



11th August 2011

Clare Hedges
MHRA
Room 3-0,
151 Buckingham Palace Road,
London, SW1W 9SZ

Dear Clare

CONSULTATION DOCUMENT: ARM 77 PARIET PHARMACY 10MG GASTRO-RESISTANT TABLETS - REQUEST TO RECLASSIFY FROM POM TO P

Response from the Guild of Healthcare Pharmacists

Thank you for the opportunity to respond to this consultation. The Guild of Healthcare Pharmacists represents UK wide around 4,000 pharmacists including the majority of hospital pharmacists, pharmacists employed by NHS Primary Care organisations and pharmacists employed by other public bodies such as Prisons and the Care Quality Commission. The Guild is part of the health sector of the union Unite.

The rationale for the reclassification of Pariet Pharmacy 10mg Gastro-resistant tablets from Prescription Only Medicine to Pharmacy Only put forward by Eisai Limited appears to be well reasoned and acceptable. Although we do not feel that the proposed reclassification poses any significant safety/risk issues for the public or any concerns for Pharmacists, we wish to propose the following changes (highlighted in red text) to the patient information leaflet, which, in our view would enhance the information provided:

1. What Pariet is and what it is used for

We feel that it would be useful to indicate to the patient the relative usefulness of PPIs and also to provide additional information regarding differential diagnosis. We therefore suggest that this reflected in the description as follows:

Pariet Pharmacy tablets contain the active ingredient rabeprazole sodium. This belongs to a group of medicines called 'Proton Pump Inhibitors' (PPIs). **PPIs are generally accepted as being amongst the most effective medicines for the relief of heartburn.** They work by lowering the amount of acid that your stomach produces. Pariet Pharmacy tablets give relief of heartburn and acid reflux (when acid and food from your stomach escapes into your food pipe).

Heartburn is often confused with the first symptoms of a heart attack. You should seek emergency medical attention if you have chest pain or heavy feeling, pain spreading to the arm or shoulder, nausea,

President: David Miller

Professional Secretary: Barry Corbett

Email: barry_corbett@hotmail.com

Website: www.ghp.org.uk

sweating, and general ill feeling.

2. Before you take Pariet Pharmacy

The SmPC states “a risk of cross-hypersensitivity reaction with other proton pump inhibitor or substituted benzimidazoles cannot be excluded” and there is evidence of cross-sensitivity between all PPIs. We therefore suggest changing the following sub-section so that it lists the other PPIs as patients may not be fully aware of this group of medicines:

Change:

Do not take Pariet Pharmacy if:

- You are allergic (hypersensitive) to rabeprazole sodium, or any of the other ingredients of Pariet Pharmacy (listed in Section 6 below)

To:

- You are allergic (hypersensitive) to rabeprazole sodium or to any other PPI – esomeprazole (Nexium), lansoprazole (Zoton), omeprazole (Losec), pantoprazole (Protium), or any of the other ingredients of Pariet Pharmacy (listed in Section 6 below)

3. How to take Pariet Pharmacy

We suggest the following changes to the introduction:

Always take Pariet Pharmacy exactly as this leaflet tells you. **Do not change your dose at any time.**

Taking this medicine

- Swallow your tablets whole with a drink of water. Do not crush or chew the tablets.

We suggest the following additions:

“Swallow your tablets whole with a **full glass** of water. Do not crush, **break** or chew the tablets **as they are specially coated to protect them from acid in your stomach. Absorption of the medicine only begins after the tablet leaves the stomach.**”

- You may not get relief of your symptoms with the first dose of Pariet Pharmacy.

We suggest the following addition:

“You may not get relief of your symptoms with the first dose of Pariet Pharmacy. **Relief may occur after a day or so of starting treatment and this will increase to a maximum effect after 3 to 4 days. If you require immediate relief of your symptoms talk to your pharmacist for advice on taking a simple antacid or antacid/alginate at the same time for the first few days of treatment, if necessary.**

If you forget to take Pariet Pharmacy

- If you forget to take a dose, take it as soon as you remember. However, if it almost time for your next dose, skip the missed dose and continue as usual.

We suggest the following additions:

If you forget to take a dose, take it as soon as you remember. However, if it almost time for your next dose **wait until then to take the medicine and** skip the missed dose and **then** continue as usual. **Do not take extra medication to make up the missed dose.**

4. Possible side effects

- Allergic reactions – the signs may include: sudden swelling of your face, difficulty.....

We suggest changing to:

- Allergic reactions – the signs may include: sudden swelling of your face, lips, tongue or throat, difficulty.....

Finally, we also suggest the inclusion of the following statement, either under section 5 or section 6:

Never share your medicines with others, and use this medicine only for the condition stated in this leaflet.

We hope these comments are of assistance. Our reply may be made freely available.

Yours faithfully

Barry Corbett
Professional Secretary
Guild of Healthcare Pharmacists

Graeme Richardson
Chair of Practice
Guild of Healthcare Pharmacists