

Specials

Introduction

Specials are individually prepared formulations made for a specific patient. They are unlicensed medicines and so will not have been assessed by the licensing authority for safety, quality and efficacy

There are certain clinical situations where a special may be judged to be the most appropriate or only available option, for example for use in children where lower doses are required or for patients who require alternatives to solid dosage forms such as in dysphagia– [link](#).

The Medicines Act allows appropriate prescribers to prescribe medicines without a license providing they are happy to assume full liability for the prescription.

Specials are usually much more expensive than standard preparations. The use of a special should only be considered when the use of a licensed preparation is not possible. There is no set pricing for most specials and no national pricing structure governing the cost to the NHS although part VIII B of the Drug Tariff lists high volume and high cost unlicensed specials with set reimbursement prices.

Considerations

As specials can be sourced from a variety of suppliers, the quality and consistency of the product can vary considerably. This can lead to potential difference in the pharmacokinetics and clinical responses to a drug. Before prescribing a special, consideration should be given to whether the medicine is needed at all. If the medicine is deemed necessary consider if an alternative, such as using a licensed product in an off label way, could be used.

The MHRA provides guidance on the hierarchy of risk on basis of product origin as follows:



- UK licensed medicines
- Off-label use of a UK licensed medicines e.g. crushing a tablet form
- An imported product licensed in the country of origin
- A UK manufactured special made in MHRA licensed facilities
- An extemporaneously dispensed medicine
- An imported product not licensed in the country of origin
- A non-UK made unlicensed medicine or food supplement

Alternatives to specials

ePACT data shows that 1460 items of specials were prescribed in Q4 2017/18 in Sheffield, costing £150,000.

The table below lists examples of some of the more commonly prescribed specials in Sheffield and nationally and alternative forms which **may** be suitable. For advice on specific drugs / preparations

the Medicines Management Team (MMT) can be contacted via the MI query line (0114 3051983) or the practices designated MMT contact.

Please note that the alternative preparations documented are not always appropriate and patients should be reviewed on an individual basis. If considering alternatives for children then advice can be sought from either MMT or the pharmacy department at Sheffield Children's Hospital (SCH) (0114 271 7567), if the child is under their care. If a special is to be initiated, SCH routinely send information to prescribers and parents/ carers advising on which preparation has been started and where a supply of the special can be sourced from. The Neonatal and Paediatric Pharmacists Group have produced a list of recommended strengths of specials for use in children for 17 medicines – appendix 1.

Special	Considerations	Possible alternative
Melatonin MR capsules / plain tablets / capsules	<p>Unlicensed melatonin preparations are black on the Sheffield traffic light list (except Melatonin 5mg/5ml oral solution, when used in line with local shared care guideline).</p> <p>Patients currently on melatonin tablets or capsules should be reviewed either in secondary care or primary care to discuss a trial of stopping treatment or switching to Circadin® 2mg prolonged release tablets.</p> <p>Circadin® is not licensed for use in children and so its use would be off label.</p> <p>See melatonin shared care guideline for more information link</p>	Circadin® 2mg prolonged release tablets
Colecalciferol	<p>Preparations to treat deficiency:</p> <p>There are now licensed colecalciferol preparations available, see local guidelines for details.</p> <p>Adults:</p> <p>Plenachol 40,000 unit capsules and InVita 25,000 unit oral solution are the formulary choices for vitamin D deficiency in adults in Sheffield, see link.</p> <p>Children:</p> <p>Thorens 10,000 unit/ml is the formulary choice for the treatment of vitamin D deficiency in children. See link to local guidelines</p> <p>Pregnant women:</p> <p>Fultium 3,200 unit capsules are first choice. See link to local guidelines</p> <p>Preparation to prevention of deficiency:</p>	<p>Plenachol® 40,000 unit capsules</p> <p>InVita® 25,000 unit oral solution</p> <p>Thorens® 10,000 units /ml drops</p> <p>Fultium® 3,200 unit capsules</p>

	<p>Self - care with low cost vitamin D supplements is recommended in Sheffield. They are readily available from pharmacies, supermarkets and health food stores.</p> <p>Eligible individuals are able to receive vitamin D via healthy start vitamins. See link for details.</p>	
Levothyroxine capsules and liquids	<p>Levothyroxine capsules are often prescribed for patients requiring lactose free formulations. Unlicensed capsules and liquids have often been used for these patients.</p> <p>If a lactose intolerance / allergy is the only reason for prescribing levothyroxine capsules or liquid then consider if they can be prescribed a lactose free tablet form of levothyroxine.</p>	<p>Teva® lactose free levothyroxine tablets http://www.tevauk.com/p/levothyroxine--367</p>
Magnesium glycerophosphate	<p>Consider if the patient can purchase OTC. See local guidelines link</p>	<p>Neomag® and Magnaspartate® are licensed formulary choices</p>
Topical Diltiazem hydrochloride	<p>Topical treatments for anal fissure are for short term use only and therefore should not be added to repeat medication lists.</p>	<p>Licensed Rectogesic® (Glyceryl trinitrate) 0.4% rectal ointment</p>
Glycopyrronium bromide	<p>Sialanar® oral solution is licensed for the treatment of chronic pathological drooling in children and adolescents aged 3-17 years and is used at Sheffield Childrens hospital – note the strength of Sialanar® is 400microgram glycopyrronium bromide per 1ml (2mg/5ml) which differs from commonly prescribed unlicensed glycopyrronium preparations (1mg/5ml).</p>	<p>Sialanar® oral solution</p>

References:

- PrescQipp (2016), Bulletin SPOT list, Accessed 25/07/2018 <https://www.prescqipp.info/resources/category/326-spot-list>
- Product SPCs accessed 25/07/2018 <https://www.medicines.org.uk/emc/>
- Medicines and Healthcare products Regulatory Authority. The supply of unlicensed medicinal products (“specials”), MHRA Guidance Note 14. 2014. Accessed 25/07/2018 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/373505/The_supply_of_unlicensed_medicinal_products_specials.pdf

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Appendix 1

BNFC published standard strengths of unlicensed Paediatric Medicines

The list below gives the 17 unlicensed medicines where a recommended strength in Paediatrics has been endorsed by NPPG and RCPCH and published under the prescribing and dispensing section for each drug on the BNFC app.

Drug name	Strength	Number of known manufacturers with suitable excipients so far
Melatonin (<i>unlicensed</i>)	1mg/ml	Veriton (Special products - Kidimel®) Rosemont, Martindale
Midazolam (<i>unlicensed</i>)	10mg/5ml	Special products
Omeprazole (<i>unlicensed</i>)	20mg/5ml	Quest, Ascot
Chloral Hydrate (<i>unlicensed</i>)	1g/5ml	No supplier found for this strength ? not sure if available yet
Hydrocortisone (<i>unlicensed</i>)	5mg/5ml	Rosemont, smpu, Nottingham
Tacrolimus (<i>unlicensed</i>)	5mg / 5ml	Rosemont, Specials lab
Clonazepam (<i>unlicensed</i>)	2mg / 5ml	Rosemont (alcohol). No other supplier found
Sertraline (<i>unlicensed</i>)	50mg/5ml	
Lisinopril (<i>unlicensed</i>)	20mg/5ml	
Sodium chloride (<i>unlicensed</i>)	5mmol/ml	Med Man, special products, Arjun
Clopidogrel (<i>unlicensed</i>)	25mg/5ml	Rosemont contains 236.7mg / 5ml alcohol)
Azathioprine (<i>unlicensed</i>)	50mg/5ml	SMPU, Rosemont
Pyrazinamide (<i>unlicensed</i>)	500mg/5ml	Guys
Ethambutol (<i>unlicensed</i>)	400mg/5ml	
Isoniazid (<i>unlicensed</i>)	50mg / 5ml	Rosemont
Phenobarbitone(<i>unlicensed</i>)	50mg / 5ml	Rosemont, Alium, special labs, UL medicines, Thame, Huddersfield
Spironolactone suspension (<i>unlicensed</i>)	50mg/5ml	Birchwood (POM), Rosemont