



Safety Information 002/16

Switching between Extended Release (XR) vs Immediate Release (IR) Formulations

25th August 2016

Distributed to:

- Chief Executives
- Directors of Clinical Governance
- Director, Regulation and Compliance Unit
- Drug and Therapeutic Committees

We recommend you also inform:

- Directors of Medical Services
- Directors of Nursing and Midwifery
- Directors of Pharmacy

Expert Reference Group

Content reviewed by:

- Office of the Chief Health Officer
- Chief Pharmacist Unit
- Clinical Excellence Commission

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Background

Many medicines are available in multiple oral product formulations, including immediate release (IR), extended release (XR), modified release (MR), slow release (SR) or utilise a controlled delivery system (CD). Even if an IR and XR/SR product contain the same active ingredient and are available in identical strengths, they are not bioequivalent and administering the wrong formulation has the potential to cause harm to patients.

Medicines which are available in both IR and XR/SR formulations include hydromorphone, metformin, metoprolol, naproxen, nifedipine, oxycodone, and verapamil. Incidents involving the incorrect tablet formulation being administered of these, and other medicines, have been reported.

The recent TGA notification (<https://www.tga.gov.au/alert/metformin-extended-release-tablets>) regarding the shortage of metformin XR tablets has led to the need for some patients to be switched from metformin XR tablets to IR metformin tablets. Often tight glycaemic control can be achieved with the XR formulation as the required dose can be given once daily (improving compliance), achieving steady blood concentrations and reducing related gastrointestinal side effects. When switching between metformin XR and IR formulations, because of the differences in absorption, the dose or frequency of metformin IR tablets will need to be altered from the XR dose and frequency.

Unavailability of metformin XR may increase the incidence of inadvertent administration of metformin IR. Metformin is used either alone or in combination with other antihyperglycaemic agents to treat Type 2 diabetes in adults. In patients also using a sulphonylurea or insulin where glycaemic control is tight mix-ups could result in hypoglycaemia, and for patients on less tight glycaemic control, there could be brief episodes of hyperglycaemia.

Prescribers should be aware of the different formulations of medications available and clearly order the intended formulation i.e. ticking the *tick if slow release* box on the NIMC for an XR formulation or selecting the correct formulation in the electronic medication management system.

Staff administering medicines should be aware of the different formulations of medicines available, the significance of the tick in the *tick if slow release* box in the NIMC and consequences of administering the wrong formulation (which will vary depending on the medicine). On occasions where the ordered extended release or immediate release medication is not available the prescriber must be contacted to amend the order.

Suggested actions by Local Health Districts/Networks

1. Ensure that this safety information is distributed to all clinical staff involved in the prescribing, administration, dispensing or supply of medicines.
2. Ensure that health professionals are aware of the different formulations available of the same active ingredient, understanding that they are not bioequivalent and to be aware of the impact the differences may have on efficacy and side effects. This can be done by conducting in-service education for nurses and doctors on medicines that are available in a range of formulations and strengths, and providing concise information for use in patient care areas.
3. Remind prescribers to use the 'Tick if Slow Release' box to indicate on the NIMC when the sustained, modified or controlled release form of an oral drug is required. If it is not ticked, then it is understood that the standard or immediate release form is to be administered.
4. Wherever possible, only stock one type of formulation on ward imprest and dispense other formulations from pharmacy. If multiple formulations are still required on ward imprest, ensure strategies are put in place to prevent stock selection error.
5. Advise patients and carers about the potential for confusion with multiple formulations available for their medication and to understand the differences between the products.
6. Ensure that patients are made aware of, and provided with written instructions regarding any formulation changes that have been made to their medicines.
7. Ensure a system is in place to document actions taken.