

## Drug Alert

### CLASS 4 MEDICINES DEFECT INFORMATION

#### Caution in Use

Date: 22<sup>nd</sup> August 2016

Our Ref: MDR 01-8/16

Dear Healthcare Professional,

**Janssen-Cilag Pharmaceutical S.A.C.I obo AM Mangion Ltd**

**Pariet tablets Gastro-Resistant 10mg - MA018/01901**

**Pariet tablets Gastro-Resistant 20mg - MA018/01902**

**(Rabeprazole sodium)**

Product Name	Batch Number	Expiry Date	Pack Size	First Distributed
Pariet 10mg	EISSJ00	08/2016	x14 tablets	10/07/2015
Pariet 10mg	FBSS500	01/2017	x14 tablets	14/08/2015
Pariet 10mg	FESSQ00	04/2017	x14 tablets	22/03/2016
Pariet 10mg	FESSQ01	04/2017	x14 tablets	05/05/2016
Pariet 10mg	FJSSB01	09/2017	x14 tablets	28/07/2016
Pariet 20mg	FESSJ00	04/2017	x14 tablets	05/11/2015
Pariet 20mg	FHSSH00	07/2017	x14 tablets	10/03/2016
Pariet 20mg	FKSSA00	10/2017	x14 tablets	03/08/2016
Pariet 20mg	FKSSD00	10/2017	x14 tablets	21/07/2016

Following the receipt of a complaint by the Medicines Authority and an investigation by AM Mangion Ltd (local representatives of Janssen-Cilag Pharmaceutical S.A.C.I), please be advised of an error in the Pariet tablets gastro-resistant Patient Information Leaflet (PIL). The error affects various batches of both Pariet strengths i.e.10mg tablets and 20mg tablets (see above).

The error occurred in Section 6 of the PIL which should read as below rather than as printed on the PIL:

- Each Pariet 10mg tablet contains 10mg of the active substance rabeprazole sodium
- Each Pariet 20mg tablet contains 20mg of the active substance rabeprazole sodium

Pharmacists are requested to bring this to the attention of their patients prior to dispensing any of the affected Pariet tablets batches.

For any enquiries please contact AM Mangion Ltd on 23976000 or email [rp@ammangion.com](mailto:rp@ammangion.com).

Yours faithfully

Karl De Marco  
Medicines Inspector

Medicines Authority Distribution (if applicable): None