

# Shortage of Enalapril 5mg tablets

Date: 17<sup>th</sup> March 2021

## Description of product affected

- Enalapril is an angiotensin-converting enzyme inhibitor (ACE inhibitor) licensed for the treatment of hypertension, symptomatic heart failure, and prevention of symptomatic heart failure in patients with asymptomatic left ventricular dysfunction. Enalapril is given once daily in the treatment of hypertension.<sup>1</sup>
- In Cambridgeshire and Peterborough, enalapril is considered a 2<sup>nd</sup> line formulary choice where lisinopril or ramipril (capsules) are unsuitable.

## Background

Current availability:

- Enalapril 5mg tablets will be out of stock in March and April 2021.
- There is not enough supply of the 2.5mg strength to bridge the gap for all patients.
- There is stock of 10mg strength available.

## Alternative agents and management options

- In the first instance, we would recommend that several local pharmacies and dispensaries are contacted by telephone to ascertain if the patient can be maintained on their usual treatment of enalapril 5mg tablets.
- As usage is high, and the stock out period relatively short, it would not be practical to switch a large number of patients to an alternative ACE inhibitor, as this would place a great deal of pressure on GPs.
- For patients stabilised on 5mg dose regimen, this leaves the option of splitting 10mg tablets, which are uncoated and scored. However, the score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses, therefore **halving the tablets to deliver a 5mg dose would be unlicensed.**<sup>1</sup> There is relatively little published information on the clinical effects resulting from the administration of split tablets to patients.<sup>2</sup>
- If a decision is taken that the most appropriate way to address an individual patient's needs is to split a 10mg tablet:
  - assess the patient's ability to understand and comply with a split tablet regimen,<sup>3</sup>
  - Discuss the use of a tablet cutter with the patient to ensure tablet is halved evenly.<sup>2-4</sup>
  - Advise the patient that they should only split one tablet at a time, which should be taken as soon as possible.<sup>2,4</sup>

- Advise patient that they should not split the entire supply of tablets to be stored for later use, as split tablets may be affected by factors such as heat, humidity and/or moisture content.<sup>2</sup>
- Issue a prescription for 10mg tablets as an **acute prescription**.
- Although tablet cutters should increase the accuracy of tablet splitting, these devices require a degree of manual dexterity. Old age or diseases such as arthritis and Parkinson's disease can cause impaired manual dexterity or decreased grip strength that renders the process of splitting tablets difficult.<sup>4</sup> In such cases, a family member or carer may need to be involved.
- Alternatively, if splitting tablets is not an option, 2.5mg tablets should be sourced if possible, to provide a 5mg dose; failing that, these patients will need to be reviewed by a GP or independent prescriber (where relevant) for an alternative ACE inhibitor.

### For pharmacies:

- Support by checking your current stock levels of these products and informing your local practices of these levels to support local management of patients.
- Where an acute prescription for 10mg tablets is issued, ensure the patient is aware of how to split the tablets safely.
- Alternatively, if a prescription for 2.5mg tablets is issued ensure the patient is aware of the change in dose and quantity of tablets to take.
- When the supply shortage of 5mg tablets has resolved, council patients on return to their normal prescription.

### References

1. SPCs accessed via electronic Medicines Compendium, 09 March 2021: <https://www.medicines.org.uk/emc/search?q=enalapril>
2. Food and Drug Administration. Best Practices for Tablet Splitting (23 Aug 2013): <https://www.fda.gov/drugs/ensuring-safe-use-medicine/best-practices-tablet-splitting>
3. Marriott JL; Nation RL. Splitting tablets. Aust Prescr 2002; 25: 133–5: <https://www.nps.org.au/australian-prescriber/articles/splitting-tablets-1>
4. Royal Pharmaceutical Society. Pharmaceutical Issues when Crushing, Opening or Splitting Oral Dosage Forms (June 2011): <https://www.rpharms.com/Portals/0/RPS%20document%20library/Open%20access/Support/toolkit/pharmaceuticalissuesdosageforms-%282%29.pdf>

### Original document prepared by:

Yuet Wan, London and South East Regional Medicines Information, Guy's and St Thomas' NHS Foundation Trust, 09 March 2021; email: [medicinesinformation@gstt.nhs.uk](mailto:medicinesinformation@gstt.nhs.uk)

### Document localised by and for any correspondence, please contact:

Cambridgeshire and Peterborough CCG Medicines Optimisation Team. 17<sup>th</sup> March 2021. Email: [CAPCCG.prescribingpartnership@nhs.net](mailto:CAPCCG.prescribingpartnership@nhs.net)

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