

Medicines Optimisation Shortages Update for GP Update -18 $^{ m th}$ October 2022

Shortage update taken from SPS Medicines Supply Toolkit on 18th October 2022. Information provided by DHSC and NHSEI Medicines Supply Teams and published on Specialist Pharmacy Services Medicines Supply Tool. Not formally reviewed by NHS Kent and Medway Medicines Optimisation.

SHORTAGE:

Delmosart 18mg modified-release tablets (Accord Healthcare Ltd)

Anticipated re-supply date: 31st December 2022 Actions:

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

- consider prescribing Concerta XL, Delmosart or Xenidate XL brands which can support the market during this time, ensuring that the patient is not intolerant to any of the excipients;
- counsel patients to reassure them that Xaggitin XL, as well as the above mentioned brands, have a similar release profile to Concerta XL (see clinical information); and
- reassure patients that any changes to their prescription will be shortterm and for the duration of the supply issue only, and they have the option to switch back to Xaggitin XL once the supply issue is resolved or continue the brand they have been switched to.

Where a patient is due to start methylphenidate treatment, clinicians should:

- defer starting any new patients on methylphenidate (Xaggitin XL) prolonged-release tablets until the supply issue is resolved; and
- consider prescribing one of the brands named above that can support an uplift in demand.

Alternatives:

The following alternative brands of methylphenidate prolonged-release tablets remain available and can support an uplift in demand:

- Concerta XL,
- Xenidate XL

Considerations and Background

Summary

- Delmosart 18mg modified-release tablets are out of stock with resupply expected late December 2022.
- Methylphenidate (Xaggitin XL) 18mg, 27mg, 36mg and 54mg prolonged-release tablets are back in stock.
- Matoride XL prolonged-release tablets remain available but are unable to support an uplift in demand.

Clinical Information:



Methylphenidate is a central nervous stimulant available in the UK in various licensed immediate, modified-release, oral, and solid dosage forms. It is a schedule 2 controlled drug, licensed for the treatment of attention deficit hyperactivity disorder (ADHD) in children aged over 6 years and adolescents and is the usual first line treatment for this condition for both children and adults.

All the modified-release methylphenidate preparations include an immediate-release component as well as an extended-release component. This allows for rapid onset of action while avoiding the need to take further doses during the day to maintain effect.

The biphasic release profiles of these products, however, are not all equivalent and contain different proportions of the immediate-release and modified-release component. The BNF states that different versions of modified-release preparations may not have the same clinical effect. To avoid confusion between these different formulations of methylphenidate, prescribers should specify the brand to be dispensed.

Of the modified-release preparations, Delmosart, Xaggitin XL and Xenidate XL tablets have been approved based on bioequivalence data compared to Concerta XL tablets. Thus, these generic brands have been granted replicate marketing authorisation to Concerta XL on the basis that they have satisfied the criteria for equivalent release profile for the reference Concerta XL product.

Links to further Information

- Concerta XL prolonged-release tablets SmPC
- Delmosart prolonged-release tablets SmPC
- Xaggitin XL prolonged-release tablets SmPC
- Xenidate XL prolonged-release tablets SmPC
- NICE guideline for attention deficit hyperactivity disorder
- Extended-release methylphenidate: A review of the pharmacokinetic profiles of available products

SHORTAGE:

Glycerol 1g suppositories

Anticipated re-supply date: 28th October 2022 Actions:

All clinicians should:

- consider prescribing half a 2g suppository in infants who require a 1g dose and where relevant, advise parents/carers to cut the suppository lengthways to ensure a more accurate dose is administered;
- 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;
- seek specialist advice on management options if a glycerol 'chip' from the 1g suppository was being used in neonates; and
- be aware that other laxatives remain available; choice will depend on stool consistency and products already tried.



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Glycerol 2g suppositories remain available and can support an increase in demand in place of the 1g suppositories.

Considerations and Background.

Summary

- Glycerol 1g suppositories are out of stock until late-September 2022.
- Glycerol 4g suppositories are back in stock as of 12 May 2022.

Supporting Information

Please refer to the links below for further information:

- SmPC Glycerol suppositories
- SmPC Docusate sodium (Norgalax®) 10g micro-enema
- BNF Treatment Summary Constipation
- BNFC Treatment Summary Constipation

SHORTAGE:

Losec MUPS 10mg gastro-resistant tablets (Neon Healthcare Ltd) Losec MUPS 20mg gastro-resistant tablets (Neon Healthcare Ltd)

Anticipated re-supply date: 15th October 2022 Actions:

For patients with insufficient supplies, clinicians should consider:

- reviewing all patients and switching patients to oral capsules or tablets if possible;
- in instances where dispersible tablets are required, please refer to the alternatives below

Alternatives:

The following alternatives remain available and can support a full uplift in demand:

- Omeprazole (Mezzopram) 10mg dispersible tablets
- Omeprazole (Mezzopram) 20mg dispersible tablets

Considerations and Background:

Summary

Omeprazole (Losec MUPS) 10mg and 20mg dispersible tablets are out of stock until 15th October 2022.

Omeprazole (Mezzopram) 10mg and 20mg dispersible tablets remain available and can support a full uplift in demand during this time.

SHORTAGE:

Hydrocortisone 2.5mg mucoadhesive buccal tablets sugar free (Accord Healthcare Ltd) 20 tablet

Anticipated re-supply date: 31st January 2023 Actions:

Clinicians considering treatment for patients presenting with oral ulcers should:

- assess the severity of the patient's ulcers including frequency and interference with daily activities;
- if treatment is required, establish whether over-the-counter products (purchased or prescribed) have already been tried, and whether it is appropriate to use/retry;
- if above mentioned treatments are not suitable, consider prescribing betamethasone soluble tablets for off-label topical use as a mouthwash, counselling patients on how to administer treatment, and stressing that the mouthwash must *not* be swallowed;



• if neither of the above options are appropriate, prescribers should seek specialist advice from the oral medicine clinic.

Alternatives:

See supporting Information

Considerations and Background:

Summary

- Other over-the-counter preparations such as topical anaesthetics, topical analgesics/anti-inflammatory agents and topical antimicrobial agents marketed as oral gels, mouthwashes and oral sprays remain available.
- Betamethasone soluble tablets for off-label topical use in the treatment of aphthous ulcers remain available.

Supporting Information

Clinical Information

Hydrocortisone muco-adhesive buccal tablets are licensed for local use in previously diagnosed aphthous ulceration of the mouth.

Topical corticosteroids are usually considered to be first-line treatment of aphthous ulcers if simple therapies such as topical anaesthetics (e.g. lidocaine hydrochloride), topical analgesics/anti-inflammatory agents (e.g. benzydamine hydrochloride), and topical antimicrobial agents (e.g. chlorhexidine mouthwash) have not provided sufficient symptomatic relief.

Betamethasone 500 microgram soluble tablet prepared as a mouthwash is used off label to treat aphthous ulceration. The BNF recommends a dose for oral ulceration in adults and children age 12 to 17 years of 500micrograms four times a day. The tablet should be dissolved in 20 mL water, rinsed around the mouth, and *not* swallowed.

Please see the below links for further information.

Links

- Hydrocortisone 2.5 mg Muco-Adhesive Buccal Tablets
- BNF: Treatment summary Oral ulceration and inflammation
- NICE CKS Scenario: Management of aphthous ulcer
- SPS: Understanding safety risks with betamethasone soluble tablets used as mouthwash
- <u>PIL: Betamethasone 500 microgram soluble tablets used as a mouthwash</u>

SHORTAGE:

Voriconazole (VFEND) 200mg/5ml oral suspension

Anticipated re-supply date: 17th October 2022 Actions:

Clinicians working in primary care should:

- identify patients who will run out before the resupply date and determine the suitability of switching to tablets; and
- if above option is not appropriate (see clinical information below), contact the pharmacy at the initiating trust to determine if they can supply, and if this is not possible, seek clinical advice from specialist on alternative treatment options.



- Secondary care pharmacy procurement teams working with the local Medication Safety Officer and clinical teams should:
- review local stock holding of voriconazole 40mg/ml oral suspension and conserve remaining supplies for children 2 to <12 years of age and for patients with enteral feeding tubes (see clinical information below); and
- work with their Regional Pharmacy Procurement Specialists (RPPS) to share stock locally, to ensure continuity of care for the two patient groups detailed above.

Clinicians working in secondary care should:

- consider prescribing voriconazole tablets, where clinically appropriate in place of voriconazole oral suspension (see clinical information below); and
- if above option is not appropriate, seek specialist advice on alternative treatment options, including advice from Pharmacy on availability of this treatment as a liquid formulation;
- consider prescribing unlicensed imports if the above options are not clinically appropriate (see clinical information below)

Clinicians should ensure appropriate counselling is provided if any changes are made to patients' prescriptions.

Alternatives:

The following alternatives remain available:

• Voriconazole 50mg, 100mg and 200mg tablets

The following specialist importers have confirmed they can source unlicensed voriconazole 40mg/ml oral suspension (please note there may be other companies that can also source supplies):

- Durbin PLC
- Mawdsley's Unlicensed
- Orifarm UK Pharma
- Smartway Pharma
- Alium Medical

Prescribers should work with local pharmacy teams to ensure orders are placed within appropriate time frames as lead times may vary.

Considerations and background Summary

- Voriconazole 40mg/ml powder for oral suspension is out of stock until mid September 2022.
- Trusts with residual stock should reserve supplies for children 2 to <12
 years of age or patients who require administration via enteral feeding
 tubes.

Clinical Information

Resources on administration of medication to patients with enteral feeding tubes or swallowing difficulties suggest that voriconazole tablets can be crushed and mixed with water for administration. However, there may be a risk of tube blockage in patients who require administration via enteral feeding tubes. The SPC for voriconazole states that oral dose recommendations for children are based on studies in which voriconazole was administered as the



powder for oral suspension; bioequivalence between the powder for oral suspension and tablets has not been investigated in a paediatric population. Considering the assumed limited gastro-enteric transit time in paediatric patients, the absorption of tablets may be different in this group compared to adults. It therefore recommends use of the oral suspension in children from 2 to 12 years of age.

Voriconazole is restricted to specialist initiation, therefore, in patients where off-label crushing of tablets or unlicensed imports of oral suspension are not considered appropriate, specialist advice should be sought on an alternative liquid formulation of an appropriate antifungal

Supporting information

Guidance on ordering and prescribing 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:

- <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)
- <u>Prescribing unlicensed medicines</u>, General Medical Council (GMC)

When prescribing a product that is 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, GPs should select:
 - Voriconazole 40mg/ml oral suspension (imported)
- Paper prescriptions where the unlicensed product is not shown on electronic prescribing systems, GPs should use a paper prescription and annotate with the following wording: "special order".

Medicine Supply Notification Number:

MSN/2021/061U

Links

- SPCs for voriconazole preparations
- Guide to swallowing tablets

SHORTAGE:

Rifampicin 100mg/5ml oral suspension

Anticipated re-supply date: 4th November 2022 Actions:

Primary Care Teams

Where further supplies are required before the resupply date, primary care should:

- continue to order Rifadin oral suspension in line with historic demand;
 and
- be aware that, where demand exceeds historic use, a prescription validation process will be implemented.

Anonymised prescriptions should be sent to Sanofi Customer Services to receive further supplies (<u>UK-GFD-DTPsupply@sanofi.com</u>), if requested.

Secondary Care Trusts

Where further supplies are required before the resupply date, Secondary care Trusts should:



- review the ongoing need for Rifadin oral suspension and switch patients to rifampicin capsules where patients can take a solid oral dosage form and the dosage required can be achieved;
- consider limiting prescriptions for Rifadin oral suspension to a maximum of 1 month's supply to ensure supplies at Trusts last as long as possible;
- order unlicensed supplies from Specialist Importers or Specials
 Manufacturers where insufficient UK licensed Rifadin oral suspension remains at Trusts
- ensure any outsourced partners (OPD and Homecare) are included in local planning; and
- maintain current practice when referring patients into primary care for ongoing supplies.

Alternatives:

Licensed Alternatives

Rifampicin 150mg and 300mg capsules remain available.

Unlicensed Imports

The following Specialist Importers have confirmed they can source unlicensed Rifadin 100mg/5ml oral suspension. Lead times may vary (please note, there may be other companies that can also source this presentation):

- Durbin PLC
- Mawdsley's unlicensed
- Smartway Pharma
- Target
- Waymade PLC

Specials

The following Specials Manufacturers have confirmed they can supply unlicensed rifampicin 100mg/5ml oral suspension (please note, there may be other companies that can also manufacture this presentation):

- Ascot Labs
- Eaststone
- IPS Pharma
- Nova Laboratories Ltd
- PCCA Ltd

Prescribers should work with local pharmacy teams to ensure orders are placed within appropriate time frames as lead times may vary.

Considerations and background

Supply Summary

- Sanofi have limited supplies of Rifadin 100mg/5ml oral suspension with resupply expected w/c 10 October 2022.
- Until w/c 10 October 2022, supplies will only remain available to primary care.
- Secondary care Trusts will need to order unlicensed supplies from Specialist Importers or Specials Manufacturers if current stock holding is insufficient to last until the resupply date.

Guidance on ordering and prescribing 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:



- <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)
- Prescribing unlicensed medicines, General Medical Council (GMC)

When prescribing a product that is 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, GPs should select:
 - o Rifampicin 100mg/5ml oral suspension (imported)
- Paper prescriptions where the unlicensed product is not shown on electronic prescribing systems, GPs should use a paper prescription and annotate with the following wording: "special order".

Medicine Supply Notification Number MSN/2022/075 Links

• SPC Rifampicin preparations

SHORTAGE:

Nafarelin 200micrograms/dose nasal spray 60 dose

Anticipated re-supply date: 23rd December 2022 Actions:

Clinicians should:

• not initiate new patients on nafarelin 200microgram/dose nasal spray until the supply issue has resolved.

Where patients have insufficient supplies to last until the re-supply date, clinicians should;

- consider switching to an alternative gonadotropin-releasing hormone (GnRH) analogue in consultation with the appropriate specialist (see clinical information below);
- where the above option is not appropriate, consider prescribing unlicensed nafarelin nasal spray. Prescribers should work with local pharmacy teams to ensure orders are placed within appropriate time frames as lead times may vary (see clinical information below); and
- if the above options are not considered appropriate, advice should be sought from specialists on management options.

When considering parenteral therapy, establish that this route of administration is acceptable to the patient, and for those switched to or initiated on a subcutaneous injection, ensure they can self-administer and are not intolerant to any of the excipients. In addition:

- Ensure the patient receives appropriate training on the administration of a subcutaneous injection and is counselled on the appropriate dose and volume to administer if self-administering.
- Signpost to online training videos if needed.



 Provide the patient with the appropriate ancillaries and a sharps bin for safe disposal of needles.

Alternatives:

Please see below for available parenteral GnRH analogues approved for licensed indications covered by nafarelin (Synarel) 200microgram/dose nasal spray

Buserelin

Presentation

Suprecur 5.5mg/5.5ml solution for injection vials.

Indication

Licensed for pituitary desensitisation.

Dose

200 – 500 microgram subcutaneous injection daily until down regulation is achieved.

Additional information

Suprefact injection is identical to Suprecur injection but differs in licensed indication, although in practice, assisted conception units use these two brands of buserelin injection interchangeably, guided by stock availability. Suprefact injection cannot support an increase in demand.

Goserelin

Presentation

Zoladex 3.6mg implant.

Indication

Licensed for endometriosis and pituitary desensitisation

Dose

One 3.6 mg depot injected subcutaneously, every 28 days.

Leuprorelin

Presentations

Prostap SR DCS 3.75 mg and Prostap 3 DCS 11.25 mg powder and solvent for prolonged-release suspension for injection in pre-filled syringe.

Indication

Licensed for endometriosis.

Dose

Prostap SR DCS 3.75 mg

3.75 mg administered as subcutaneous or intramuscular injection every month.

Prostap 3 DCS 11.25 mg

One intramuscular injection every 3 months.



Triptorelin

Presentations

Decapeptyl SR 3mg and Decapeptyl SR 11.25mg powder and solvent for suspension for injection

Indication

Licensed for endometriosis.

Dose

Decapeptyl SR 3mg

One intramuscular injection every 28 days.

Decapeptyl SR 11.25mg

One intramuscular injection every 6 months

Unlicensed Imports

The following specialist importers have confirmed they can source unlicensed nafarelin (Synarel) 200microgram/dose nasal spray (please note there may be other companies that can also source supplies):

- Alium Medical Limited
- Oripharm UK Limited

Prescribers should work with local pharmacy teams to ensure orders are placed within appropriate time frames as lead times may vary.

Considerations and background

Clinical Information

Nafarelin (Synarel) 200microgram/dose nasal spray contains a GnRH analogue, administered twice daily. It is licensed for the hormonal management of endometriosis, including pain relief and reduction of endometriotic lesions, and for use in controlled ovarian stimulation programmes prior to in-vitro fertilisation, under the supervision of an infertility specialist.

Off-label use

Triggering follicular maturation in in-vitro fertilisation cycles.

Self-administration of injection

In cases where it may be appropriate to train patients to self-administer the subcutaneous injection, it is recommended that initial doses should be administered under close medical supervision due to the possibility of hypersensitivity reactions. Patients should cease injections and seek medical attention should any adverse event occur, particularly an allergic reaction. Please refer to the links below for further information.

Guidance on prescribing 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:



- <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)
- Prescribing unlicensed medicines, General Medical Council (GMC).

Links

- BNF Buserelin
- BNF Goserelin
- BNF Leuprorelin
- BNF Nafarelin
- BNF Triptorelin
- SmPC Suprecur[®]
- SmPC Zoladex®
- SmPC Prostap®
- SmPC Synarel®
- SmPC Decapeptyl[®]

SHORTAGE:

Balneum 84.75% bath oil (Almirall Ltd)

Balneum Plus bath oil (Almirall Ltd)

Anticipated re-supply date:

Balneum 84.75% bath oil (Almirall Ltd)-31st October 2022 Balneum Plus bath oil (Almirall Ltd)-15th December 2022

Actions:

Clinicians should be aware that:

- Balneum Bath Oil and Balneum Plus Bath Oil are out of stock;
- bath and shower products are no longer considered an essential component of total emollient therapy, as the amount of bath additives deposited on the skin is lower than with directly applied emollient creams or ointments. They provide no clinical benefit when added to standard eczema care in children (BATHE Study);
- an alternative approach is to use a regular leave-on emollient as a soap substitute. Many standard emollients can be used in this way e.g. by applying it to the skin before showering then rinsing it off. Alternatively, 1-2 tablespoons of any ointment (except LP:WSP 50/50 Ointment) can be dissolved in some hot water and added into bath water, as a bath additive;
- bath products will coat the bath and make it slippery, and patients should be warned to take extra care; and
- dermatologists may in exceptional circumstances, recommend bath/shower emollient products in cases of severe atopic eczema and ichthyosis when the patient requires more intensive emollient therapy and standard emollients used as soap substitutes have already been trialled. This is on the basis that these patients have severe skin disease, which is not represented in the BATHE study.

Alternatives:



| | Alternative bath and shower products and creams continue to remain available. |
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| | Considerations and Background: Summary: Balneum Bath Oil and Balneum Plus Bath Oil are out of stock with resupplies expected late October 2022 and mid-December 2022, respectively. |
| | Einks BNF emollient bath and shower products, soya-bean oil-containing monograph NHSE Items which should not routinely be prescribed in primary care: Guidance for CCGs |
| SHORTAGE: | Anticipated re-supply date: 24 th October 2022 |
| Venlalic XL 300mg tablets (Ethypharm UK Ltd) 30 tablet | Alternatives: Venlafaxine (Venlalic XL) 150mg modified release tablets remain available and can support the uplift in demand. |
| | Considerations and Background: Venlafaxine (Venlalic XL) 300mg modified release tablets are currently out of stock. |
| | SmPC Venlalic XL tablets |
| SHORTAGE: | Anticipated re-supply date: 17 th October 2022 |
| Indivina 2mg/5mg tablets (Orion Pharma (UK) Ltd) | Actions: For patients with insufficient supplies, clinicians should consider: • Prescribing estradiol valerate 1mg / Medroxyprogesterone 2.5mg (Indivina) tablets to make up the required dose (off-label); • Or consider alternative HRT products. |
| | Alternatives: Estradiol valerate 1mg / Medroxyprogesterone 2.5mg (Indivina) tablets remain available and can support an uplift in demand. Use other available HRT products where appropriate. Please see links for further advice on alternative hormone replacement therapies: |
| | CKS Hormone replacement therapy British Menopause Society – HRT preparations and equivalent alternatives. |
| | Considerations and Background: Summary |



| | Kent and Medway |
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| | Indivina 2 mg/5 mg tablets tablets are out of stock until mid-August 2022 Indivina 1mg /2.5mg tablets remain available and can support a full uplift in demand. |
| SHORTAGE: Ozempic 1mg/0.74ml solution for | Anticipated re-supply date: 14 th October 2022 |
| injection 3ml pre-filled pens (Novo Nordisk Ltd) 1 pre-filled disposable injection | Actions: The advice below has been put together with input from the Specialist Pharmacy Service's Medicines Information department. Clinicians in primary and secondary care should: |
| | ensure that Ozempic is being used for licensed indications only; not initiate new patients on Ozempic until full supplies become available in January 2023; |
| | contact patients with prescriptions due during this time, to establish if they have sufficient supplies to last until the re-supply date (w/c 10th October), and if so then delay issuing the prescription until then. Please see advice below if the patient does not have sufficient supplies to last until the re-supply date. |
| | For patients who have insufficient supplies to last until the re-supply date, clinicians should: |
| | consider appropriateness of extending the dosing interval (e.g., administer every 10 days) of existing stock of Ozempic 1mg held by the patient to last, if possible, until the resupply date; if the above option is not suitable, consider appropriateness of decreasing the dose of Ozempic to 0.5mg weekly, working with local pharmacy teams to understand the availability of this strength, and issue a prescription, to last until resupply of 1mg strength in October; consider for those patients who are also on insulin therapy, and unable to obtain a supply of Ozempic, whether the dose of insulin can be increased to accommodate the period off Ozempic treatment, without needing to switch to an alternative GLP-1 receptor agonists (RA); prescribe an alternative GLP-1 RA for patients who need to be continued on this therapy and have insufficient supplies of Ozempic. Clinicians involved in prescribing or dispensing the new medicine for this patient should ensure that the patient is counselled on the dose schedule and how to operate the new pen injector (if parenteral therapy is selected), as well as checking for intolerance to any of the excipients (see Supporting Information below); and seek advice from specialists if there is uncertainty about selecting the most appropriate management option or about the dose of alternative GLP-1 RA. |
| | Alternatives: Liraglutide The following brand is available in the presentation below: • Victoza 6mg/ml solution for injection in prefilled pen |



Dose

Initially 0.6 mg **once daily** for at least 1 week, then increased to 1.2 mg once daily for at least 1 week, then increased if necessary to 1.8 mg once daily. Indication

Type 2 diabetes mellitus as monotherapy (if metformin inappropriate), or in combination with other antidiabetic drugs, (including insulin) if existing treatment fails to achieve adequate glycaemic control.

Exenatide

The following brands are available in the presentations below:

- Byetta 5micrograms/0.02ml solution for injection 1.2ml pre-filled pens
- Byetta 10micrograms/0.04ml solution for injection 1.2ml pre-filled pens
- Bydureon 2mg/0.85ml prolonged-release suspension for injection 1.2ml pre-filled pens

Dose

Byetta

Initially 5 micrograms **twice daily** for at least 1 month, then increased if necessary up to 10 micrograms twice daily, dose to be taken within 1 hour before 2 main meals (at least 6 hours apart)

Bydureon

2 mg once weekly

Indication

Type 2 diabetes mellitus in combination with other antidiabetic drugs (including insulin) if existing treatment fails to achieve adequate glycaemic control.

Dulaglutide

<u>Dulaglutide is available as the brand Trulicity however it is unable to support an</u> uplift in demand.

Semaglutide

Available in the brands and presentations below:

- Ozempic 0.5mg solution for injection; remains available but can only support a partial uplift in demand.
- Rybelsus 3mg, 7mg and 14mg tablets; remain available but can only support a partial uplift in demand.

Considerations and background Clinical Information

Ozempic is a parenteral GLP-1 RA licensed for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise:



as monotherapy when metformin is considered inappropriate due to intolerance or contraindications
 in addition to other medicinal products for the treatment of diabetes.

The starting dose is 0.25 mg once weekly. After 4 weeks the dose should be increased to 0.5 mg once weekly. After at least 4 weeks with a dose of 0.5 mg once weekly, the dose can be increased to 1 mg once weekly to further improve glycaemic control. After at least 4 weeks with a dose of 1 mg once weekly, the dose can be increased to 2 mg once weekly to further improve glycaemic control.

Semaglutide is also available as a once daily tablet (Rybelsus). Other parenteral GLP-1 RAs that remain available include exenatide and liraglutide. The GLP-1 RAs differ in dose schedule and tolerability, as well as evidence base for effectiveness and clinical outcomes (evidence for cardiovascular and renal benefit is much greater for the injectables). Local formularies and guidelines will aid product selection, and a pragmatic approach will be needed for this short stock out period, with patients assessed on a case by case basis. Please see the links below for further information.

- SmPC Ozempic (semaglutide) solution for injection in pre-filled pen
- NICE Guidelines: Type 2 diabetes
- BNF treatment summary: type 2 diabetes
- SmPC Victoza 6 mg/ml (liraglutide) solution for injection in pre-filled pen
- SmPC Bydureon (exenatide) 2 mg prolonged release suspension for injection in pre-filled pen
- SmPC Rebelsus (semaglutide tablets)

SHORTAGE:

Co-beneldopa 12.5mg/50mg capsules (Teva UK Ltd)

Anticipated re-supply date: 31st October 2022

Alternatives: Madopar 50mg/12.5mg capsules (Roche Products Ltd) remain available and can support a full uplift in demand.

Considerations and background Summary:

Generic co-beneldopa 12.5mg/50mg capsules are out of stock until October 2022.

SHORTAGE:

Varilrix vaccine powder and solvent for solution for injection 0.5ml vials (GlaxoSmithKline UK Ltd)

Anticipated re-supply date: 21st January 2023

Actions:

Clinicians in all healthcare settings should:

- only order Varivax[®] injection based on an actual usage and not stockpile during this time;
- prescribe Varivax® where varicella vaccine is indicated for the duration of the supply issue with Varilrix®



| | Alternatives: See supporting Information |
|--|--|
| | Considerations and background |
| | Summary |
| | Varilrix® injection is out of stock and resupply is expected in Jan 2023. Supplies of Varivax® are available from Alliance Healthcare and can support a full uplift in demand. |
| SHORTAGE: | Anticipated re-supply date: 5 th November 2022 |
| Losec MUPS 10mg gastro-resistant | Actions for prescribers |
| tablets (Neon Healthcare Ltd) Losec MUPS 20mg gasto-resistant | For patients with insufficient supplies, clinicians should consider: reviewing all patients and switching patients to oral capsules or tablets if possible; |
| tablets (Neon Healthcare Ltd) | in instances where dispersible tablets are required, please refer to the alternatives below |
| | Alternatives The following alternatives remain available and can support a full uplift in demand: |
| | Omeprazole (Mezzopram) 10mg dispersible tablets |
| | Omeprazole (Mezzopram) 20mg dispersible tablets |
| | Considerations and background |
| | Summary Omeprazole (Losec MUPS) 10mg and 20mg dispersible tablets are out of stock until 5th November 2022. |
| | Omeprazole (Mezzopram) 10mg and 20mg dispersible tablets remain available and can support a full uplift in demand during this time. |
| SHORTAGE: | Anticipated re-supply date: 16 th December 2022 |
| Calcichew 500mg chewable | Astions |
| tablets (Forum Health Products Ltd) | Actions Clinicians should be aware that: |
| , | Calcichew 500mg chewable tablets currently remain out of stock until mid- December 2022. |
| | Alternatives: The following alternatives remain available and can support an uplift in demand: Calcichew-D3 500 mg/200 IU chewable tablets |
| | Other calcium carbonate chewable tablets remain available. |
| | Considerations and background |
| | Supply overview Calcichew 500mg Chewable Tablets currently remain out of stock until mid- December 2022. |
| SHORTAGE: | Anticipated re-supply date: 11 th November 2022 |
| Mucodyne 250mg/5ml syrup | |
| (Sanofi) | Actions: Clinicians should be aware that: |
| | Mucodyne 250mg/5ml syrup remains unavailable until mid November 2022. |



| Alternatives Generic carbocisteine 250mg/5ml oral solution remains available from other suppliers and can support an uplift in demand. Carbocisteine 375mg capsules are unaffected by supply issues and remain available. Links SmPC Mucodyne Syrup SmPC Carbocisteine 250 mg/5 ml oral solution |
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| BNF Carbocisteine |
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All Serious Shortage Protocols (SPP's) can be found:

 $\underline{https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/serious-shortage-protocols-ssps}$

Shortage update taken from SPS Medicines Supply Toolkit on 18th October 2022. Information provided by DHSC and NHSEI Medicines Supply Teams and published on Specialist Pharmacy Services Medicines Supply Tool. Not formally reviewed by NHS Kent and Medway Medicines Optimisation. Practices are encouraged to register for access to the SPS website https://www.sps.nhs.uk/ and access this tool directly in real time.