

Safety Alert

OxyNorm® Concentrate 10mg/mL Oral Solution (oxycodone)

Issue:

There have been medication errors in Ireland involving 10 fold overdoses with OxyNorm® concentrate 10mg/mL oral solution (oxycodone). Patients are occasionally prescribed doses of less than 5mg oxycodone, which necessitates using the oral liquid. Although the product presentation provides guidance on dosage in mg and mL, and includes a syringe for accurate measurement of the dose, errors, specifically in the dispensing and administration process have occurred, and have reached the patient.

Evidence of Harm:

- Dispensing and administration errors involving 10-fold overdose have been reported in both primary and secondary care in Ireland.
- A 2.5mg dose of oxycodone is contained in 0.25mLs of OxyNorm® Concentrate 10mg/mL. **A volume of 0.25mL is an unusual adult dose volume.** Labelling and administration errors have been reported where 2.5mLs (25mg oxycodone) was erroneously drawn up instead of 0.25ml (2.5mg oxycodone).
- The British National Formulary lists two oxycodone oral liquid products – 1mg/mL and 10mg/mL. The 1mg/mL formulation is not yet available in the Republic of Ireland. Mundipharma, manufacturers of OxyNorm® are in the process of applying for an Irish licence for OxyNorm® 1mg/mL oral solution.
- The IMSN is aware of near misses involving the above product being confused with the parenteral administration product.
- Sound Alike Look Alike drug (SALAD) errors involving the following products have been reported in Ireland & the UK.
 - OxyNorm® concentrate 10mg/mL oral solution, (oxycodone)
 - OxyNorm® 10mg/mL solution for injection, (oxycodone)
 - Oramorph® 10mg/5mL oral solution, (morphine sulphate)
 - Oramorph® concentrate 20mg/mL oral solution, (morphine sulphate).

How to reduce the risk:

- Communicate this safety alert within organisations using OxyNorm® concentrate 10mg/mL oral solution (oxycodone) to raise awareness and avoid patient harm from inadvertent overdose. Provide a copy of this alert with every bottle of OxyNorm® concentrate 10mg/mL dispensed.
- Restrict prescribing (e.g. palliative care only) or remove product from use.
- Over label the product with a fluorescent warning label highlighting the strength, stating e.g. 5mg = 0.5mL
- Endorse the corresponding dose volume in hospital inpatient medication records
- If appropriate, counsel the patient/carer to ensure the prescribed dose and corresponding volume for administration of OxyNorm® concentrate 10mg/mL is understood.

About the IMSN

The Irish Medication Safety Network (IMSN) is an independent group of pharmacists and other specialists working in the acute sector, whose principal aim is to improve patient safety with regard to the use of medicines through collaboration, shared learning and action.

The Irish Medication Safety Network can be contacted via irishmedsafety@gmail.com