pharmacycouncil
Te Pou Whakamana Kaimatu o Aotearoa

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Safety Alert - Caution Required with Compounded Oral Liquid Formulations

Compounding oral liquid formulations from tablets or capsules poses many potential risks that can lead to patient harm. Adverse events have been reported nationally and internationally and common themes include:

1. Calculation errors e.g. using too many tablets to give the required strength
2. Prescribing or interpreting an incorrect strength which is then dispensed without verification
3. Changing the strength that the patient/caregiver has been used to e.g. dispensing a more concentrated formulation which is then given as the previous dose volume resulting in overdose
4. Unrecognised physical instability e.g. a soluble drug visibly precipitating out of solution which is continued to be used with resulting potential for overdose
5. Incorrect administration or dosage errors by the patient/caregiver
6. Inappropriate storage or failure to shake suspensions prior to administration

There are reports of fatalities in children from other countries which were linked to errors and problems involved with compounding oral liquids. The risk and consequences of a serious event is increased with high-risk medicines such as those with a narrow therapeutic index, poor physical stability, concentrated formulations and those with potential confusion between different strengths.

Examples of high risk formulations include baclofen, flecainide, levetiracetam, tramadol, thyroxine, phenobarbitone and clobazam.

Recommendations to minimise risk of adverse events

1. Be especially vigilant of the potential for adverse events with high risk medicines and use commercial preparations or therapeutic alternatives if possible to reduce compounding-related risks.
2. Use standardised batch sheets where these are available. The New Zealand Standard Oral Formulations (NZSOF) are available from the PSNZ website. The information on the pharminfotech web site and eMixt is no longer available.
3. Use formulas as stated with no substitutions, changes to strength or to storage conditions as any changes can affect stability.

4. Check calculations carefully and always double check doses with a reputable resource such as the New Zealand Formulary for Children (NZFC). All steps in the batch sheets should be completed and checked by a second person. Reconcile the number and strength of tablets used with the required volume and strength of the final preparation.
5. Do not modify the strength that the patient/caregiver has been used to unless there is a clear reason to do so, for example to change to a standardised formulation. In all cases, ensure that the change in dose volume is clearly understood. There should be appropriate counselling for the patient/caregiver and ideally this should be documented. If possible, check what the patient/caregiver has been used to and if appropriate check with secondary care to see what has been used during an admission. Use strengths from standard batch sheets if available.
6. Inform patients/caregivers to report immediately any changes they observe in the oral liquid. These include appearance of cloudiness, particles, precipitation, changes in colour, smell or taste. If suspensions become difficult to suspend, e.g. with excessive caking, they should not be used, and the pharmacist should be contacted.
7. Ensure that patients/caregivers know how to administer the medicine correctly so that this will deliver the correct dose. Ensure there is access to appropriate oral measuring devices.
8. Ensure that patients know how to store the oral liquid correctly and, if appropriate, to shake well before use.

Please report errors (including near misses) associated with compounding through your usual organisational reporting channels and also to CARM. Reporting to CARM will help to identify further safeguards including revisions to standard batch sheets.

Standard batch sheets for oral formulations are available on the PSNZ website

URL https://www.psnz.org.nz/Category?Action=View&Category_id=387

The batch sheets are regularly reviewed and revised as appropriate. Practitioners should be always be vigilant for any formulation issues (clumping, caking, colour changes etc.) and report these to the Pharmaceutical Society (email practice@psnz.org.nz).