

Issue date

22 February 2023

Distributed to:

Chief Executives
 Directors of Clinical Governance
 Director, Regulation and Compliance Unit

Action required by:

Chief Executives
 Directors of Clinical Governance

We recommend you also inform:

Directors, Managers and Staff of:

- Emergency Departments
- Intensive Care Units
- Neurology
- Infectious Diseases
- Public Health Units

Expert Reference Group

Content reviewed by:

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Clinician Alert – Foodborne Botulism

Situation

Inside Out[®] has recalled a range of their non-dairy milk products due to the presence of botulinum toxin in a sample of 'JS Health x Inside Out[®] Unsweetened Almond Milk Collagen + Calcium + Prebiotics'. This product and further recalled products were not correctly labelled with directions to 'keep refrigerated'.

A possible case of foodborne botulism has been reported in someone who had consumed a product subject to this recall.

Botulism should be considered as a potential diagnosis in patients who have consumed these products recently (within 10 days) and subsequently experienced symptoms consistent with botulism.

Background

Foodborne botulism is transmitted by ingesting toxins produced by the spore-forming obligate anaerobic bacillus *Clostridium botulinum*. Foodborne botulism is a rare but serious disease with a case-fatality rate of up to 10 per cent.

Initial investigations have confirmed the presence of botulinum toxin in a sample of 'JS Health x Inside Out[®] Unsweetened Almond Milk Collagen + Calcium + Prebiotics'. The products listed below, with use by dates up to and including 18 May 2023, have been recalled in association with the investigation (further information [here](#)):

- JS Health x Inside Out[®] Unsweetened Almond Milk Collagen + Calcium + Prebiotics, 1L
- JS Health x Inside Out[®] Unsweetened Oat Milk Collagen + Calcium + Prebiotics, 1L
- JS Health x Inside Out[®] Barista Oat Milk Collagen + Calcium + Prebiotics, 1L.

The affected products have been in circulation since **November 2022**.

Assessment

The initial symptoms of foodborne botulism are non-specific and include weakness, marked fatigue and vertigo. These symptoms are usually followed by a distinctive syndrome of symmetrical cranial nerve palsies, followed by bilateral, symmetric, descending flaccid paralysis, affecting proximal before distal limb musculature, that can progress to respiratory failure and death.

Foodborne botulism may present with symptoms consistent with other diagnoses, such as Guillain-Barré syndrome or stroke. Clinicians should consider the possibility of botulism as a differential diagnosis.

In foodborne botulism, symptoms may begin from as early as 6 hours or as late as 10 days after consuming the contaminated food.

Most cases can recover if diagnosed and treated early with botulism antitoxin, which arrests the progression of paralysis.

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Clinical Recommendations

- Increased clinical suspicion of botulism.
- Clinicians should continue to consider botulism in patients who report consuming any of the above products and who, within 6 hours to 10 days after consumption, develop any of the following signs and symptoms: blurred vision, diplopia, dysphagia or pooling of oral secretions, dysarthria, ptosis, extraocular palsy or fatigability, symmetrical facial paresis, fixed pupils, descending paralysis that begins with cranial nerves.
- Botulism should be considered when myasthenia gravis or Guillain-Barré syndrome are suspected and in patients with unexplained symmetric cranial nerve palsies, with or without paresis of other muscles.
- Intensivists and Neurologists are requested to consider reviewing medical records for patients that presented with botulism-like illness since November 2022 where a diagnosis was not confirmed and to determine whether botulism may be the cause of illness.
- An Infectious Diseases Specialist should be consulted on any patient with possible or suspected foodborne botulism.
- Urgently contact your Public Health Unit on **1300 066 055** in all cases of possible or suspected botulism to discuss specialised testing and access to botulism antitoxin if required. **NOTE:** Specialised testing will need to be carried out at the Institute of Clinical Pathology and Medical Research (ICPMR).

Required actions for the Local Health Districts/Networks

1. Distribute this Safety Notice to all relevant clinicians and clinical departments for awareness and include a copy in relevant handovers and safety huddles.
2. Undertake a local risk assessment and develop strategies to mitigate the risk of missed or delayed diagnosis of foodborne botulism.
3. Report all cases of possible or suspected botulism to your Public Health Unit on **1300 066 055**.
4. Confirm receipt and distribution of this Safety Alert within **48 hours** to CEC-MedicationSafety@health.nsw.gov.au.