National Patient Safety Alert

Department of Health & Social Care

NHS

Shortage of pyridostigmine 60mg tablets

Date of issue:	24-May-23	Reference no:	NatPSA/2023/006/DHSC

This alert is for action by: All organisations using pyridostigmine 60mg tablets

This is a safety critical and complex National Patient Safety Alert. Implementation should be co-ordinated by an executive lead (or equivalent role in organisations without executive boards) and supported by clinical leaders in Pharmacy, Community Pharmacy, GP practices, Care Home settings, clinical leaders in Neurology and those working in the Health and Justice Sector.

Explanation of identified safety issue:

Pyridostigmine 60mg tablets are out of stock, resupply is expected week commencing 12 June 2023.

There are three suppliers of pyridostigmine 60mg tablets:

- Viatris
- Teva
- Flynn Pharma

The supply disruption is caused by a combination of manufacturing issues and a resulting increase in demand to other suppliers.

Pyridostigmine is licensed in myasthenia gravis, paralytic ileus and post operative urinary retention. In myasthenia gravis, it is used to stabilise patients therefore, interruption in supply increases the risk of relapse resulting in swallowing difficulties or respiratory failure. There is no clinical alternative to pyridostigmine.

Consideration has been given to suggesting a reduced dose for individual patients (assuming they have already been optimised by their neurologist) in order to preserve tablet supply however, clinical advice suggests that this may well result in symptom recurrence or exacerbation.

Pyridostigmine 12mg/1ml oral solution remains available and can support patients in primary care switching from tablets during this period. Once tablets are back in stock (w/c 12 June 2023), patients should be switched back to the tablet formulation to preserve supplies of the oral solution for those who require a liquid formulation.

Unlicensed imports of pyridostigmine 60mg tablets can be sourced. Lead times vary.

Actions required

Actions to be completed by 26/05/2023

1. Prescribers, pharmacists and staff working in GP practices and specialist clinical teams to identify all patients currently prescribed pyridostigmine 60mg tablets.
2. Prescribers and pharmacists to determine if patients have sufficient stock to last until expected resupply date, week commencing 12 June 2023.
3. Patients with insufficient supplies should be referred to their prescriber for a prescription for pyridostigmine 12mg/ml oral solution.
4. Prescribers should only prescribe sufficient pyridostigmine 12mg/1ml oral solution to cover until week commencing 12 June 2023.[NOTE A]
5. Pharmacists and prescribers should ensure patients are not intolerant to any excipients, are appropriately counselled on the switch to oral solution and equivalent volume of liquid to be administered.
6. Prescribers may consider prescribing unlicensed imports of pyridostigmine 60mg tablets if the licensed oral solution formulation is not considered suitable and work with local pharmacy teams to ensure supplies are ordered in a timely manner. [NOTE B]
7. Pharmacy procurement teams should utilise mutual aid in secondary care if there is an urgent need and it is appropriate.
8. Prescribers should immediately refer patients to a specialist for advice on alternative treatments if above options are not suitable.

For further detail, resources and supporting materials see: Enter specific webpage provided by alert issuer

For any enquiries about this alert contact: DHSCmedicinesupplyteam@dhsc.gov.uk

Failure to take the actions required under this National Patient Safety Alert may lead to CQC taking regulatory action

Additional information:

Clinical Information

The licensed dosage for adults with myasthenia gravis is 30–120 mg be given at suitable intervals throughout the day when maximum strength is needed (for example, on rising and before mealtimes). The usual duration of action of a dose is 3 to 4 hours in the daytime but a longer effect (6 hours) is often obtained with a dose taken on retiring for bed. The total daily dose is usually in the range of 5 – 20 tablets (of 60mg strength), but it is inadvisable to exceed a total daily dose of 450 mg in order to avoid acetylcholine receptor down-regulation. Patients requiring doses exceeding 450 mg daily will usually require input from a specialised neuromuscular service. Immunosuppressant therapy is usually considered if the dose of pyridostigmine exceeds 360 mg daily.

There is no direct clinical alternative to pyridostigmine, patients with myasthenia gravis are at risk of relapse resulting in swallowing difficulties or respiratory failure.

Patients with severe disease will be taking oral immunosuppressants; if these patients are still taking pyridostigmine this would indicate that they will not be in remission. Reducing the dose of pyridostigmine to preserve tablet supply may result in symptom recurrence or exacerbation.

Pyridostigmine 60 mg tablets should be stored in its original package and the bottle tightly closed to protect from moisture and light.

Notes:

A. Guidance on ordering short dated pyridostigmine 12mg/ml oral solution from Viatris

Viatris have short-dated stock of pyridostigmine 12mg/ml oral solution that will be available to order directly from wholesalers. This stock is due to expire at the end of November 2023.

B. Guidance on ordering and prescribing unlicensed imports

Unlicensed imports of pyridostigmine 60mg tablets have been sourced and orders should be placed at the earliest opportunity as lead times vary.

Any decision to prescribe an unlicensed medicine must consider the relevant guidance and NHS trust or local governance procedures. Please see the links below for further information:

- The supply of unlicensed medicinal products, Medicines and Healthcare products Regulatory Agency (MHRA)
- Professional Guidance for the Procurement and Supply of Specials, Royal Pharmaceutical Society
- Prescribing unlicensed medicines, General Medical Council (GMC)

References

- BNF pyridostigmine
- SmPC pyridostigmine tablets
- SmPC pyridostigmine oral solution
- Myasthenia gravis: Association of British Neurologists' management guidelines

Stakeholder engagement

The following stakeholders have been engaged in the management and consulted in the drafting of this alert: Specialist Pharmacy Service Medicines Advice, Medicine Shortage Response Group, NHS England National Clinical Directors for Neurology, NHS England Patient Safety and the Devolved Governments.

Advice for Central Alerting System (CAS) officers and risk managers

This is a safety critical and complex National Patient Safety Alert. In response to CHT/2019/001 your organisation should have developed new processes to ensure appropriate oversight and co-ordination of all National Patient Safety Alerts. CAS officers should send this Alert to the executive lead nominated in their new process to coordinate implementation of safety critical and complex National Patient Safety Alerts, copying in the leads identified on page 1.