

**SHORTAGE:**

Fesoterodine (Toviaz) 4mg and 8mg modified release Tablets

**Anticipated re-supply date: 27<sup>th</sup> May 2022**

**Actions for prescribers:**

Where patients have insufficient supplies to last until the re-supply date, prescribers should:

- review if treatment is still required, and if deemed necessary, consider prescribing an alternative oral antimuscarinic agent, the choice of which will be determined by treatments already tried, if fesoterodine was not being used as a first-line treatment; and
- prescribers and pharmacists should counsel patients on the switch and advise them to seek advice from prescribers if there is a worsening in symptom control or they experience unacceptable side-effects.

**Alternatives:****Alternative oral anti-muscarinic agents****Solifenacin**

Available in 5mg and 10mg immediate release tablets and a 1mg/ml oral suspension.

Dose

5mg to 10mg daily.

Supply position

In stock and can support a full uplift in demand for the immediate release tablets.

**Tolterodine**

Available in 1mg and 2mg standard release tablets, as well as 2mg and 4mg prolonged-release capsules.

Dose for standard release tablets

1mg to 2mg twice daily.

Dose for prolonged-release capsules

2mg to 4mg daily.

Supply position

Both formulations are in stock and can support full uplift in demand.

**Darifenacin**

Available in 7.5mg and 15mg prolonged release tablets.

Dose

7.5mg to 15mg daily.

Supply position

In stock but cannot support an uplift in demand.

**Trospium**

Available in 20mg standard release tablets and 60mg prolonged-release capsules.

Dose for standard release tablets

20mg twice daily

Dose for prolonged-release capsules

60mg daily

Supply position

Standard release tablets are in stock and can support a partial uplift in demand.

Prolonged release capsules are in stock and can support a full uplift in demand.

**Oxybutynin\***

Available in 2.5mg and 5mg standard release tablets, as well as a 2.5mg/5ml and 5mg/5ml oral solution.

Dose

5mg twice daily or up to three times daily (2.5mg twice daily for elderly patients)

Supply position

|   |   |
|---|---|
|   | <p>In stock and can support a full uplift in demand for the immediate release tablets.</p> <p><i>*Lyrinel XL® 5mg and 10 mg tablets are being discontinued in July 2022.</i></p> <p><b>Considerations and background</b></p> <p><b>Summary</b></p> <ul style="list-style-type: none"> <li>• There will be intermittent supply of fesoterodine (Toviaz®) 4mg and 8mg modified release tablets until the end of April 2022.</li> <li>• Alternative antimuscarinic agents remain available and can support an uplift in demand.</li> <li>• Generic fesoterodine 4mg and 8mg modified release tablets are being launched and will be available from the beginning of May 2022</li> </ul> <p><b>Clinical Information</b></p> <p>Fesoterodine is an antimuscarinic agent licensed for the treatment of symptoms (increased urinary frequency and/or urgency and/or urgency incontinence) that may occur with overactive bladder syndrome. Dose is 4mg to 8mg once daily.</p> <p>If fesoterodine is not being used as a first line treatment, choice of alternative antimuscarinic agent will be determined by treatments previously tried. In addition, some of the standard formulations must be administered more than once a day, which may not be as suitable for patients accustomed to a once-daily regimen or where adherence may be an issue.</p> <p>Dry mouth is the most common and troublesome adverse effect of antimuscarinic medications. Newer agents such as solifenacin, tolterodine and darifenacin, may cause dry mouth to a lesser extent than oxybutynin. Extended-release preparations are also expected to reduce the risk of dry mouth. Oxybutynin (standard release) should usually be avoided in elderly, frail patients who are at greater risk of adverse reactions.</p> <p>Please see the following links for further information:</p> <ul style="list-style-type: none"> <li>• <a href="#">SmPC oxybutynin oral preparations</a></li> <li>• <a href="#">BNF oxybutynin</a></li> <li>• <a href="#">SmPC tolterodine oral preparations</a></li> <li>• <a href="#">BNF tolterodine</a></li> <li>• <a href="#">SmPC solifenacin oral preparations</a></li> <li>• <a href="#">BNF solifenacin</a></li> <li>• <a href="#">SmPC darifenacin oral preparations</a></li> <li>• <a href="#">BNF darifenacin</a></li> <li>• <a href="#">SmPC trospium oral preparations</a></li> <li>• <a href="#">BNF trospium</a></li> </ul> |
| <p><b>SHORTAGE:</b><br/>Disopyramide 250mg modified release tablets<br/>(Rythmodan Retard 250mg tablets<br/>(Neon Healthcare Ltd)</p> | <p><b>Anticipated re-supply date: 20<sup>th</sup> May 2022</b></p> <p><b>Alternatives:</b><br/>Parallel imports of disopyramide 250mg modified release tablets are available and can cover the demand.<br/>Orders can be placed directly with following suppliers:</p> <ul style="list-style-type: none"> <li>• Drugsrus (email <a href="mailto:nhs@drugsrus.co.uk">nhs@drugsrus.co.uk</a> for further information)</li> </ul>  |
| <p><b>SHORTAGE:</b><br/>Havrix Junior Monodose vaccine suspension for injection 0.5ml vials (GlaxoSmithKline UK Ltd)</p>              | <p><b>Anticipated re-supply date: 8<sup>th</sup> July 2022</b></p> <p><b>Alternatives:</b><br/>Havrix Junior Monodose vaccine suspension for injection 0.5ml vials packs of 10's are available and can support the uplift in demand.</p>  |
| <p><b>SHORTAGE:</b><br/>Chloral hydrate 143.3mg in 5ml oral solution</p>  | <p><b>Anticipated re-supply date: 30<sup>th</sup> June 2022</b></p> <p><b>Actions for prescribers:</b></p>  |

|   |  |
|---|--|
|   | <p>Where patients have insufficient supplies, clinicians should:</p> <ul style="list-style-type: none"> <li>• review ongoing need for treatment</li> <li>• prescribe 143.3mg in 5ml chloral hydrate solution as a special if ongoing treatment is deemed necessary.</li> </ul> <p><b>Alternatives:</b><br/>Available specials<br/>The following specials manufacturers have confirmed they can manufacture chloral hydrate oral solution to meet demand of the licensed product (please note, there may be other companies that can also manufacture this product).</p> <p><b>Ascot labs</b><br/>143.3mg in 5ml oral solution</p> <p><b>Alium Medical</b><br/>143.3mg in 5ml oral solution</p> <p><b>Target Healthcare</b><br/>143.3mg in 5ml oral solution</p> <p><b>Certificates:</b><br/>Note that Alium and Target products are not batch manufactured and the supplier will only provide a certificate of conformity (CoC). Suppliers providing batch manufactured products will provide a certificate of analysis (CofA).</p> <p><b>Considerations and Background</b></p> <p><b>Using Unlicensed Medicines</b><br/>Any decision to prescribe an unlicensed medicine must consider the relevant guidance and NHS Trust or local governance procedures. Please see the links below for further information:</p> <ul style="list-style-type: none"> <li>• <a href="#">The supply of unlicensed medicinal products</a>, Medicines and Healthcare products Regulatory Agency (MHRA);</li> <li>• <a href="#">Professional guidance for the procurement and supply of specials</a>, Royal Pharmaceutical Society (RPS); and</li> <li>• <a href="#">Prescribing unlicensed medicines</a>, General Medical Council (GMC).</li> </ul> <p>When prescribing chloral hydrate 143.3mg in 5ml oral solution not licensed in the UK, due to a supply issue with the licensed alternative, prescribers must indicate on the FP10 prescription that an unlicensed product is required.<br/>This can be done in one of the following two ways:</p> <p><b><u>Electronic prescriptions</u></b><br/>If the required unlicensed product is shown on electronic prescribing systems, GP's should select: <b>chloral hydrate 143.3mg in 5ml oral solution (special order)</b></p> <p><b><u>Paper prescriptions</u></b><br/>Where the unlicensed product is not shown on electronic prescribing systems, GP's should use a paper prescription and annotate with the following wording: <b>special order.</b></p> |
| <p><b>SHORTAGE:</b><br/><b>Pepto-Bismol</b></p> | <p><b>Anticipated re-supply date: 26<sup>th</sup> August 2022</b></p>  |

|   |  |
|---|--|
| <p>Bismuth subsalicylate 17.5mg/1ml oral suspension sugar free</p> <p>Bismuth subsalicylate 262.5mg chewable tablets sugar free</p> | <p><b>Alternatives:</b><br/>Alternative medicines for acid reflux, indigestion, diarrhoea and nausea remain available.</p>   |
| <p><b>SHORTAGE:</b><br/>Linezolid (Zyvox®) 100mg/5ml granules for oral suspension</p>   | <p><b>Anticipated re-supply date: 27<sup>th</sup> May 2022</b></p> <p><b>Actions:</b><br/>NHS provider trust pharmacy procurement teams should work with appropriate clinical leads and their local Medication Safety Officer (MSO) to:</p> <ul style="list-style-type: none"> <li>• review local stock holding of linezolid (Zyvox®) 100mg/5ml granules for oral suspension and reserve remaining supplies for use in neonates and children up to 12 years of age who require a dose of less than 600mg;</li> <li>• support requests for mutual aid regionally, which will be managed by the Regional Pharmacy Procurement Specialists (RPPS);</li> <li>• prescribe linezolid 600mg tablets as the first line option to deliver full doses (i.e. 600mg twice daily); and</li> <li>• consider crushing and dispersing linezolid tablets in water for administration for patients with swallowing difficulties (off label use; see supporting information); and</li> <li>• where patients are being discharged with the advice to crush tablets, ensure they are counselled on how to crush and disperse the tablets appropriately for administration (off label use; see Supporting Information)</li> </ul> <p><b>Alternatives:</b><br/>Linezolid 600mg film-coated tablets remain available and can support an increase in demand.</p> <p><b>Considerations and Background</b></p> <p>Supporting Information:<br/><b><u>Clinical information from SPS MI on crushing tablets</u></b><br/>The SmPC states that absorption from the oral suspension is similar to that achieved with the film-coated tablets. According to <a href="#">NEWT guidelines for administration of medication to patients with enteral feeding tubes or swallowing difficulties</a>, linezolid tablets can be crushed and dispersed in water for administration. Please note this is unlicensed practice. Please refer to BNF and SPC via links below for further information:</p> <ul style="list-style-type: none"> <li>• <a href="#">Linezolid SmPCs</a></li> <li>• <a href="#">Linezolid BNF</a></li> <li>• <a href="#">Linezolid BNFC</a></li> </ul> |
| <p><b>SHORTAGE:</b><br/>Imdur 60mg modified-release tablets (TopRidge Pharma (Ireland) Ltd)</p>                                     | <p><b>Anticipated re-supply date: 20<sup>th</sup> May 2022</b></p> <p><b>Alternatives:</b><br/>Parallel imports remain available as well as other brands of isosorbide mononitrate 60mg modified release tablets.</p> <p><b>Considerations and Background:</b><br/>If the brand is switched, reassure patients that they are receiving the same treatment and to seek advice in the unlikely event of experiencing an increase in side effects, such as headache, or an increase in use of glyceryl trinitrate.</p>  |

|  |  |
|--|--|
|  |  |
| <p><b>SHORTAGE:</b><br/>FemSeven Sequi patches<br/>(Theramex HQ UK Ltd)</p>  | <p><b>Anticipated re-supply date: 1<sup>st</sup> September 2022</b></p> <p><b>Alternatives:</b><br/>Specialist importers can source unlicensed products. Lead times vary. Use other <a href="#">available HRT products</a> where appropriate.</p>  |
| <p><b>SHORTAGE:</b><br/>Glycerol 1g and 4g suppositories</p>                 | <p><b>Anticipated re-supply date: 1g- 17<sup>th</sup> June 2022</b><br/><b>4g-20<sup>th</sup> May 2022</b></p> <p><b>Actions:</b><br/>All clinicians should:</p> <ul style="list-style-type: none"> <li>• Consider prescribing half a 2g suppository in infants who require a 1g dose and where relevant, advise parents/carers to cut the suppository <b>lengthways</b> to ensure a more accurate dose is administered;</li> <li>• consider prescribing docusate sodium enemas in adults who require a rectal stool softener, if glycerol 4g suppositories are unavailable, and the oral route is not suitable;</li> <li>• seek specialist advice on management options if a glycerol ‘chip’ from the 1g suppository was being used in neonates; and</li> <li>• be aware that other laxatives remain available; choice will depend on stool consistency and products already tried.</li> </ul> <p><b>Alternatives:</b><br/>Glycerol 2g suppositories remain available and can support an increase in demand in place of the 1g suppositories.</p> <p><b>Considerations and Background</b><br/><b>Summary</b></p> <ul style="list-style-type: none"> <li>• Glycerol 1g suppositories are out of stock until mid-June 2022.</li> <li>• Glycerol 4g suppositories are in limited supply until mid-May 2022.</li> </ul> <p>Supporting Information:<br/>Please refer to the links below for further information:<br/><a href="#">SmPC Glycerol suppositories</a><br/><a href="#">SmPC Docusate sodium (Norgalax®) 10g micro-enema</a><br/><a href="#">BNF Treatment Summary – Constipation</a><br/><a href="#">BNFC Treatment Summary – Constipation</a></p> |
| <p><b>SHORTAGE</b><br/>Co-beneldopa 12.5mg/50mg capsules (Generic)</p>       | <p><b>Anticipated re-supply date: 7<sup>th</sup> October 2022</b></p> <p><b>Alternatives:</b><br/>Madopar 50mg/12.5mg capsules (Roche Products Ltd) remain available and can support a full uplift in demand.</p>  |
| <p><b>RECALL:</b><br/>Quinapril 5mg, 10mg, 20mg, 40mg (Accupro®) tablets</p> | <p><b>Summary of recall:</b><br/>Pfizer have voluntarily <a href="#">recalled</a> all stock of quinapril (Accupro®) tablets as a precautionary measure due to the identification of a nitrosamine impurity above the acceptable limit.</p> <p>Clinicians should be aware that quinapril 10mg/hydrochlorothiazide 12.5mg (Accuretic®) tablets were <a href="#">recalled previously</a> for the same reason.</p> <p><b>Actions for prescribers:</b><br/>All healthcare professionals in primary and secondary care should:</p> <ul style="list-style-type: none"> <li>• defer initiating any new patients on quinapril (Accupro®) tablets;</li> </ul>  |

- identify affected patients and refer to local or national treatment guidelines to switch to an alternative ACE inhibitor (see Supporting Information);
- monitor patients for changes in blood pressure and/or symptom control when prescribing alternative medications; and
- counsel patients on new medication, dose regime and potential side-effects.

**Alternatives:**

Alternative ACE inhibitors remain available and can support an uplift in demand.

**Considerations and Background:**

**Clinical Information**

Quinapril is licensed for essential hypertension and congestive heart failure when given concomitantly with a diuretic and/or cardiac glycoside. It is administered as a single dose or divided into 2 doses. Usual dose range in hypertension is 10 mg to 40 mg/day (up to 80 mg/day) and in heart failure is 10 mg to 20 mg/day (up to 40 mg/day).

When switching to an alternative ACE inhibitor, there are no definitive dose conversion data so treatment should be titrated according to the patient's clinical response. Refer to dosing advice in the BNF, SmPC's or Clinical Knowledge Summary (CKS).

Please refer to the links below for further information:

[Quinapril \(Accupro®\) tablets SmPC](#)

[BNF \(drugs affecting the renin-angiotensin system\)](#)

[CKS \(hypertension\)](#)

[CKS \(chronic heart failure\)](#)

[NICE guideline for hypertension](#)

Access this recall on the MHRA website via the link below:

<https://www.gov.uk/drug-device-alerts/class-2-medicines-recall-pfizer-limited-accupro-5mg-10mg-20mg-40mg-film-coated-tablets-el-22-a-slash-21>

All Serious Shortage Protocols (SPP's) can be found:

<https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/serious-shortage-protocols-ssps>

Shortage update taken from SPS Medicines Supply Toolkit 13<sup>th</sup> May 2022