2020
Champix 0.5mg/1mg	EH7896	12-2022	x11/x14 tablets	09 <sup>th</sup> June 2021
Champix 1mg	00022123	08-2022	x28 tablets	08 <sup>th</sup> April 2020
Champix 1mg	EH5970	02-2023	x28 tablets	15 <sup>th</sup> March 2021

Yours faithfully

Eloise Buontempo  
Senior Medicines Inspector  
Malta Medicines Authority

Medicines Authority Distribution (if applicable):  
Licensing Authority  
Superintendent of Public Health