Health Quality & Safety Commission New Zealand
Kupu Taurangi Hauora o Aotearoa

Te Kāwanatanga o Aotearoa
New Zealand Government

Medication alert

Baclofen oral liquid

For the attention of: All pharmacists, prescribers and nurses

For information to: Quality leads, paediatric services, PHO clinical leads

Purpose of this alert

- **To advise that the Aotearoa New Zealand standardised batch sheet for baclofen oral suspension will change to a 1 mg/mL concentration from 1 November 2021.**
- To highlight **actions** for all prescribers, pharmacists and nurses to reduce the risk of inadvertent under- or overdosing with baclofen oral liquid or suspension.

Background

Baclofen is a muscle-relaxant medication used for severe muscle spasm (spasticity). It is often used in children with cerebral palsy or other conditions that affect the brain or spinal cord.

Baclofen suspension is extemporaneously compounded (prepared) in community pharmacy from baclofen tablets as there is currently no funded *proprietary* oral liquid available in primary care. Until now, the standardised batch sheet was for a 10 mg/mL concentration, supported by published stability data. In contrast, a proprietary 1 mg/mL oral liquid is funded on the Hospital Medicines List (although unapproved by Medsafe, a section 29 medicine).

The National Medication Safety Advisory Group (NMSAG) and the Compounding Working Group (CWG) are aware of a number of serious overdose and underdose medication errors related to the inconsistency in the concentration of baclofen suspensions used across hospital and community health care settings. Most of the serious errors have occurred soon after a transition between community- and hospital-based care, or a change of community pharmacy.

The Aotearoa New Zealand standardised batch sheet for baclofen oral suspension will change from 10 mg/mL to 1 mg/mL concentration from **1 November 2021.**[1] This change will promote consistency and help reduce medication errors, especially at transitions of care.

Risk

Medication dosing errors have the potential to result in serious consequences including fatality for patients who may receive significant overdoses (eg, 10 times the intended dose), or ineffective management of their condition (eg, spasticity) caused by underdosing.

Case study: A paediatric patient usually receiving 7 mL of the 1 mg/mL suspension (7 mg) was given 7 mL of the 10 mg/mL suspension (70 mg) in error, due to confusion with a different concentration of the suspension in hospital compared to at home. This was a 10 times overdose and led to symptoms such as confusion, sedation, respiratory depression, seizures[2] and intensive care unit admission.

Standardising the concentration of baclofen oral liquid to 1 mg/mL concentration:

- will make it easier to measure the small doses needed by some paediatric patients
- will simplify dose calculations
- will ensure consistency in concentration across hospital and community settings
- is supported by recently published stability data from the University of Auckland.[3]

From 1 November 2021, baclofen is available as:

- **oral tablets, 10 mg** (Pacifen®)
- **oral suspension prepared by a pharmacy, 1 mg/mL**
- **oral liquid available ready-made at some hospitals, 1 mg/mL.**

Note: The baclofen tablets can be crushed and dispersed in water prior to administration. This may be a useful alternative for high baclofen doses, which would require large volumes of the oral suspension or oral liquid.

Actions to be taken

All

- Communicate changes to all staff whom this change may affect.
- In consultation with the patient and/or caregiver, health care professionals to plan for a safe transition to the baclofen 1 mg/mL concentration where applicable (or to tablets if suitable).
- Inform patients and/or caregivers of the change in concentration and how it impacts them (eg, change in the volume to give or take if they previously used a different concentration).
- Provide information on baclofen for patients and/or caregivers if needed.[4]
- Remind users and administrators to update the relevant databases as soon as possible to ensure electronic systems reflect the changes.

Nurses

- Follow standard procedures for the administration of medicines.
- Before administration, always calculate the volume to administer using the dose (unit) and concentration available.
- If you are unsure, check with a senior colleague or pharmacist before administering the medicine.

Prescribers

- Continue to prescribe all medicines with medicine name, dose, units (eg, mg) and frequency according to the Medication Charting Standard.[5]
- Check with paediatrician, specialist or pharmacist if unsure about a baclofen dose.

Pharmacists and pharmacies

System changes

- Hospitals to use the proprietary baclofen 1 mg/mL product where possible.
- From 1 November 2021, use only the standardised baclofen 1 mg/mL oral suspension batch sheet,[1] to reduce the risk of medication errors.
- Update the baclofen suspension batch sheet to the standardised 1 mg/mL concentration[1] on all dispensing systems and hard copies (if any).
- Delete or archive any batch sheets for baclofen 10 mg/mL suspension and/or concentrations other than 1 mg/mL.

Additional communication

- Highlight on the dispensing container the change in the concentration and volume to be given or taken where appropriate.
- Ensure the patient and/or caregiver has an appropriate oral syringe to measure the new dose volume.

References

1. New Zealand Standardised Oral Formulation Batch Sheets. www.psnz.org.nz/practice/oralformulations (accessed October 2021).
2. Medsafe Data Sheet. Mylan New Zealand Limited, Pacifen, 10 mg tablet. Revision date 29 January 2021. URL: www.medsafe.govt.nz/profs/datasheet/p/Pacifentab.pdf (accessed October 2021).
3. Purohit T et al. 2021. Formulation and stability evaluation of an extemporaneously prepared baclofen suspension (1 mg/mL). *Journal of Pharmacy Practice and Research*. doi: https://doi.org/10.1002/jppr.1750 (accessed October 2021).
4. New Zealand Formulary for Children. Information leaflets for parents and carers. https://nzfchildren.org.nz/nzfc_70291 (accessed October 2021).
5. Health Quality & Safety Commission. 2012. *Medication Charting Standard*, Version 3. URL: www.hqsc.govt.nz/assets/Medication-Safety/Med-Rec-PR/Medication_Chart_Standard_v3.pdf (accessed October 2021).

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These recommendations are based on a review of currently available information to help practitioners. Recommendations are general guidelines only and are not intended to be a substitute for individual clinical decision-making in specific cases.