

## Medicines Optimisation updates – January 2023

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### Safety considerations with Metolazone preparations

Historically, Metolazone has only existed in the UK as an unlicensed imported product, however a licensed formulation is now available. This licensed product is known as Xaqua and available in 5 mg Tablets.

It has become apparent that the bioavailability of the licensed Metolazone (Xaqua) is twice as potent as the unlicensed Metolazone preparation, whereby 5mg of Xaqua would be equivalent to 10mg of the historical unlicensed product. It is important to note both unlicensed and licensed (Xaqua) Metolazone preparations are currently in circulation.

We are working closely with our local trusts and asking them to assist with safely switching our patients from the unlicensed Metolazone preparation to the licensed product, Xaqua.

In the meantime, we are asking all primary, secondary and community colleagues to exercise caution when ordering, prescribing, and dispensing Metolazone.

Please ensure that the prescribing and supply of metolazone is product specific. Please ensure where possible that patients and/or carers are aware that their brand of metolazone should not be switched, unless advised by their healthcare professional.

For further information please see:

[Differences between metolazone preparations and safety considerations – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice](#)

## Over the counter medicines resources

The Medicines Optimisation Team have put together a selection of patient information posters to promote the use of self-care [General practice communication and engagement resources :: NHS Kent and Medway \(icb.nhs.uk\)](#)

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## IT Support: Ardens/EMIS – please share learning hub link with practice staff – \*with updated link to request training

Is your practice team struggling to run the right searches on Ardens and EMIS? If this resonates with you, the most simplest of tasks, to update/extract information, may be taking you too long and not providing you with the right information. Support is available, either through the [South Central and West Commissioning Support Unit \(SCWCSU\) Learning Hub](#) which has a number of videos and training courses that are free to access/sign up to, or you can email the [team \(training.scwcsu@nhs.net\)](mailto:training.scwcsu@nhs.net) and request support for the practice. Each practice is allocated up to 3 hours of one-to-one support per year free of charge. Have a discussion with the team to identify the practice's training needs and take up the offer of one-to-one support (3 hours, per practice, per year), or

explore the range of videos and training to see how your practice can be best supported and upskilled. Please also see links below that you may find useful:

[Click here to review the EMIS Now article which details how to create a search in EMIS web](#)

[Click here to review the EMIS Now article which details how to export a search in EMIS web](#)

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## Medicines Optimisation MHRA Drug Safety Update – Dec 2022

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 December 2022 Drug Safety Update includes:

[\*\*Valproate: reminder of current Pregnancy Prevention Programme requirements; information on new safety measures to be introduced in the coming months\*\*](#)

In view of data showing ongoing exposure to valproate in pregnancy, this article reminds healthcare professionals of the risks in pregnancy and the current Pregnancy Prevention Programme requirements, and provides information about the potential risks of valproate in other patients following a review of the latest safety data. Following advice from the Commission on Human Medicines (CHM), new safety measures for valproate-containing medicines are to be put in place in the coming months.

The CHM has established an implementation group with a cross-health sector membership to support the safe introduction of the new measures into clinical practice. This will be via a phased programme currently under development according to patient safety priorities, and developed in collaboration with the healthcare bodies, to ensure ongoing patient care is not disrupted. No action is currently needed from patients.

Patients currently taking valproate must be advised not to stop taking it unless they are advised by a specialist to do so. Any patient who thinks they are pregnant while on valproate should be advised to talk to a specialist urgently. Before initiating valproate in patients younger than 55 years, healthcare professionals should consider all other suitable therapeutic options and [consult the findings of the epilepsy medicines in pregnancy review](#).

Please follow the link in the title above for more information and resources.

### [COVID-19 vaccines and medicines: updates for December 2022](#)

### [Letters and medicine recalls sent to healthcare professionals in November 2022](#)

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

*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.*

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## MHRA Class 4 Medicines Defect Information:

### [Class 4 Medicines Defect Information: Galderma \(U.K.\) Limited, Epiduo 0.1% / 2.5% gel \(45 g\), EL \(22\)A/52](#)

Galderma (U.K.) Limited has informed the MHRA that the Patient Information Leaflet (PIL) packaged in the above batches of Epiduo 0.1% / 2.5% gel contains outdated safety information regarding pregnancy. Please follow the link in the title above for the full details and action on this MHRA alert issued by CAS on 19<sup>th</sup> December 2022.

### [Class 4 Medicines Defect Information: Albireo AB, Bylvay 1200 micrograms Hard Capsules, EL \(23\)A/01](#)

Albireo AB has informed the MHRA that the side panel of the bottle label of a specific batch of Bylvay 1200 micrograms Hard Capsules erroneously reflected the content of the active ingredient as 400 micrograms odevixibat (as sesquihydrate). This should state: "Each capsule contains 1200 micrograms odevixibat (as sesquihydrate)".

Please follow the link in the title above for the full details and actions on this MHRA alert issued by CAS on 3<sup>rd</sup> January 2023.

## MHRA - Class 2 Medicines Recall: UCB Pharma Ltd, Dioctyl 100 mg Capsules, EL (23)A/02

UCB Pharma Ltd is recalling one batch of Dioctyl 100 mg Capsules as a precautionary measure due to the presence of a foreign capsule being found in a sealed pack. This recall was issued on 18/1/2023 for action within 48 hours.

[Class 2 Medicines Recall: UCB Pharma Ltd, Dioctyl 100 mg Capsules, EL \(23\)A/02 - GOV.UK \(www.gov.uk\)](#)

## January Shortages

Please find attached the medicines shortages update (16<sup>th</sup> January 2023).

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.

## Medicines Supply Notifications

**Issued on 23.12.22:**

- **A Tier 2 medicine supply notification for the shortage selegiline (Eldepryl®) 5mg and 10mg tablets (attached).**

### ***Shortage of Selegiline – Action needed***

Please be aware of the current shortage of Selegiline (Eldepryl) 5mg and 10mg tablets which has an anticipated re-supply date of 28<sup>th</sup> April 2023.

Practices in primary care should proactively identify any patients on selegiline, contact them to establish how much supply they have left, and make arrangements to prescribe an alternative agent if patient has insufficient supply. This should be done as soon as possible so that those patients who have run out or are low in supply

minimise/avoid the break in treatment and risk of disease deterioration.

For further information regarding alternatives, considerations and background please see the following page on the [SPS Medicines Supply Tool](#) , and the MSN.

- **A Tier 2 medicine supply notification for the shortage of prochlorperazine (Stemetil®) 12.5mg/ml solution for injection ampoules** which are out of stock until the week commencing 16th January 2023 (attached). The anticipated date of re-supply has been subsequently updated to 13<sup>th</sup> February 2023 on the SPS Medicines Supply Tool.

#### **Issued on 17.01.23:**

- **A Tier 2 medicine supply notification for the shortage of Vigabatrin (Sabril) 500mg tablets** which are out of stock until the week commencing 3<sup>rd</sup> March 2023 (attached).
- **Tier 2 Medicine Supply Notification for various Insuman® products**
- We would like to inform colleagues that there is a Tier 2 medicine supply notification for various Insuman® products.

#### **Summary**

- Insuman® Comb 25 100units/ml suspension for injection 3ml cartridges and prefilled pens will be discontinued with stocks being exhausted in May and June 2023 respectively.
- Insuman® Basal 100units/ml suspension for injection 3ml cartridges and prefilled pens will be discontinued with stocks being exhausted in June 2023.
- Insuman® Rapid 100units/ml suspension for injection 3ml cartridges will be discontinued with stocks being exhausted in May 2023.
- Humalog® Mix 25 remains available, as do other biphasic insulin preparations

- Alternative human isophane insulins remain available
- Alternative neutral (soluble) insulins remain available

### **Actions Required**

- Prescribers should:
  - not initiate any new patients on Insuman® products.
  - review all patients prescribed Insuman® Comb 25 100units/ml suspension for injection 3ml cartridges; and consider prescribing Humalog® Mix 25 in the first instance consider prescribing another biphasic insulin preparation if the above option is not deemed suitable
  - review all patients prescribed Insuman® Basal and consider prescribing alternative human isophane insulin preparations
  - review all patients prescribed Insuman® Rapid and consider prescribing alternative neutral (soluble) insulin
  - ensure that after switching, patients are counselled on how to use the new device, explain that the dose of insulin remains the same, but adjustments may be needed depending on blood glucose levels and signs of hypoglycaemia.

<b>Medicine</b>	<b>Out of stock</b>	<b>Alternatives</b>
Insulin isophane biphasic human 25/75 (Insuman® Comb 25) 100units/ml suspension for injection 3ml cartridge	Until May 2023	<ul style="list-style-type: none"> <li>• Humalog® Mix 25</li> <li>• Alternative human isophane and neutral (soluble) insulins.</li> <li>• See MSN for details.</li> </ul>
Insulin isophane biphasic human 25/75 (Insuman® Comb 25 SoloStar) 100units/ml suspension for injection pre-filled pens	Until June 2023	
Insulin human isophane (Insuman® Basal) 100units/ml suspension for injection 3ml cartridge	Until June 2023	
Insulin human isophane (Insuman® Basal SoloStar) 100units/ml suspension for injection 3ml pre-filled pens	Until June 2023	

Neutral (soluble) insulin (Insuman® Rapid) 100units/ml suspension for injection 3ml cartridge	Until May 2023	
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- For more info please see the full MSN attached, if you have any queries please contact [DHSCmedicinesupplyteam@dhsc.gov.uk](mailto:DHSCmedicinesupplyteam@dhsc.gov.uk)
- The DHSC and NHSE have now launched an online [Medicines Supply Tool](#), which provides up to date information about medicine supply issues. The contents of this MSN can now be viewed on the Tool.
- The Tool also details any changes to resupply dates and updates to the entries. To access the Tool you will be required to register with the [SPS website](#).

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## Serious Shortage Protocols:

SSPs are now available to view here on the NHS Business Service Authority (NHSBSA)'s [dedicated SSP web page](#), along with supporting guidance.

If you have any questions regarding the SSPs please contact the NHS Prescription Service:

Email: [nhsbsa.prescriptionservices@nhsbsa.nhs.uk](mailto:nhsbsa.prescriptionservices@nhsbsa.nhs.uk)

Telephone: 0300 330 1349

Textphone: 18001 0300 330 1349

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