NSW Health

Risk of severe allergic reactions from products containing *Andrographis paniculata*

SAFETY NOTICE 018/24

Issue date:	5 July 2024
Content reviewed by:	Interagency Management Team, Medication Safety Expert Advisory Committee, Representatives from the NSW Poisons Information Centre and Office of the Chief Health Officer
Distributed to:	Chief Executives; Directors of Clinical Governance; Director, Regulation and Compliance Unit
KEY MESSAGE:	Inform NSW Health clinicians of the risk of severe allergic reactions associated with medicines containing *Andrographis paniculata* (andrographis) which include life-threatening anaphylaxis.
ACTION REQUIRED BY:	Chief Executives, Directors of Clinical Governance
REQUIRED ACTION:	1. Distribute this Safety Notice to all relevant clinicians and clinical departments where patients may present with anaphylactic reactions. 2. Ensure that clinicians and other relevant staff are aware of the *Recommendations* of this Safety Notice and take appropriate action. 3. Confirm receipt and distribution of this Safety Notice within **72 hours** to: CEC-MedicationSafety@health.nsw.gov.au.
DEADLINE:	COB 9 July 2024
We recommend you also inform:	Directors, Managers and Staff of: • NSW Ambulance • Emergency Departments • Intensive Care Departments • Immunology Departments • Medical Services • Pharmacy Departments • Nursing/Midwifery Services • Outpatient Clinics • Drug and Therapeutics Committees Other relevant clinicians, departments and clinical areas.
Website:	https://www.health.nsw.gov.au/sabs/Pages/default.aspx http://internal.health.nsw.gov.au/quality/sabs/index.html
Review date:	July 2025

Contact: Clinical Excellence Commission
02 9269 5500
CEC-MedicationSafety@health.nsw.gov.au

Risk of severe allergic reactions from products containing *Andrographis paniculata*

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Situation

There have been ongoing reports of severe allergic reactions including life-threatening anaphylaxis in consumers taking medicines or supplements containing the herb *Andrographis paniculata* (andrographis). Severe allergic reactions have been reported to occur in consumers who had used the product previously without any reaction.

The Therapeutic Goods Administration (TGA) recently released a Safety Alert regarding medicines containing *Andrographis paniculata.* They have also released information relating to this issue previously (Safety review and Safety advisory in October 2015), made changes to labelling requirements for these medicines in December 2019 and undertook a targeted compliance review of these labelling requirements in 2022.

Between 1 January 2024 and 20 June 2024, there have been 45 cases of adverse events reported nationally with an andrographis containing medicine suspected as the causative agent in the TGA Database of Adverse Event Notifications. 12 cases were reported as anaphylactic reactions, and 1 case had a reported outcome of death in another jurisdiction.

This Safety Notice is to inform NSW Health clinicians of the risk of severe allergic reactions associated with andrographis-containing products and advise that a heightened degree of suspicion for these products is warranted when treating a patient experiencing an allergic reaction.

Background

Andrographis is a widely used medicinal herb taken to support immune function and relieve cold and flu symptoms. It may be present in some complementary medicines and multi-ingredient herbal medicine products.

Andrographis-containing products can be bought from supermarkets, health food shops and pharmacies without a prescription. There are no andrographis-containing products listed on the NSW Medicines Formulary. Andrographis-containing products are not stocked within NSW Health Pharmacy Departments, however patients may present to NSW Health facilities after initiating use of these products in the community setting.

Assessment

The Australian Register of Therapeutic Goods (ARTG) currently lists over **90 medicines** containing andrographis. The TGA have received reports of adverse events relating to the following andrographis-containing products (but not limited to):

- ArmaForce® branded products
- Centrum® Immune Defence & Recovery
- Herbs of Gold® Cold & Flu Strike
- Eagle® Defence Support Tablets
- Nature's Sunshine® Andrographis.

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While use of products listed on the ARTG containing andrographis are usually safe, there is a potential risk of allergic reactions, including severe reactions such as anaphylaxis, associated with the use of these medicines. For more information on adverse reactions to complementary and alternative medicines, refer to Australasian Society of Clinical Immunology and Allergy Frequently Asked Questions (FAQ).

Severe allergic reactions, including anaphylaxis, can occur and require **immediate** medical treatment. Other symptoms can include (but not limited to): hives, difficulty breathing, swelling, difficulty talking and loss of consciousness.

It should be noted that more than 80% of the adverse events reported relating to andrographis, are for multi-ingredient medicines that contain both andrographis and *Echinacea* species (echinacea) together with other ingredients. Echinacea is another herbal ingredient often used in medicines for relief of cold and flu symptoms and has also been reported to cause allergic reactions, including anaphylaxis.

Clinicians are advised to have heightened suspicion for andrographis-containing products in consumers when presenting with symptoms of severe allergic reactions. Similarly, echinacea may also be involved in allergic reactions.

Recommendations

- Patients presenting with any type of allergic reaction after taking andrographis-containing products should avoid products containing this herbal ingredient in the future.
- When treating patients who are presenting with symptoms of an allergic reaction, consider whether a complementary medicine could be involved. When conducting a best possible medication history, ensure specific information regarding both prescription and complementary medicines/herbal supplements are obtained, including ingredients, **brand**, and recommended and administered dose.
- If a severe allergic reaction to andrographis-containing products is suspected, treat appropriately and seek expert advice from Immunology or a critical care physician regarding ongoing management.
- Report any cases of anaphylactic or other reactions associated with andrographis-containing products:
    - via the local incident management system (e.g., ims+)
    - to the medicine sponsor
    - to the Therapeutic Goods Administration.
- Allergies and adverse drug reactions to any medicine or herbal supplement should be clearly documented in the patient's healthcare record.

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