NHS
Kent and Medway

Medicines Optimisation Update Newsletter – [September 2022 Issue 38]

Clozapine Safety

Mental health specialists from the Kent and Medway NHS and Social Care Partnership Trust (KMPT), were invited to speak about antipsychotics, such as Clozapine, during a recent educational PCN seminar. The following are some key points about what can be expected of primary care in terms of Clozapine safety:

- **Missed Clozapine dose for 48hours+**
  The patient must be referred to KMPT or another specialist if they have not taken Clozapine for more than 48 hours because this medication needs to be re-titrated.
- **Constipation**
  Patients should be frequently counselled on the significant risk of constipation and life-threatening bowel issues; the need to stay hydrated, the importance of a high fibre diet and exercise. At each regular clinical assessment, the patients should be asked about bowel function and be encouraged to monitor it. Patients taking Clozapine and their carers should be advised to seek immediate medical advice before taking the next dose of clozapine if constipation develops.
- **Smoking**
  Patients, carers, and healthcare professionals should be advised to inform the responsible clinician if the patients start or stops smoking. Please note it is the hydrocarbons in the tobacco smoke that can affect Clozapine absorption and not the nicotine, therefore nicotine replacement therapy (NRT) does not affect Clozapine metabolism.
- **EMIS coding**
  Ensure Clozapine is ALWAYS coded as *hospital only* on EMIS clinical notes.
- **Clozapine monitoring**
  Primary care monitoring of Clozapine is NOT expected, and patients will remain under the care of KMPT or another specialist.

Product Discontinuation: Seroxat (paroxetine hydrochloride) 20mg/10ml oral suspension

GSK UK Limited, in agreement with the MHRA would like to inform you that Seroxat (paroxetine hydrochloride) 20mg/10ml oral suspension will be discontinued from the UK and other markets in October 2022 for commercial reasons. *(This does not impact the tablet formulations of Seroxat).*

Action reguired by Health Care Providers:

- For paroxetine (in common with other SSRIs), abrupt discontinuation should be avoided as this may result in withdrawal symptoms (refer to the Summary of Product Characteristics for details)
- In general, switching or stopping medicines can carry medical risk and should be supervised by a physician.
- Physicians should consider switching patients to a solid formulation of paroxetine if suitable.

Further advice from the DHSC on the management of this discontinuation, e.g. in patients with swallowing difficulties, is viewable on the Specialist Pharmacy Service Medicine Supply Tool.

Product Discontinuation: Insuman Infusat 100units/ml solution for injection 3.15ml cartridges (Sanofi) 5 cartridge

Sanofi have informed healthcare professionals that Insuman Infusat 100units/ml solution for injection 3.15ml cartridges (5 cartridge) will be discontinued from the UK market on 30th September 2022. There are no other available preparations of Insuman Infusat.
Action required by healthcare professionals:

- Sanofi have advised that patients be reviewed in order to select a new insulin regimen
- Prescribing data is expected to show low levels of prescribing of Insuman Infusat across Kent and Medway. The NHS Kent and Medway Medicines Optimisation team will contact practices where recent

prescribing is identified. Please be aware this data is 3 months behind, so searches should be carried out within practices to check if any patients have been prescribed Insuman Infusat recently.

Links:
SmPC Insuman Infusat
The notification of the product discontinuation was provided by DHSC and NHSEI Medicines Supply Teams, and is viewable on the Specialist Pharmacy Service Medicine Supply Tool

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Amoxicillin Prescribing and Duration

The NICE summary of antimicrobial prescribing guidance – managing common infections available here recommends a shorter **5 day** course length for Amoxicillin for the following infections:

- Acute exacerbation of COPD
- Acute cough
- Community acquired pneumonia*

*Stop antibiotics after 5 days unless microbiological results suggest a longer course is needed or the person is not clinically stable.

Pack sizes are available in 21 capsules (7 day supply) and 15 capsules (5 day supply). Please ensure the appropriate quantity is prescribed to cover the appropriate duration for the infection you are treating.

Reminder: Best Practice Guidance for Care Homes

A reminder that integrated Care Team have developed a number Medicines Management Best Practice Guidance for use within care homes across Kent and Medway. These are available on each HCP formularies and will soon be available on the Medway Council Portal. The Best practice guidance aims to support care home staff to deliver safe and effective medicines management to residents within care homes.

If you require any help or support, or have any questions please email the following address: KMCCG.ICMOPharmacyteam@nhs.net

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Medicines Optimisation MHRA Drug Safety Update – August 2022 (for September 2022 MO Newsletter)

The latest MHRA Drug Safety Updates can be accessed at https://www.gov.uk/drug-safety-update. This includes links to alerts, recalls and safety information and to the monthly Drug Safety Update PDF newsletter.

The August 2022 Drug Safety Update includes:

Nebulised asthma rescue therapy in children: home use of nebulisers in paediatric asthma should be initiated and managed only by specialists

"Use of a nebuliser purchased independently of medical advice for use in the home to deliver nebulised asthma rescue medications to children can mask a deterioration in the underlying disease and may increase the risk of potentially fatal delays in seeking medical attention if asthma deteriorates. If home use of a nebuliser for the acute treatment of asthma in children under 18 years of age is considered necessary, this should be initiated and managed by an appropriate specialist. This is consistent with current clinical guidance." Please follow the link in the title to see the alert.

COVID-19 vaccines and medicines: updates for August 2022

Letters and medicine recalls sent to healthcare professionals in July 2022

The MHRA Central Alerting System alerts can be accessed at https://www.cas.mhra.gov.uk/Home.aspx.

National Patient Safety Alerts can be accessed at https://www.england.nhs.uk/patient-safety/patient-safety-alerts/.

We are reviewing our response to MHRA and National Patient Safety Alerts to include local advice. In the meantime, we have included a summary of the MHRA Drug Safety Update.

This update is prepared by the NHS Kent and Medway Medicines Optimisation Team.

Shortages Summary September 2022

Please find the medicines shortages update (14th September 2022) embedded below. Practices are encouraged to register for access to the SPS website https://www.sps.nhs.uk/ and access the full medicines supply tool directly in real time.

Shortages Summary Sept 2022.docx

Medicine Supply Notification – Temazepam 10mg and 20mg tablets – and Local Recommendations

Since the September medicines shortages update/summary (see above) was written, a medicines supply notification (MSN) has been issued for temazepam 10mg and 20mg tablets. This is Tier 2 – medium impact, therefore please see the MSN embedded below:

MSN_2022_078 Temazepam 10mg ar

Local recommendations (in alignment with KMPT):

- Review current patients on temazepam, discuss prolonged shortage and uncertainty around its availability by estimated return date (December 2022);
- Consider a gradual dose reduction via alternative benzodiazepine or z-drug with a view to discontinuing due to potential withdrawal symptoms associated with abrupt discontinuation.
    - For those willing to discontinue, convert them to diazepam and do a gradual withdrawal (5mg diazepam is equivalent to 10mg temazepam), being particularly careful with the older population who may have residual effects the following day (e.g. daytime sedation and falls).
    - For those who are not willing to discontinue, look at switching them to zopiclone (7.5mg dose is equivalent to 10 mg of temazepam) – as there is no direct benzodiazepine alternative to temazepam. See 'Benzodiazepine & z-drug deprescribing algorithm' (page 7) – supports recommendations in NICE guideline 215 on medicines associated with dependence or withdrawal symptoms.

MHRA – Class 4 Medicines Defect Information: Rosuvastatin 5 mg, 10 mg and 20 mg film-coated tablets EL (22)A/35

This article might merely be a reminder since this communication may have been circulated through other communication channels last month.

The MHRA released a Class 4 medicines defect information alert which affects some Accord Healthcare Rosuvastatin products, due to an error with the patient's information leaflets (PILs). A few batches contain an older version of the PIL which do not include the most up to date safety information.

The information missing from the PILs are as below:

Section 2 Other medicines and Rosuvastatin tablets:

Tell your doctor if you are taking any of the following:

Regorafenib (used to treat cancer), any of the following drugs used to treat viral infections, including HIV or hepatitis C infection, alone or in combination (please see

Warnings and precautions): atazanavir, ombitasvir, paritaprevir, dasabuvir, velpatasvir, grazoprevir, elbasvir, glecaprevir, pibrentasvir.

Section 4 Possible side effects:

Stop taking Rosuvastatin tablets and talk to your doctor immediately

- If you experience muscle rupture
- If you have lupus-like disease syndrome (including rash, joint disorders and effects on blood cells).

Rosuvastatin tablets may cause the following possible side effects:

Rare (may affect up to 1 in 1,000 people)

- Severe allergic reaction – signs include swelling of the face, lips, tongue and/or throat, difficulty in swallowing and breathing, a severe itching of the skin (with raised lumps). If you think you are having an allergic reaction, then stop taking Rosuvastatin tablets and seek medical help immediately
- Muscle damage in adults – as a precaution, stop taking Rosuvastatin tablets and talk to your doctor immediately if you have any unusual aches or pains in your muscles which go on for longer than expected
- Lupus-like disease syndrome (including rash, joint disorders and effects on blood cells).

Advice for healthcare professionals

There is no risk to product quality as a result of this issue, therefore the affected batches are not being recalled. Healthcare professionals are advised to exercise caution when dispensing the product and where possible, provide an updated PIL. The updated PIL is available via the MHRA website:

Rosuvastatin 5 mg film-coated tablets-PIL

Rosuvastatin10 mg film-coated tablets-PIL

Rosuvastatin 20 mg film-coated tablets-PIL

Accord Healthcare Limited have confirmed that all future batches will contain the updated PIL and that upon request they will send hard copies by post of the updated PIL to wholesalers and pharmacies, so that any remaining stock in the dispensary can be supplemented with the updated PIL information.

Further Information

For more information or medical information queries please contact: Accord Medical Information Department on 01271 385257, email medinfo@accord-healthcare.com.
For stock control queries, please contact: Accord Customer Services Team on 0800 373573
For updated PIL requests please contact contact@accord-healthcare.com or phone: 01271 385200

MHRA – Class 4 Medicines Defect Information: Rosemont Pharmaceuticals Ltd, Atorvastatin 4mg/ml Oral Suspension & Sildenafil 10mg/ml Oral Suspension, EL (22)A/39

Rosemont Pharmaceuticals Ltd. has made the MHRA aware that the expiry dates stamped on the base of the bottle are incorrect for two batches of Atorvastatin 4mg/ml Oral Suspension and two batches of Sildenafil 10mg/ml Oral Suspension.

Product description

Atorvastatin 4mg/ml Oral Suspension PL 00427/0256

Batch Number	Expiry Date	Pack Size	First Distributed
ATV21001	Apr-2024	150 ml	28-Apr-2022
ATV21002	Apr-2024	150 ml	13-Jul-2022

Active Pharmaceutical Ingredient: Atorvastatin

Sildenafil 10mg/ml Oral Suspension PL 00427/0258

Batch Number	Expiry Date	Pack Size	First Distributed
SLD22001	Mar-2025	122 ml	Not yet distributed
SLD22002	Apr-2025	122 ml	22-Jun-2022

Active Pharmaceutical Ingredient: Sildenafil

Brief description of the problem
Rosemont Pharmaceuticals Ltd. has made the MHRA aware that the expiry dates stamped on the base of the bottle are incorrect for the above 2 batches of Atorvastatin 4mg/ml Oral Suspension (indicated for hypercholesterolaemia and prevention of cardiovascular disease) and 2 batches of Sildenafil 10mg/ml Oral

Suspension (indicated for pulmonary arterial hypertension). The correct expiry dates (as stated in the above table) are printed on the bottle label and on the outer carton. All other product details are correct, including the serial numbers and batch numbers.

Advice for healthcare professionals
There is no risk to product quality as a result of this issue, therefore the affected batches are not being recalled. Healthcare professionals should advise patients of the issue when dispensing these products. The products can be used until the expiry date printed on the bottle label and the outer carton. The expiry date stamped on the base of the bottle should be ignored. No other batches of Atorvastatin 4mg/ml Oral Suspension or Sildenafil 10mg/ml Oral Suspension marketed by Rosemont Pharmaceuticals are affected by this discrepancy.

Advice for patients
Patients should note that the expiry date printed on the **base of the bottle** for these products is incorrect and should be ignored. There are no concerns about the safety or quality of the medicine. The expiry date is correct on the bottle label and the outer carton (box). Patients should use these products until the expiry date on the bottle label and outer carton. If a patient has any concerns, they should contact their pharmacist.

Further Information
For further information please contact: pharmacovigilance@rosemontpharma.com

The full notification can be accessed here

MHRA – Class 2 Medicines Recall: Dysport 500 Units Powder for Solution for Injection, EL (22)A/36

The UK Marketing Authorisation Holder has confirmed that a batch of Dysport 500 Units Powder for Solution for Injection is falsified and has been supplied by unauthorised distributors to the UK.

Company name
Ipsen Limited

Product name
Dysport 500 Units Powder for Solution for Injection PL 34926/000

Batch number	Expiry date	Pack size	First distributed
U14534	11/2023	1 x 500U vial	unknown

Active Pharmaceutical Ingredient: clostridium botulinum type A toxin-haemagglutinin complex

Brief description of the problem
The Medicines and Healthcare products Regulatory Agency (MHRA) has been investigating a report of a falsification of the above product in the UK.

The UK Marketing Authorisation Holder has confirmed that the batch above is falsified and has been supplied by unauthorised distributors to the UK.

See below for further details on identifying the falsified packs. This is also referenced in a Medical Product Alert issued by the World Health Organization (RPQ/REG/ISF/Alert N°4/2022):

- The falsified carton in the UK includes an incorrect serialisation number (DYN7PCXH84UNBF) and an incorrect GTIN number (03582186006207)

This recall is to remove falsified products from the supply chain. The MHRA has not received any reports indicating patient harm related to this issue but will monitor the situation closely.

Advice for healthcare professionals
Stop supplying the above falsified batch immediately. Quarantine all remaining stock and return it to your supplier for onward investigation by Ipsen Limited.

If patients felt unwell after the administration of the affected batch above, please report this to the Marketing Authorisation Holder and complete a Yellow Card report via the MHRA Yellow Card scheme.

Advice for patients
Patients are not required to take any action at this time. This product is administered by healthcare professionals only.

If you are concerned about this notification, please contact your healthcare professional. If you have an adverse reaction after administration of Dysport, please seek medical attention. Side effects should also be reported via the MHRA's Yellow Card scheme.

Further Information
For medical information enquiries, please contact Ipsen Limited at medinfo.uk-ie@ipsen.com

Falsified Medicines Directive
This notification covers regulation as defined in the Falsified Medicines Directive where it applies. Falsified Medicines Directive (FMD) 2011/62/EU introduced new requirements to enhance the security of the European supply chain. Where the MHRA has identified risks to the security of the supply chain, FMD Alerts will be issued. Following the UK's departure from the EU, the 'safety features' Delegated Regulation (EU) 2016/161 no longer applies in Great Britain (England, Scotland and Wales) but still applies in Northern Ireland.

For further information about FMD and safety features, please see this link on GOV.UK.

The full notification can be accessed here

The latest MHRA Drug Safety Updates can be accessed at https://www.gov.uk/drug-safety-update. This includes links to alerts, recalls and safety information and to the monthly Drug Safety Update PDF newsletter.

MHRA – Class 2 Medicines Recall: Novartis Pharmaceuticals UK, Sandimmum Oral Soultion, EL (22)A/40

Novartis Pharmaceuticals UK are recalling a batch of Sandimmun Oral Solution due to the presence of crystals in the solution.

Product name
Sandimmun Oral Solution PL 00101/0124

Batch number	Expiry date	Pack size	First distributed
ADP326002	November 2024	50 ml	06/05/2022

Active Pharmaceutical Ingredient: ciclosporin

Brief description of the problem
Novartis Pharmaceuticals UK are recalling the above batch due to the presence of crystals in the solution. The crystals have been identified as the active substance (ciclosporin). The presence of crystals has been observed in some finished product packs marketed in other countries that share the same master batch as the UK batch

above. Therefore, this UK batch is recalled as a precautionary measure. Novartis Pharmaceuticals UK have confirmed no other batches of the product are impacted.

Advice for healthcare professionals
Stop supplying the above batch immediately. Quarantine all remaining stock and return it to your supplier using your supplier's approved process.

Advice for patients

- Patients should not stop taking Sandimmun Oral Solution without speaking to your doctor or other healthcare professionals, as stopping your treatment may increase the risk of your transplanted organ being rejected.
- The Marketing Authorisation Holder in the UK has not received any product complaints or adverse reactions related to the issue above. However, if you feel unwell whilst taking medicines from this batch then please seek urgent medical attention. Adverse reactions should also be reported via the MHRA Yellow Card scheme.
- If you have any questions about your Sandimmun Oral Solution or observe crystallised particles in the solution, talk to your pharmacist, transplant team or other healthcare professionals for advice.

Further Information
For more information, medical or supply enquiries, please contact 01276 698370, or email medinfo.uk@novartis.com

The full notification can be accessed here