April 2024 Issue 27

necs A care system support organisation

NHS England North East and Yorkshire

Controlled Drugs: Learning from incidents

This bulletin contains local and national CD information for shared learning.

ORAL LIQUID CD INCIDENTS

There have been a number of prescribing and dispensing incidents throughout the last six months within our region involving Controlled Drug Oral Solutions. These include Clobazam, Morphine Sulphate and Gabapentin.

Morphine Oral Solution: Two babies were recently treated in the Accident & Emergency department following an overdose of morphine sulphate oral solution, due to administration of a dose higher than the intended dose. The parents of the baby were supplied with a bottle of 10mg/5ml oral solution instead of the 100 micrograms/ml oral solution. The 100 micrograms/ml oral solution is a 'RED DRUG – HOSPITAL ONLY DRUG' AVAILABLE AS A 'SPECIALS' PRODUCT on most regional formularies. RED drugs should be initiated by specialists only, and the prescribing and dispensing retained within secondary care. For further information please see alert circulated July 2023 Portal (cdreporting.co.uk) resource #107

Clobazam Suspension: The label was correctly produced following the prescription for Clobazam 5mg/5ml Suspension but the wrong strength, Clobazam 10mg/5ml was selected during the dispensing process and not picked up during the checking process. The child usually received clobazam 5mg/5ml liquid and their dose is 1.5mg (1.5ml) twice per day. The family had been give a bottle of clobazam by the community pharmacy which was 10mg/5ml but the label on the box was labelled as if it was 5mg/5ml (ie label stated 5mg/5ml give 1.5ml). Therefore child had been receiving double the dose they were meant to receive. The incident was highlighted when the child was admitted to hospital with an unrelated issue. No harm was suffered by the child. The pharmacy was informed and investigated the incident.

Gabapentin Oral Solution: Pharmacy received prescription for Gabapentin 50mg/ml oral solution SF. Prescription direction stated 'Take 5ml (50mg) at night'. Direction should have been 'Take 1ml (50mg) at night.' Pharmacist did not realise the prescribing error. Incident was brought to pharmacist's attention when patient rang the pharmacy to query about another prescription. A new prescription was received by the pharmacy for the same medication with the correct dose 'Take 1ml (50mg) at night' 16 days later. Even though the new supply was labelled correctly, the patient did not read or follow the instructions and continued to follow the direction from the previous supply and took 5mls at night instead of 1ml. The patient did not experience any adverse drug reactions. GP had also contacted the patient.

When dealing with Controlled Drug Oral Solution prescriptions:

Pharmacies should:

- Calculate and add the volume to be administered at each dose on the pharmacy dispensing label
- At point of supply, counsel the patient/parent/representative, showing them the medication bottle and clarify the dose and volume to be administered
- Ensure that the person administering the medicine has the appropriate measuring device e.g oral syringe
- Speak directly to the prescriber for medication queries with high risk drugs/or patients with complex conditions.
- Record this in the patient's PMR

Prescribers should:

- When writing prescriptions, quantities less than 1 mg should be written in micrograms, e.g. 100 micrograms, not 0.1 mg. 'micrograms' and 'nanograms' should not be abbreviated
- Communicate with the pharmacy when dealing with very complex medication issues which may require direct clinician to clinician conversations. Make sure there is a clear record in the patients notes of any communications.
- Add weight and date of weighing on paediatric prescriptions to assist pharmacists complete their clinical assessment of the prescription and reduce the need to further contact the prescriber/parents
- Be aware of Specialised Red Drugs that are ONLY to be prescribed within Secondary Care

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Controlled Drugs Records in Pharmacy

Everyone within a healthcare organisation is responsible for managing records appropriately. It is therefore important that you understand how records relating to Controlled Drugs should be managed within the pharmacy.

Please find the recommendations for the retention of records relating to Controlled Drugs (CDs) in all hospital pharmacy, community pharmacy and secure environment settings here.

Consumer liability legislation should be considered when handling manufacturing records. This is explained under the Consumer Protection Act 1987. which allows patients to claim for injury due to a defective product (medicine) up to 10 years after a medicine has been administered. Records of manufactured products (e.g. extemporaneous CD worksheets) can prove that the product was or was not defective. The prescription or other clinical records will only indicate that the patient was prescribed or dispensed an item, but will not give any indication how the product was made and what ingredients were used. If the problem is a contaminated ingredient, it is possible to partially pass the responsibility to the supplier of the defective ingredient.

CHANGES TO PARAMEDIC CONTROLLED DRUG PRESCRIBING

The long-awaited legislative change in relation to paramedic prescribing has been laid before parliament and took effect on 31st December 2023. Amongst other things, it allows the prescribing of 5 controlled drugs by paramedic independent prescribers. These are covered by insertion of regulation 6D The Misuse of Drugs (England and Wales and Scotland) (Amendment) (No. 2) Regulations 2023 (legislation.gov.uk)

2) A paramedic independent prescriber can prescribe any of the following controlled drugs for the treatment of organic disease or injury provided the controlled drug is prescribed to be administered by the specified method:

(a) Morphine sulphate by oral administration or by injection;
(b) Diazepam by oral administration or by injection;
(c) Midazolam by oromucosal administration or by injection;
(d) Lorazepam by injection;
(e) Codeine phosphate by oral administration.

The explanatory memo provides a useful summary: uksiem_20231345_en.pdf (legislation.gov.uk)

We are aware that this list is quite limited and is based on the original consultation on paramedic prescribing dating back to 2015. Paramedic roles have changed considerably since then, so careful consideration needs to be made to ensure that they are only able to prescribe within this limited list and that there are mechanisms for monitoring this and providing necessary support and guidance, as appropriate.

Managing Controlled Drugs Waste

The Home Office has advised that all Controlled Drugs in Schedules 2, 3 and 4 (part 1) should be denatured and, therefore, rendered irretrievable before being placed into waste containers. CD denaturing kits are widely available. More information can be found within Medicines Ethics and Practice (RPS membership required) and from Community Pharmacy England.

Where the CD is a Schedule 2 stock item, there is a legal requirement for the denaturing to be witnessed by an Authorised Witness.

It is good practice for all other CD waste to be denatured in the presence of another member of staff (preferably a registered healthcare professional).

Contact your local CD Team if you require a CD Destruction:

Yorkshire and Humber :england.yhcdao@nhs.net

Northeast North Cumbria: england.cumbrianortheast-cds@nhs.net

CODEINE LINCTUS:

Codeine linctus (codeine oral solution): reclassification to prescription-only medicine (POM).

MHRA Advice for healthcare professionals:

- Codeine linctus has now been reclassified from a pharmacy-only medicine (P) to a prescription-only medicine (POM) owing to the risk of dependence, addiction, and overdose.
- Codeine linctus is only authorised for the treatment of dry cough.
- Codeine linctus is only considered to be effective in the treatment of chronic cough lasting over 8 weeks.
- Advise patients that those with a long-term cough should see a healthcare professional, for review of symptoms and may require medical assessments to check for other conditions which may be the cause of the cough.

If you need advice, or would like an article to be included in a future issue, please contact the relevant member of the Controlled Drug Team below, for your area:

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