

Safety Notice 005/23

Issue date 6 March 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 of Medical Services
- Directors of Pharmacy
- Directors of Nursing and Midwifery
- Nurse/Midwifery Unit Managers
- Drug and Therapeutics Committees

All other relevant clinicians and clinical departments where these products are prescribed, stored and administered

Expert Reference Group

Content reviewed by:

Medication Safety Expert Advisory Committee

Clinical Excellence Commission

Tel: 02 9269 5500

Email Internet Intranet

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Potential for error: look-alike medicines presented in blue medicine bottles

Situation

There is potential for errors involving various Viatris branded medicines due to the similar presentation (or "look-alike" nature) of these products. They are all packaged in similarly sized, blue-coloured medicine bottles.

Assessment

All of the affected products are presented in similarly sized, blue medicine bottles, featuring labels of similar design and colour schemes (see Figure 2 for an example; and Appendix A for a list of affected products that are/will be available in NSW Health facilities). Furthermore, they are often located in close proximity in medication storage areas, for example:

- · in the same draw of medication trolleys
- side by side on imprest shelves, dispensary shelves or within locked drug cupboards.

High-Risk Medicine - Warfarin

Warfarin is a high-risk medicine that can result in significant injury or harm if used in error. Previously, Viatris-branded warfarin (Coumadin®) was presented in white bottles with coloured lids to assist with the differentiation of strength (see Figure 1). Recently, the presentation of Coumadin® has changed and now all strengths are presented in a blue bottle with a blue lid with the colour differentiation limited to the label and tablet inside in the bottle, similar to many other Viatris products (see Figure 2).

Figure 1: Previous Coumadin® packaging



Figure 2: New Coumadin® packaging



Note - image of 5 mg product unavailable at time of publication

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Safety Notice 005/23

Clinical Recommendations

It is recommended that clinicians involved in the prescribing, dispensing and administration of these products be made aware of the risk of selection error due to their look-alike presentation, and that local risk mitigation strategies be employed to minimise the risk of selection errors. Recommendations include:

In accordance with NSW Health Policy Directive Medication Handling PD2022 032:

- Clinicians should adhere to local policy regarding safe and accurate medication administration, including
 the 6 Rights (right patient, right drug, right dose, right time, right route and right documentation) and
 independent second person checks. These checks should include (but are not limited to) carefully
 reading the medication label to verify the name, strength, form and route of administration against the
 medication order, rather than relying on packaging or label recognition.
- Reviews of medication storage equipment (e.g., trolleys)/areas (e.g., imprest cupboards, dispensary shelves) should be regularly performed to ensure medicines are in their correct locations and any lookalike medicines are appropriately flagged and physically separated.

Consider the Australian Commission on Safety and Quality in Health Care (ACSQHC) <u>Principles for the safe selection and storage of medicines</u>, including (but not limited to):

- Physically separating different medicines and strengths in storage areas by using shelf dividers or
 positioning in separate drawers or shelves. Storage of look-alike medicines within the same multiplecompartment drawer should be avoided (including within automated dispensing cabinets).
- Utilising barcode scanning to conduct checks when restocking automated storage systems, and during the dispensing process in Pharmacy Departments.
- Considering the use of additional warning labels on shelving or medicine packaging to differentiate products (e.g., by using Tall Man lettering) or to alert to the potential risk of selection error involving lookalike products (e.g., 'PLEASE CHECK CAREFULLY medicine with a similar name or appearance').
- Rationalising the range of look-alike products kept as imprest stock in clinical areas based on clinical need within the particular area. This should include restricting the availability of multiple strengths of the same medicine.

Specificially for warfarin, in accordance with NSW Health Policy Directive <u>High-Risk Medicines Management</u> PD2020 045:

- A second person check is required for administration of warfarin.
- Patients receiving warfarin should be closely monitored for signs of bleeding, including laboratory testing (e.g. INR results) and clinical observation. Instructions for managing a high INR result and instructions for reversal must be documented.
- Patients who are discharged home on warfarin should be provided with information about their medication and its safe use. This should include information about the packaging change and education to exercise caution if also using other medicines presented in blue bottles.

Required actions for the Local Health Districts/Networks

- 1. Distribute this Safety Information to all relevant clinicians and clinical departments where Viatris products that are presented in blue bottles (such as those outlined in Appendix A) may be dispensed, stored or administered.
- 2. Report any incidents associated with these products via the local incident management system (e.g., ims+) and to the TGA.
- 3. Acknowledge receipt and distribution of this Safety Notice within 72 hours via email.

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Safety Notice 005/23

APPENDIX A. The following Viatris[®] branded products presented in blue bottles are/will be available in NSW Health facilities (this list is not exhaustive).

Generic medicine name	Brand/trade name	Strength
folic acid	Megafol	0.5 mg (500 microg)
folic acid	Megafol	5 mg
hydralazine	Alphapress	25 mg
hydralazine	Alphapress	50 mg
hydrocortisone	Hydrocortisone Mylan/Viatris	4 mg
hydrocortisone	Hydrocortisone Mylan/Viatris	20 mg
hydrocortisone	Hysone	4 mg
hydrocortisone	Hysone	20 mg
levodopa plus carbidopa	Kinson	100 mg/25 mg
labetalol	Presolol	100 mg
labetalol	Presolol	200 mg
naproxen	Inza	500 mg
propranolol	Deralin	10 mg
propranolol	Deralin	40 mg
spironolactone	Spironolactone Viatris	25 mg
spironolactone	Spironolactone Viatris	100 mg
verapamil	Anpec	40 mg
verapamil	Anpec	80 mg
warfarin	Coumadin	1 mg
warfarin	Coumadin	2 mg
warfarin	Coumadin	5 mg

