

**From the Chief Medical Officer
Professor Sir Michael McBride**



Department of
Health

An Roinn Sláinte

Mánnystrie O Poustie

www.health-ni.gov.uk

HSS(MD) 27/2023

FOR ACTION

Chief Executives, Public Health Agency/HSC Trusts/NIAS
Deputy Secretary SPPG

GP Medical Advisers, SPPG

All General Practitioners and GP Locums (for onward
distribution to practice staff)

OOHs Medical Managers (for onward distribution to staff)

PLEASE SEE ATTACHED FULL CIRCULATION LIST

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Our Ref: HSS(MD) 27/2023

Date: 25 May 2023

Dear Colleague

NATIONAL PATIENT SAFETY ALERT – SHORTAGE OF PYRIDOSTIGMINE 60MG TABLETS

Actions for all healthcare professionals who prescribe or dispense pyridostigmine 60mg tablets:

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. **Viartis 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.**
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.
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.

Summary 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 12th 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 currently be sourced from Alium and Target Healthcare. Lead times vary.

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.

Guidance on ordering and prescribing unlicensed imports

Unlicensed imports of pyridostigmine 60mg tablets have been sourced from Alium and Target Healthcare 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 HSC Trust 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)

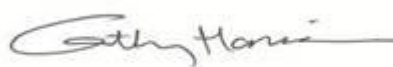
References

- [BNF pyridostigmine](#)
- [SmPC pyridostigmine tablets](#)
- [SmPC pyridostigmine oral solution](#)
- [Myasthenia gravis: Association of British Neurologists' management guidelines](#)

Yours sincerely



pp Prof Sir Michael McBride
Chief Medical Officer



Prof Cathy Harrison
Chief Pharmaceutical Officer

Circulation List

Director of Public Health/Medical Director, Public Health Agency (*for onward distribution to all relevant health protection staff*)

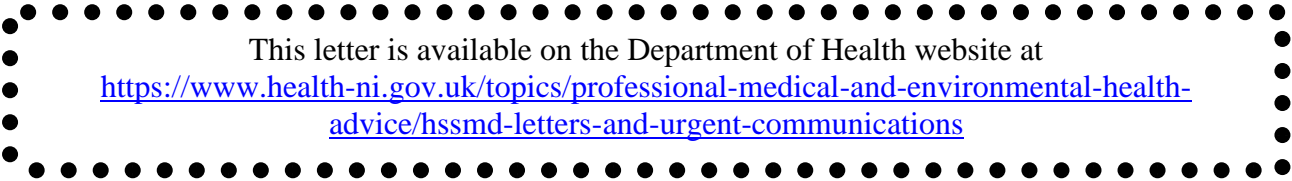
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