SHORTAGE:

Trulicity 4.5mg/0.5ml solution for injection prefilled pens (Eli Lilly and Company Ltd)

Trulicity 3mg/0.5ml solution for injection prefilled pens (Eli Lilly and Company Ltd) Anticipated re-supply date 18 April 2022

Actions for prescribers

Where patients have insufficient supplies to last until the re-supply date, clinicians should consider temporarily prescribing 1.5mg dulaglutide (see advice on alternatives and clinical information below). If such a dose reduction is not considered suitable, options include:

- Switching to an alternative GLP-1 agonist; the choice of which will likely require specialist input, as well as training on the new pen device; or
- the off-label use of multiple 1.5mg injections to make up required dose, though there are no data on efficacy and safety of this approach, and acceptability to patient would need to be ascertained.

Specialist advice should be sought if there is uncertainty about the most appropriate management option.

Alternatives

Other GLP-1 agonists

There are two other once weekly GLP-1 agonists licensed for the treatment of type 2 diabetes mellitus, Bydureon® (exenatide) and Ozempic® (semaglutide), as well as a once daily agent, Victoza® (liraglutide). If a switch to these preparations is being considered, advice should be sought from specialists on which agent to switch to, and patients will require training on using the new pen device.

Making up dose with multiple 1.5mg injections

Lilly have advised that there is no data on efficacy and safety of this off label use. A decision to do so will also need to take into account patient preference. Those who have noticed a clinically significant improvement on the higher dose of dulaglutide compared to the 1.5 mg dose may be willing to receive multiple injections till shortage resolves; for others, the inconvenience of multiple injections may outweigh any benefits and they may prefer to opt for the 1.5 mg dose in the interim.

Dulaglutide (Trulicity®) 0.75mg/0.5ml and 1.5mg/0.5ml solution for injection prefilled pens remain available and can support an uplift in demand.

Clinical Information

Dulaglutide

This long-acting GLP-1 agonist is licensed for the treatment of adults with insufficiently controlled type 2 diabetes mellitus. As add on therapy, the recommended dose is 1.5 mg once weekly. If needed, the dose may be increased after at least 4 weeks to 3.0 mg once weekly, and after at least 4 weeks to 4.5 mg once weekly, the maximum dose. Data from a 52-week active controlled study comparing the three doses (1.5mg, 3 mg and 4.5 mg) of dulaglutide as add-on to metformin showed small gains in improved HbA1c from increasing doses (change in HbA1C from baseline at week 36 = -1.53%, -1.71% and -1.87%, respectively and at week 52 = -1.5%, -1.71% and -1.8%%). Therefore, consideration could be given to prescribing 1.5mg injection to those patients who run out of the 3.0 and 4.5mg injections until the shortage resolves.

Monitoring

Advice from a Specialist suggests:

Most patients on a GLP-1 analogue will likely already be carrying out some self-blood glucose monitoring and that would continue.

For patients transferred to 1.5 mg weekly dose on a temporary basis, and based on resupply date of mid-April, HbA1c can be rechecked after they have been reestablished on the higher dose (after at least 3 months).

For patients switched to an alternative GLP-1 analogue, HbA1c can be rechecked after 3 months.

Links for further information:

SmPC dulaglutide (Trulicity®)

Trial data from 52-week active controlled study comparing 1.5 mg, 3 mg and 4.5 mg of dulaglutide as add-on to metformin can be found in table 11 in section 5.1 of SmPC NICE Guidelines: Type 2 diabetes

Once weekly GLP-1 agonists:

SmPC Bydureon® (exenatide) 2 mg prolonged release suspension for injection in prefilled pen

SmPC Ozempic® (semaglutide) solution for injection in pre-filled pen Once daily GLP-1 agonists:

Victoza® 6 mg/ml (liraglutide) solution for injection in pre-filled pen

SHORTAGE:

Asacol 400mg MR gastroresistant tablets (Allergan Ltd) 18 March 2022 Asacol 800mg MR gastroresistant tablets (Allergan Ltd) Anticipated re-supply date 18 March 2022.

Actions for prescribers

For patients with insufficient supplies, clinicians should consider the following options:

- prescribing Octasa® MR tablets and reassure patients that this is a similar preparation to Asacol® MR gastro-resistant tablets;
- if Octasa® MR tablets are not considered appropriate refer to the SPS Q&A document for further information on licensed indications and dosing of other brands of mesalazine tablets, taking into account different release characteristics and counselling patients on any new product prescribed;
- monitoring patients for disease control and tolerability of treatment after switching products and ensuring they are maintained on this brand if the switch is successful; and
- deferring initiating any new patients on Asacol® MR gastro-resistant tablets until the supply issue is resolved.

Alternatives

Availability of alternative products

Interchangeable mesalazine tablet preparations

Octasa® MR 400mg and 800mg tablets – In stock and can support full uplift in demand.

Other mesalazine tablet preparations

The following mesalazine tablet preparations with different release characteristics remain available, should Octasa® MR tablets not be considered appropriate.

Zintasa® EC 400mg tablets – In stock

Salofalk® 250mg tablets, 500mg gastro-resistant tablets and 1g gastro-resistant tablets – In stock

Pentasa® 500mg and 1g slow-release tablets – In stock

Supporting Information

Alternative mesalazine tablet preparations

The BNF states 'there is no evidence to show that any one oral preparation of mesalazine is more effective than another; however, the delivery characteristics of oral mesalazine preparations may vary'.

Octasa® MR tablets were launched after publication of the BNF statement; they are a branded generic version of Asacol® tablets and have virtually the same in vitro dissolution profile, pH for release, site of drug release and same formulation.

Please refer to the relevant SmPC for further information on alternative preparations. SPS Q&A document – What are the differences between different brands of mesalazine tablets?

SHORTAGE: Xylocaine 1% with Adrenaline

Anticipated re-supply date 1% - 31 March 2022, 2% - 28 Feb 2022.

Actions for prescribers

100micrograms/20ml (1 in 200,000) solution for injection vials (Aspen Pharma Trading Ltd)

Xylocaine 2% with Adrenaline 100micrograms/20ml (1 in 200,000) solution for injection vials (Aspen Pharma Trading Ltd)

General Practice and other sites that use Xylocaine® 1% and 2% with adrenaline 100micrograms/20ml should:

- note the available alternative products (see supporting information); and
- consult the Medicines Information department at their local NHS Trust for advice where required.

Alternatives

Alternative local anaesthetic with adrenaline products

Due to the fixed dose of adrenaline in the alternative products, clinicians should be aware of the risk of administering a larger dose of adrenaline than intended.

Lidocaine 0.5% with adrenaline 1:200,000 10ml ampoule

Supplier – Torbay

Supply – In stock. Unlicensed product.

Lidocaine 1% with adrenaline 1:200,000 10ml ampoule

Supplier -Torbay.

Supply – Out of stock. Resupply date to be confirmed. Unlicensed product.

Lidocaine 2% with adrenaline 1:200,000 10ml ampoule

Supplier - Torbay.

Supply – Out of stock. Resupply date to be confirmed. Unlicensed product.

Bupivacaine 0.25% with adrenaline 1:200,000 10ml ampoule

Supplier – Advanz.

Supply – In stock. Cannot support an increase in demand.

Bupivacaine 0.5% with adrenaline 1:200,000 10ml ampoule

Supplier - Advanz.

Supply – In stock.

Lidocaine 1% with adrenaline 1:200,000 injection

Supplier – Specialist Importers.

Supply – Unlicensed product. See below.

Lidocaine 2% with adrenaline 1:200,000 injection

Supplier – Specialist Importers.

Supply – Unlicensed product. See below.

Unlicensed imports

The following specialist importers have confirmed they can source unlicensed lidocaine 1% or 2% with adrenaline 1:200,000 injection. Lead times may vary (please note, there may be other companies that can also source supplies):

Alium Medical - 1%

Durbin PLC - 1% and 2%

Mawdsley's Unlicensed - 1%

Smartway Pharma – 1%

Target Healthcare – 1% and 2%

UL Global Pharma – 1% and 2%

Guidance on unlicensed imports

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:

The supply of unlicensed medicinal products, Medicines and Healthcare products Regulatory Agency (MHRA)

Prescribing unlicensed medicines, General Medical Council (GMC) SHORTAGE: Diamox SR 250mg capsules (Advanz

Pharma)

Anticipated re-supply date 31 May 2022

Actions for prescribers

Pharmaceutical Society

For patients with insufficient supplies, clinicians should consider:

Professional Guidance for the Procurement and Supply of Specials, Royal

- prescribing acetazolamide immediate release 250mg tablets and monitoring patients after the switch (see clinical information); or
- prescribing acetazolamide oral suspension specials (various strengths available) if acetazolamide 250mg tablets are not appropriate; and
- deferring initiating any new patients on acetazolamide (Diamox® SR) 250mg modified-release capsules until the supply issue is resolved.

Alternatives

Alternative licensed products

Acetazolamide immediate release 250mg tablets remain available and can support an uplift in demand.

Specials

The following companies have indicated they can supply specials of acetazolamide oral suspension in various strengths (please note, there may be other companies that can manufacture supplies):

Eaststone Specials

IPS Pharma

Nova Labs

PCCA Ltd

Quantum Pharmaceutical

Rokshaw Ltd

Clinical Information

Acetazolamide is a carbonic anhydrase inhibitor. In the eye, it decreases the secretion of aqueous humour and results in a drop of intraocular pressure. Acetazolamide (Diamox® SR) modified-release capsules are a sustained release formulation designed to obtain a smooth and continuous clinical response. This formulation is licensed for the treatment of glaucoma and is administered at a dose of 250-500mg once daily.

The licensed dose in glaucoma of acetazolamide immediate release tablets is 250-1000mg per 24 hours, usually in divided doses (plasma half-life of acetazolamide ~ 4 hours).

Advanz Pharma has advised that for glaucoma, patients on acetazolamide (Diamox® SR) 250mg modified-release capsules twice daily could possibly be switched to acetazolamide 250mg tablets four times daily. This conversion is based simply on the maximum licensed dose of each formulation and would be at the discretion of the prescriber, as there are no bioequivalence studies comparing the two formulations.

The following data provided by the manufacturer from a single dose study of tablets and modified-release capsules may be helpful when making a dosing decision:

Formulation - immediate release Onset (hours) 1 Peak (hours) 1-4 Duration (hours) 8-12

Formulation - modified release capsule Onset (hours) 2 Peak (hours) 3-6 Duration (hours) 18-24

Modified-release capsules may be better tolerated than the equivalent dose of immediate release tablets, possibly due to the avoidance of high peak levels.

Alternatively, oral suspension specials are available in various strengths. If the liquid is used, dosing will be as for the immediate release tablets, with the aforementioned caveats.

Further information

Please see the following links for further information:

SmPC acetazolamide 250mg tablets

SmPC Diamox® SR 250mg prolonged-release capsules

Unlicensed medicines guidance

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:

The supply of unlicensed medicinal products, Medicines and Healthcare products Regulatory Agency (MHRA)

Professional guidance for the procurement and supply of specials, Royal Pharmaceutical Society (RPS)

Prescribing unlicensed medicines, General Medical Council (GMC)

Shortage: Cavilon Barrier Cream

3M has confirmed that there is a shortage in the supply of the following Cavilon products:

Cavilon Durable Barrier Cream, 92g Tube	Resupply expected April 2022
Cavilon Durable Barrier Cream, 28g Tube	Resupply expected April 2022
Cavilon Durable Barrier Cream, 2g Sachet	Resupply expected April 2022
Cavilon No Sting Barrier Film, 1ml Foam Applicator	Resupply expected April 2022

Actions:

For patients with insufficient supplies to last until the resupply date, clinicians should prescribe an alternative barrier cream.

Alternative:

• Medi Derma-S barrier cream

SHORTAGE: Chloral Hydrate 143.3mg/5ml oral solution BP

Anticipated re-supply date 30 April 2022.

Actions for prescribers

Where patients have insufficient supplies, clinicians should:

- review ongoing need for treatment
- prescribe 143.3mg in 5ml chloral hydrate solution as a special if ongoing treatment is deemed necessary.

Alternatives

Available specials

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).

Ascot labs

143.3mg in 5ml oral solution

Alium Medical

143.3mg in 5ml oral solution

Target Healthcare

143.3mg in 5ml oral solution

Certificates

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).

Considerations and background

Using unlicensed medicines

Guidance

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:

- <u>The supply of unlicensed medicinal products</u>, Medicines and Healthcare products Regulatory Agency (MHRA);
- <u>Professional guidance for the procurement and supply of specials</u>, Royal Pharmaceutical Society (RPS); and
- Prescribing unlicensed medicines, General Medical Council (GMC).

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.

This can be done in one of the following two ways:

Electronic prescriptions

If the required unlicensed product is shown on electronic prescribing systems, GP's should select: chloral hydrate 143.3mg in 5ml oral solution (special order)

Paper prescriptions

Where the unlicensed product is not shown on electronic prescribing systems, GP's should use a paper prescription and annotate with the following wording: special order.

SHORTAGE:

Estradiol (FemSeven)
100 microgram / 24 hrs
transdermal patches.

Anticipated re-supply date March 31st 2022

Alternatives

A range of potential alternative HRT products exist. Specialist importers can source unlicensed products. Lead time will vary.

SHORTAGE:

Aspirin Suppositories
Aspirin 300mg
suppositories
(Martindale
Pharmaceuticals Ltd)
Aspirin 150mg
suppositories
(Martindale
Pharmaceuticals Ltd)

Anticipated re-supply date April 18 2022.

Actions for prescribers

Clinicians should:

- review all patients on aspirin suppositories and switch patients to oral therapy if possible;
- consider using an alternative licensed medication(s) where a switch to oral therapy is not possible;
- prescribe appropriate Specials or unlicensed imports where the above actions are not considered appropriate (see information on SPS Medicines Supply Tool).

Alternatives

- Use oral therapy if possible.
- Consider an alternative licensed medication where oral therapy is not possible.
- Use specials or unlicensed imports where licensed alternatives are not considered appropriate (see information SPS Medicines Supply Tool)

SHORTAGE:

Anticipated re-supply date Feb 3, 2022.

Cimetidine Tablets	
	Alternatives
	Oral products
	'
	Cimetidine solutions, syrups and tablets
	Cimetidine 200mg/5ml oral solution / syrup is currently available. Supplies of
	cimetidine 200mg and 400mg tablets are now available.
	Famotidine - Oral famotidine is currently available.
	Nizatidine - Oral nizatidine capsules are currently available.
	Other H2 receptor antagonists - Supply issues continue to affect ranitidine; other H2
	receptor antagonists remain available.
	Unlicensed products - Specialist importers have confirmed they can source an
	unlicensed product. Lead times vary.
SHORTAGE:	Anticipated re-supply date 21st February 2022 (120mg) and 25th Feb 2022 (240mg).
Paracetamol 120mg	Actions for prescribers
suppositories	Community pharmacists may supply paracetamol 125mg and 250mg
(Martindale	suppositories in accordance with the SSP for eligible patients.
Pharmaceuticals Ltd)	If the above option is not deemed appropriate, clinicians should:
Paracetamol 240mg	consider prescribing paracetamol 125mg and 250mg suppositories, and counsel
suppositories	patients regarding the switch at the point of prescribing.
(Martindale	Alternatives
Pharmaceuticals Ltd)	Paracetamol 125mg and 250mg suppositories remain available from other suppliers
	and can support the uplift in demand.
PDF	and can support the upment demands
SSP form	
paracetamol supposit	
SHORTAGE:	Anticipated re-supply date February 25, 2022 .
Estriol 0.1% cream	Alternatives
(Ovestin 1mg cream)	Alternative estriol vaginal products remain available.
SHORTAGE:	Anticipated re-supply date March 15, 2022.
Diclofenac (Voltarol	Alternatives
Ophtha Multidose) 0.1%	Voltarol Ophtha unit dose packs (preservative free) remain available and can fully
eye drops 5 ml	support during this time.
	State of the state
SHORTAGE:	Anticipated re-supply date March 31, 2022.
Voractiv tablets	Actions for prescribers
	Pharmacy procurement, clinical teams (including prescribers, TB nurses and
	clinicians) and any outsourced partners should work together to ensure that:
	The state of the s
	stock holding of TB agents is reviewed regularly
	alternatives are ordered for the products that are in short supply
	 prescriptions are amended in cases where the usual or preferred product is
	unavailable so that treatment is not delayed or interrupted
	, , , , , , , , , , , , , , , , , , , ,
	advice given within the page as that may precipitate further out of stock
	periods
	patients are appropriately counselled about changes to their usual or
	expected medication
	if products that have not been flagged as out of stock cannot be obtained, this is a solution of the
	this is escalated to your Regional Pharmacy Procurement Specialist
	orders for products are placed in line with actual patient demand, ordering
	patterns will be monitored and may be challenged.
	Alternatives

	Prescribe/dispense as individual ingredients to meet immediate patient need until resupply.	
	Individual components	
	The following individual ingredients are in stock:	
	 Rifampicin 150mg capsules (Sanofi, Mylan) Rifampicin 300mg capsules (Sanofi, Sandoz, Mylan, DrugsRUs) Rifampicin 100mg/5ml syrup (Sanofi) Pyrazinamide 500mg tablets (Thornton & Ross, Macleod's, Morningside) Isoniazid 50mg tablets (RPH Pharmaceuticals) Isoniazid 100mg tablets (RPH Pharmaceuticals) Ethambutol 100mg tablets (Morningside, Thornton & Ross, Kent, Intrapharm) Ehambutol 400mg tablets (Morningside, Thornton & Ross, Kent, Intrapharm) 	
SHORTAGE:	Anticipated re-supply date Feb 28, 2022 .	
Adrenaline (base)		
1mg/1ml (1 in 1000)	Alternatives	
solution for injection pre-	Adrenaline 1:1000 solution for injection ampoules (1mL) are available and can	
filled syringes	support an uplift in demand.	
SHORTAGE:	Anticipated re-supply date Feb 18, 2022	
Clomifene 50mg tablets	Alternatives	
(Clomid)	Generic Clomifene tablets remain available and can support an uplift in demand.	
All Serious Shortage Protocols	(SPP's) can be found:	
https://www.nhsbsa.nhs.uk/p	harmacies-gp-practices-and-appliance-contractors/serious-shortage-protocols-ssps	
Shortage update taken from S	PS Medicines Supply Toolkit 15 th Feb 2022	