

# BNF and Drug Safety Updates, March 2023

## BNF Updates



### Significant Changes:

- Aripiprazole (Abilify® and generic brands):  
risk of pathological gambling [MHRA/CHM advice].
- Empagliflozin:  
update to advice on use in renal impairment, including new indication for chronic kidney disease.
- Quinolones:  
must now only be prescribed when other commonly recommended antibiotics are inappropriate [MHRA/CHM advice] (see example in ciprofloxacin).
- Type 2 diabetes:  
updated guidance for management.
- Vitamin B12:  
advise patients with known cobalt allergy to be vigilant for

sensitivity reactions [MHRA/CHM advice] (advice in cyanocobalamin, hydroxocobalamin; see example in hydroxocobalamin).

### Dose Changes:

- Secukinumab  
[update to dosing for psoriatic arthritis with concomitant moderate to severe plaque psoriasis].

### New Monographs:

- Inaqovi® [decitabine with cedazuridine].
- Litfulo® [ritlecitinib].
- Livmarli® [maralixibat].
- Veoza® [fezolinetant].

### Deleted Monographs:

- Cinchocaine hydrochloride with fluocortolone caproate
- Fluocortolone pivalate

- Simvastatin with fenofibrate.

## BNF for Children Updates



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risk of pathological gambling [MHRA/CHM advice].
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advise patients with known cobalt allergy to be vigilant for sensitivity reactions [MHRA/CHM advice] (advice in cyanocobalamin, hydroxocobalamin; see example in hydroxocobalamin).

### New Monographs:

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## Trust Issued Drug Safety Updates

- [Sodium Chloride 0.9% 10ml ampoules](#)
- [Trurapi 100units/ml solution for injection pre-filled pen](#)
- [Co-trimoxazole 40mg 200mg 5mL oral suspension – update](#)
- [Fluoroquinolones advice update](#)
- [Shortage of GLP-1 receptor agonists used in the management of type 2 diabetes semaglutide, dulaglutide, liraglutide, exenatide - \(update\)](#)
- [Hyoscine ButylBromide 1.5mg \(Scopoderm\) Patches](#)

## National Drug Alerts

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- **Aripiprazole (Abilify and generic brands): risk of pathological gambling**
  - Healthcare professionals prescribing aripiprazole are reminded to be alert to the risk of addictive gambling and other impulse control disorders.
- **Vitamin B12 (hydroxocobalamin, cyanocobalamin): advise patients with known cobalt allergy to be vigilant for sensitivity reactions**
  - The medicines used to treat vitamin B12 deficiency (hydroxocobalamin, cyanocobalamin) contain cobalt. There are case reports in the literature describing cobalt sensitivity-type reactions in patients being treated for vitamin B12 deficiency.
- **Codeine linctus (codeine oral solutions): reclassification to prescription-only medicine**
  - Advice for healthcare professionals on the reclassification of codeine linctus to a prescription-only medicine (POM), following a public consultation.
- **Pseudoephedrine: very rare risk of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS)**
  - There have been very rare reports of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS) with pseudoephedrine.

- **Valproate (Belvo, Convulex, Depakote, Dyzantil, Epilim, Epilim Chrono or Chronosphere, Episenta, Epival, and Syonell ▼): new safety and educational materials to support regulatory measures in men and women under 55 years of age**
  - The Trust Valproate Working Group are developing resources to support the implementation of the new regulatory guidance and will provide updates via Staff Comms.
- **Omega-3-acid ethyl ester medicines (Omacor/Teromeg 1000mg capsules): dose-dependent increased risk of atrial fibrillation in patients with established cardiovascular diseases or cardiovascular risk factors**
  - Systematic reviews and meta-analyses of randomised controlled trials have highlighted a dose-dependent increased risk of atrial fibrillation in patients with established cardiovascular diseases or cardiovascular risk factors treated with omega-3-acid ethyl ester medicines compared to placebo.

## SWB Pharmacy updates

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- The Brand Eliquis (apixaban) will be switching to generic apixaban tablets.

## Medicines Recalls

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- [Class 4 Medicines Defect Information: Quadrant Pharmaceuticals Ltd, Cozaar 100mg film-coated tablets, EL\(24\)A/01.](#)
  - MHRA informed of an error with the Patient Information Leaflets (PILs) that have been packed in the listed batches of Cozaar 100mg film-coated tablets.
  - No affected batches at SWB so no further action
- [Class 4 Medicines Defect Information: USV UK Limited, Sugammadex 100 mg/ml solution for injection \(2 ml vial\), EL\(24\)A/02.](#)
  - MHRA informed that some 2mL vials may contain less than total amount.
  - No affected batches at SWB so no further action
- [Class 4 Medicines Defect Information: Cadila Pharmaceuticals \(UK\) Limited, Pantoprazole 40 mg Gastro-Resistant Tablets, EL \(24\)A/03.](#)
  - MHRA regarding an error with the European Article Number (EAN) barcode on the cartons of the above-mentioned batches of Pantoprazole 40 mg GastroResistant Tablets distributed by Crescent Pharma Limited. When scanned, the EAN barcode identifies the product as Bicalutamide 150 mg Tablets.
  - No affected batches at SWB so no further action

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FOR FURTHER INFORMATION CONTACT

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