NHS Forth Valley

Prescriberfile

From the Primary Care Prescribing Group

Temazepam - Controlled Drugs Legislation Changes

The Controlled Drugs Accountable Officers Network has issued the attached newsletter detailing key changes to the Misuse of Drugs Regulations.

Of particular note:
From 1st June, Temazepam will no longer be exempt from CD prescription writing requirements.

From **1st June** all **Temazepam** prescriptions **must have:**

- **Legally acceptable dosage instructions** which **must** include the actual dose to be taken eg **ONE** to be taken when required.

'As directed' is not legally acceptable, but 'ONE as directed' would be as it specifies the dose.

- **The total quantity in words and figures.**
- Any **instalment prescriptions** will require the **quantity per instalment** as well as the **interval** between instalments (see Prescriberfile March 2014).

Practices should check all existing prescriptions to ensure that they have legally compliant dosage and instalment instructions.

- Prescribers are reminded that the dosage form and strength is also required, including handwritten scripts.
- No new patients should be started on Temazepam due to ongoing increased price.

It is hoped that EMIS will implement changes in the system prior to the 1st June to **automatically add the quantity in words and figures** to Temazepam prescriptions.

- Any prescriptions written **before** 1st June but presented for dispensing on or after 1st June will require to meet the legal requirements and as such community pharmacists may refer these back to the prescriber for amendment or request a new prescription.
- Any prescriptions written **for instalment dispensing** which started before 1st June, but which would require instalments to be dispensed after 1st June will also require to be dealt with on an individual basis. Community pharmacists will contact the surgery to make arrangements on an individual basis for any affected instalment prescriptions

Lithium Prescribing

Lithium salts have a narrow therapeutic/toxic ratio and the different branded preparations vary widely in bioavailability. Therefore patients prescribed lithium should always receive the same brand. Currently there are three brands of lithium available – Camcolit®, Liskonum® and Priadel®.

- Priadel® offers the greatest flexibility in dosing for patients and therefore it has been agreed that **Priadel® is now the first choice of lithium brand** prescribed for all **NEW PATIENTS** started on this medication.
- We recommend that this information is annotated clearly in clinic letters and discharge prescriptions to GPs for any patient newly started on lithium.
- **EXISTING patients currently stabilised** on their current brand of lithium (Camcolit® or Liskonum®) **should remain on their current brand**.
- Lithium should always be prescribed by **BRAND NAME.**

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Please Circulate to All Staff

Inside this issue:

Key Points of interest:

- Temazepam is now subject to all CD prescription writing requirements.
- To ensure continuity of treatment, prescribe Lithium by **brand** name—Priadel® for NEW patients.
- Various Drug Safety updates.
- New Formulary Choice emollients: Zerobase®, Zerocream® and Zeroderm®.
- Update on Palliative Care use of Dexamethasone Injection.
- Pneumovax II® now called 'Sanofi Pasteur MSD Pneumococcal polysaccharide vaccine'.
- Reminder of potential for abuse with gabapentin and pregabalin.
- CD adverse events—robust procedures and increased awareness vital.
- The new PRISMS User Access System for account requests.

Drug Safety Updates

Selected highlights from recent Drug Safety Update Bulletins from the MHRA (https://www.gov.uk/drug-safety-update)
Prescribers are encouraged to subscribe directly to the Drug Safety Updates Bulletin which is only available by email.
https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/email-signup

Zolpidem is associated with a risk of **impaired driving ability the next day**. To reduce this risk, patients should be advised to take only one dose per night and to leave **at least 8 hours** between taking zolpidem and performing skilled tasks (e.g. driving, or operating machinery). (May 2014 Update)

Prescribers are reminded that the June 2014 Update advised of new warnings for **combination use of medicines from different classes of renin-angiotensin system blocking agents**. Combination use is **associated with** an **increased risk of hyperkalaemia, hypotension, and impaired renal function** and new warnings were agreed following an EU-wide review. In particular, prescribers are advised that **people with diabetic nephropathy should not be given an ACE-inhibitor with an angiotensin-receptor blocker** as they are already prone to developing hyperkalaemia. Combining **aliskiren** with an ACE-inhibitor or angiotensin-receptor blocker is **contraindicated** in people with kidney impairment or diabetes. See the June 2014 Update for full information.

The December 2014 Update advised of the **risk of cardiac side-effects** (bradycardia, atrial fibrillation, and other cardiovascular risks) **with Ivabradine** in the symptomatic treatment of angina. **New advice to minimise risk.** Only start ivabradine if the resting heart rate is at least 70 beats per minute. Do not prescribe ivabradine with other medicines that cause bradycardia. Monitor patients regularly for atrial fibrillation and consider stopping ivabradine if there is only limited symptom improvement after 3 months. See the December 2014 Update for full information on new advice on dosing, titration and monitoring.

Prescribers and pharmacists are reminded of the importance of providing clear information to patients and caregivers regarding risk of **accidental patch transfer and ingestion of Fentanyl patches**, and need for **appropriate disposal** of patches. Advise patients and caregivers to follow the instructions on the patch carton and in the accompanying leaflet. If a patch is transferred to another person, it should be removed and the individual should get medical help immediately. If a patch is swallowed, the individual should get medical help immediately. Children are at risk as they may touch, suck, chew, or swallow a patch that has not been disposed of properly—children have a lower threshold for fentanyl overdose than adults. See the July 2014 Update for further information. Please report any cases of accidental exposure where harm has occurred or suspected side effects via the Yellow Card Scheme (www.mhra.gov.uk/yellowcard).

A number of MHRA 'Medicines learning modules' are available including Antipsychotics, Benzodiazepines, Corticosteroids, Opioids, Oral anticoagulants, Selective serotonin reuptake inhibitors (SSRIs). These have been have been approved for Continuing Professional Development (CPD) accreditation by The Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians.

Denosumab is associated with a **risk of osteonecrosis of the jaw (ONJ) and** with a risk of **hypocalcaemia**. Before starting denosumab treatment, a dental examination and appropriate preventive dentistry are now recommended to reduce the risk of ONJ. This applies to all patients considered for denosumab 120mg for cancer and to patients with ONJ risk factors considered for denosumab 60mg for osteoporosis. Tell patients to maintain good oral hygiene and report any oral symptoms. The risk of hypocalcaemia increases with the degree of renal impairment. Monitor calcium levels depending on the indication and tell patients to report symptoms of hypocalcaemia. The September 2014 Update provides details of the ONJ risk factors and signs of hypocalcaemia.

Nitrofurantoin is now **contraindicated** in patients with an estimated glomerular filtration rate **(eGFR) of less than 45**ml/min/1.73m^2.

However, a short course (3 to 7 days) may be used with caution in certain patients with an eGFR of 30 to 44 ml/min/1.73m^2—only prescribe to such patients to treat lower urinary tract infection with suspected or proven multidrug resistant pathogens when the benefits of nitrofurantoin are considered to outweigh the risks of side effects. This contraindication allows nitrofurantoin to be used in patients for whom it was previously not recommended (previously contraindicated in patients with a Creatinine Clearance of <60ml/min). Consider checking renal function when choosing to treat with nitrofurantoin, especially in the elderly. Closely monitor for signs of pulmonary, hepatic, neurological, haematological, and gastrointestinal side effects during treatment, as previously advised in the summary of product characteristics (September 2014 Update).

NSAIDS and cardiovascular safety—following the restrictions on **Diclofenac** prescribing in 2013 due to cardiovascular risks, the drug has now additionally been removed from over-the-counter sale, and is now only available on prescription. The contraindications for a further NSAID, **Aceclofenac** have been revised in line with the restrictions for diclofenac and COX-2 inhibitors (January 2015 Update).

Drug Safety Updates (Cont'd)

Strengthened advice and warnings on the use of **valproate, valproic acid and valproate semi-sodium in females** (female children, female adolescents, in women of childbearing potential and pregnant women) has been issued by the MHRA, following a Europe-wide review of the risk of abnormal pregnancy outcomes. See the January 2015 Update for advice. Any local advice will be issued in due course.

Updated choice of Formulary Emollient Products

The dermatology section of the Forth Valley Formulary has recently been reviewed. Dermatology guidelines do not specify which emollient should be prescribed as any emollient should suit the needs of the individual patient.

E45® Cream has been **removed** from the formulary. Diprobase® and Epaderm® remain in the formulary.

On the basis of near equivalence to existing products (in terms of constituents and texture) and cost-effectiveness the following products should be considered as the updated formulary emollients of choice:

- **Zerobase® CREAM** (Liquid paraffin 11%)
- **Zerocream® CREAM** (Liquid paraffin 12.6%)
- **Zeroderm® OINTMENT** (Liquid paraffin 40%)

The cost savings for the 'Zero®' products over their equivalent products are shown below (prices from dm+d and Scottish Drug Tariff, May 2015)

New Product	Cost/500g	Alternative to	Saving/500g over alternative
Zerobase® Cream	£5.26	Diprobase® Cream	£1.06
Zerocream® Cream	£4.08	E45® Cream	£1.54
Zeroderm® Ointment	£4.10	Epaderm® Ointment	£2.43

Dexamethasone Injection—Palliative Care Recommendations

Dexamethasone injection presentations have changed recently, and the commonly used 4mg/ml injection is now no longer available. Other preparations available are: 3.8mg/ml injection (manufacturer, Aspen), this is a fridge line and as such comes with issues regarding storage and stability information for syringe pumps. The other preparation is 3.3mg/ml injection (manufacturers, Hospira and Hameln). If any further information is required please contact Anne Wilson (anne.wilson1@nhs.net) or Amy Forsyth (amy.forsyth@nhs.net) Palliative Care Pharmacists at Strathcarron Hospice.

- Within palliative care the recommendation is that the 3.3mg/ml preparation is used and doses should still be prescribed in 2mg and 4mg increments.
- For site reactions at syringe pumps sites the dose should be altered to enable ease of measuring to 330micrograms over 24 hours. **Please see table below for volumes.**
- The 3.3mg/ml product is available in 1ml and 2ml ampoules—the Palliative Care Community Pharmacy Network stock list includes the **1ml ampoules**.

Adult dose of dexamethasone	Volume of dexamethasone 3.3mg/ml required
330 micrograms	0.1ml
1mg	0.3ml
2mg	0.6ml
4mg	1.2ml
6mg	1.8ml
8mg	2.4ml
10mg	3ml
12mg	3.6ml
16mg	4.8mls

Pneumovax II® Name Change—this is now listed on EMIS as 'Sanofi Pasteur MSD Pneumococcal polysaccharide vaccine solution for injection 0.5ml vial'.

Gabapentin and Pregabalin—Risk of Misuse

Public Health England recently published '*Advice for prescribers on the risk of the misuse of pregabalin and gabapentin*'. This provides detailed information on the potential for misuse of these drugs and suggestions for balanced and rational use. The Controlled Drugs Accountable Officer (CDAO) Network in Scotland, in association with the Scottish Prescribing Advisers Association and Specialist Pharmacists in Substance Misuse have issued a bulletin with a useful summary of the advice.

The full bulletin (http://tinyurl.com/Gaba-Pregab-Advice) contains advice on clinical indications, evidence for misuse, undesirable effects and advice on tapering dosage schemes as well as information on the volume of prescribing.

Key Messages from the CDAO Bulletin on pregabalin and gabapentin:

- Prescribers should be aware of the risk of dependence misuse and diversion as well as the potential benefits of these drugs.
- Practitioners should be able to identify and manage misuse if it arises as a result of prescribing.
- Patients should be given enough information to consent to the treatment plan, should be aware of the likely efficacy of the drugs and the risk of harms, including dependence.
- Prescribe with caution for patients with a known or suspected propensity to misuse, divert or become dependent on drugs.
- Less harmful alternatives can often be used first-line instead of pregabalin or gabapentin, and may be preferred in higher risk settings or in patients more likely to be harmed.

Controlled Drug Adverse Events Report 2013-14

One of the roles of the Controlled Drugs Accountable Officers' (CDAO) Network is to gather information about adverse events and concerns involving Controlled Drugs (CDs) in Scotland and to share any lessons learned. The Network has recently published their CD Adverse Event 2013-14 report. This report describes common themes observed in some Scottish Health Board areas, which are similar to those identified in 2012/13.

- Four drugs (methadone, morphine, oxycodone, fentanyl/alfentanil) are commonly implicated in CD adverse events. Improving procedures around the use of these drugs would reduce the likelihood of adverse events and improve patient safety.
- Adverse events can be reduced by improving and adhering to robust procedures and an increased awareness of incidents and contributory factors.

As part of any review of CD adverse events healthcare professionals should:

- Consider what steps you can put in place to help prevent a recurrence.
- Ensure that the learning is used to raise awareness and inform best practice as part of a strategy to reduce errors and improve patient safety in all healthcare settings.

PRISMS User Access System

Applications for user accounts to access prescribing data in PRISMS and other prescribing datamarts hosted by NHS National Services Scotland (NSS) is now managed through the User Access System (UAS). All applications should be completed using the online forms.

For users with current access to PRISMS and other datamarts, the system will automatically generate reminder emails when renewal of your access is required.

GP Practices will have been previously contacted by the Information Services team at NHS NSS requesting identification of authorisers for access to GP Practice-level data for practice staff.

- Individuals with access to prescribing datamarts eg PRISMS and SPARRA Online are advised to login to the User Access System (UAS) and check that their email contact details are correct.
- Users are advised to request access renewal through the UAS when reminder emails are received, otherwise access will be removed automatically by the system.
- The UAS is accessed via https://useraccess.nhsnss.scot.nhs.uk/ and can only be accessed from an N3 connection.
- New users will require to register for a new UAS account.
- Information and support on the UAS is available at:

  http://www.isdscotland.org/Products-and-Services/Datamarts/User-Support/

Contact Information:

General Primary Care Prescribing Advice:
Contact your Primary Care Pharmacist; or alternatively
Primary Care Prescribing Support Team on 01786-431200
Email: FV-UHB.prescribingsupport@nhs.net

For Advice Related to Management of Controlled Drugs:
Hannah Miller, Interim Inspection Officer for Controlled Drugs,
NHS Forth Valley, Forth Valley Royal Hospital Tel: 01324-566743
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