

Northern Ireland Medicines Management

# Specials Supplement

Healthcare professionals should explore all alternatives before deciding to prescribe a 'special'.

In the first nine months of 2020, nearly £6 million has been spent on 'specials' in Northern Ireland. In many cases, the patients' needs could have been met with a licensed medicine or a more competitively priced 'special' could have been sourced. With increasing demands on the Health Service budget, money spent on 'specials' could be better invested in other areas of healthcare.

'Specials' are special-order unlicensed medicines made to meet the needs of an individual patient. Unlicensed medicines may be prescribed in clinical situations where it is judged that, on the basis of the available evidence, unlicensed use is in the best interest of the patient.



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## The cost of 'specials'

In the first 9 months of this year nearly £6 million was spent on 'specials' in NI.

'Specials' can be very expensive and may not represent a cost effective treatment to the Health Service. Prescribers may not know the cost of a 'special' when it is prescribed.

A 'special' may be expensive if it involves high-cost ingredients and complicated manufacturing processes. Additionally, a distributor may levy charges that increase the total cost paid by the Health Service for the 'special'.

The price of an individual 'special' can vary greatly from one 'specials' manufacturer to another. This price variation depends on which supply route is chosen by the community pharmacy. For example, the price of one bottle of omeprazole 10mg/5ml oral suspension was found to range from £30 to £610.

Prescribers should ensure that they know the cost of a 'special' before prescribing, and discuss with community pharmacy colleagues the costs associated with prescribing and supply of 'specials', including where they are concerned about variations in price.

### Top 10 most costly 'specials' in Northern Ireland (Jan 2020 to Sep 2020)

	Drug	Cost
1	Melatonin oral liquids	£626,346
2	Omeprazole oral liquids	£540,412
3	Sucralfate (tablets, enemas, oral liquids)	£344,623
4	Levomepromazine (tablets, oral liquids)	£307,728
5	Melatonin caps/tabs	£292,211
6	Hepa-Merz sachets	£172,955
7	Mexiletine capsules	£160,906
8	Metolazone tablets	£156,986
9	Tacrolimus oral liquids	£149,008
10	Coal tar ointments	£144,097

See also section on 'Specials' manufacturers and suppliers on page 3

## Legal issues in prescribing and dispensing 'specials'

'Specials' have not been assessed by the MHRA (regulatory authority) for safety, quality and efficacy in the same way as licensed medicines. Therefore they have no Summary of Product Characteristics (SPC) outlining the dose, contra-indications, storage and side effect profile. Patient information leaflets are not routinely available for 'specials'.



'Specials' can be obtained from a range of sources by pharmacists and are not all manufactured in the same way. This means that the quality, bioavailability, ingredients and consistency of 'specials' can vary, even where the same product is prescribed.

**Prescribers:** if a prescriber writes a prescription for a licensed medicine, in line with the licensed dose and indication, then any untoward effects that may occur to the patient as a result of the patient taking the medicine, are the legal responsibility of the pharmaceutical company. However, for unlicensed products / 'specials' the prescriber takes full responsibility in law for any adverse effect a patient suffers (unless it can be proven that the product was faulty).

**Pharmacists:** pharmacists have a professional responsibility to make prescribers aware of the unlicensed nature of any 'special' before procuring a 'special'.

## Managing patients with swallowing difficulties and feeding tubes

Given the additional clinical and governance risks associated with prescribing and dispensing unlicensed medicines, doctors, pharmacists and nurses have a duty to consider carefully the need for a 'special' in the first place.

Patients with swallowing difficulties or patients with feeding tubes in place are often cited as a reason for prescribing of 'specials' in liquid form. However this is seldom needed if a **stepped approach** is followed:



<b>STEP 0</b>	<b>Is the medicine needed?</b> Review medications to ensure they are still needed.
<b>STEP 1</b>	<b>Is there an alternative licensed product that could be used?</b> E.g. consider changing sertraline tablets to an alternative SSRI available as a liquid (e.g. fluoxetine liquid 20mg/5ml) if swallowing problems likely to be long-term.
<b>STEP 2</b>	<b>Could a licensed product be used off-label?</b> E.g. are tablets suitable for crushing / opening capsule? Could a 1ml oral syringe be used to facilitate measurements other than 5ml?
<b>STEP 3</b>	If the answer is 'no' to steps (1) and (2), an unlicensed manufactured 'special' could be considered.

### Guidance on swallowing difficulties

- HSC Guideline - Advice for Health Professionals: Choosing medication for patients unable to take solid oral dosage forms in [Swallowing Difficulties and Thickening Agents](#) section of NI Formulary.
- PrescQIPP info bulletin 188: Care Homes — Assisting people with swallowing difficulties <https://www.prescqipp.info/>.
- Specialist Pharmacy Service Q&As:
  - ◇ [Thickening agents: what to consider when choosing a product?](#)
  - ◇ [How can people who need thickened fluids take medicines?](#)
  - ◇ [Thickening agents and thickened fluids-do they interact with medicines?](#)



## 'Specials' manufacturers and suppliers

'Specials' are available directly from 'special-order' manufacturers (NHS and non-NHS), or via third party distributors or specialist-importing companies. Details of companies are available in the BNF under '[Special-order Manufacturers](#)'. Prices for a 'special' vary considerably from one manufacturer / supplier to the next.



### NHS manufacturing units

NHS manufacturing units are 'special-order' manufacturers/suppliers that are attached to NHS hospital pharmacy departments. 'Specials' from NHS manufacturing units are usually supplied at more competitive prices than those supplied by non-NHS manufacturing units or suppliers. 'Pro-File' ([www.pro-file.nhs.uk](http://www.pro-file.nhs.uk)) is a database that lists the 'specials' that are made by NHS manufacturing units. Access is restricted to NHS pharmacy staff and is available via the Regional Medicines and Poisons Information Service (Tel 028 9504 0558 or email: [nirdic.nirdic@belfasttrust.hscni.net](mailto:nirdic.nirdic@belfasttrust.hscni.net)).

Victoria Pharmaceuticals (based in the Belfast Trust) is the NHS manufacturing unit for Northern Ireland (Tel 028 9615 1000).

### UNDER REVIEW: The HSC Agreed List of Paediatric Liquid Formulations: Standardisation of the most common liquid medicines in paediatrics

A project was undertaken in 2017 to improve the safety regarding the prescribing of liquids as children make the transition between secondary and primary care. As a result of this work, the five Trust Pharmacy Departments in Northern Ireland standardised the products that they stock and dispense / supply for a number of commonly prescribed oral liquids for children (both licensed and unlicensed liquids).



**This ensures continuity of supply between primary and secondary care, helping to reduce the likelihood of errors occurring due to incorrect dosing / strengths (enhancing patient safety) and also ensures that Health and Social Care Northern Ireland secures good value from its expenditure.**

#### Cost-effective supply via Victoria Pharmaceuticals

For the unlicensed liquids on the agreed HSC list, Victoria Pharmaceuticals (ordered via Movianto Northern Ireland, Tel 028 9079 5799) hold stock for access by community pharmacists at a competitive price.

#### Action for prescribers:

- Refer to the [agreed HSC list](#) when prescribing oral liquid medicines for children. Prescribe these products generically, exactly as described on the list, with particular attention to the formulation and strength specified.

#### Action for pharmacists:

- Check suppliers for cost-effective prices to ensure value for money for the Health Service.
- Consider ordering the unlicensed liquids on the [agreed HSC list](#) from Victoria Pharmaceuticals.

**Note:** at the time of publication of the Specials Supplement (Nov 2020), the HSC Agreed List of Paediatric Liquids was under review. The updated list will be uploaded to the NI Formulary website '[Specials](#)' section as soon as it is available.

### Hepa-Merz®: New supply option

- Given the wide variation in price for Hepa-merz®, community pharmacies are encouraged to order from a cost-effective supplier such as Victoria Pharmaceuticals (VP) via Movianto.
- As a pilot (commencing 3/8/20), VP will also offer through Sangers/AAH at the same price (current price £45.53/pack 30 sachets).

## Commonly prescribed 'specials'

### Melatonin

There is a licensed melatonin 1mg/ml sugar free oral solution available (by Colonis), indicated for short-term treatment of jet-lag in adults. There are also several unlicensed 'special' oral solutions of melatonin available, e.g. Martindale, Kidmel, Quantum Pharmaceuticals, and Kidnaps.

There are three notable excipients present in liquid formulations of melatonin (with varying quantities depending on the product) that require careful consideration if prescribing for children: propylene glycol, sorbitol and ethanol. See [HSCB letter on melatonin preparations](#) for full details.

**For this reason, tablets should be the formulation of choice; melatonin oral liquid should only be considered for those who are unable or unwilling to swallow tablets.**

It is important to note that whilst there are now a variety of newly licensed melatonin tablet and capsule formulations available, they are only licensed for a very limited range of specific indications. **Circadin® 2mg prolonged release tablets can be prescribed off-label in children and is the preferred first line choice.** Licensed melatonin tablets and capsules are detailed below:

Melatonin tablets/capsules	
	Licensed indications
Circadin® 2mg prolonged release tablets	Licensed for the short-term treatment of primary insomnia characterised by poor quality of sleep in patients who are aged 55 or over.  Melatonin may be prescribed off-label in children and is the current preferred first line choice in Northern Ireland. Tablets may be crushed to aid swallowing or for immediate release - see <a href="#">Interface Pharmacy Shared care guideline</a> for further information.
Slenyto® 1mg or 5mg prolonged release tablets	Licensed for treatment of insomnia in children and adolescents aged 2 -18 with Autism Spectrum Disorder and / or Smith-Magenis syndrome, where sleep hygiene measures have been insufficient.  Tablets can be put into food such as yoghurt, orange juice or ice-cream to facilitate swallowing and improve compliance. If the tablets are mixed with food or drink, they should be taken immediately and the mixture not stored.
Melatonin 3mg tablets (e.g. Colonis, Pharma Nord), 2mg, 3mg and 5mg capsules (Colonis)	Licensed in adults for short-term treatment of jet-lag ( <b>Note:</b> it is not appropriate to prescribe for jet lag under the Health Service. Therefore these products should not be prescribed on HS21 for jet lag).

Further information at <https://www.medicines.org.uk/emc/>

**\* Any decision taken regarding prescribing or dispensing an unlicensed or off-label medication should be made on an individual patient basis \***

### Levomepromazine 6mg tablets

Levomepromazine 6mg tablets (by Morningside Healthcare Ltd) have recently been licensed and are available in Northern Ireland. They are indicated for second or third-line treatment of adults with refractory nausea unassociated with chemotherapy, where other agents have failed to give adequate control. See [SPC](#) for more details.

Therefore, from November 2020, prescriptions written for levomepromazine 6mg tablets should be coded for the licensed product and payment will be based on the licensed product price. Further information can be found [here](#).

## Omeprazole / lansoprazole / ranitidine

Choosing a suitable formulation of omeprazole / lansoprazole / ranitidine for infants can be problematic. Clinical practice does not always reflect the licensed products available.

Medicine	Preferred formulation
Omeprazole oral suspension	<ul style="list-style-type: none"> <li>Omeprazole <b>tablets are preferred</b> for patients (both children and adults) who cannot swallow the oral capsules.</li> <li>If a liquid is necessary, use the licensed formulations, i.e. omeprazole <b>10mg/5ml oral suspension sugar free</b> x 75ml (Rosemont).</li> </ul>
Lansoprazole oral suspension	<ul style="list-style-type: none"> <li>Lansoprazole <b>orodispersible tablets are preferred</b> for patients (both children and adults) who cannot swallow the oral capsules.</li> </ul>
Ranitidine oral liquid *	<ul style="list-style-type: none"> <li>The licensed product, ranitidine 150mg/10ml (Zantac<sup>®</sup> syrup), plus a 1ml oral syringe if necessary.</li> </ul>

\* **Note:** Ranitidine is currently unavailable. This is following a [MHRA Medicines Recall](#), due to a possible risk with the ingredients.

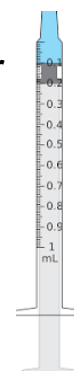
### Further information

- Refer to [Medicines Management Newsletter Supplement February 2017 for further information on omeprazole / lansoprazole / ranitidine in infants](#) and
- Patient information leaflets on Administration of Lansoprazole / Omeprazole tablets to an infant or a child, available in the [Patient Zone](#) section of NI Formulary.

### Oral syringes

**Oral syringes are available from community pharmacies to facilitate measurements other than 5ml**

- Community pharmacies can order 1ml, 3ml and 5ml oral syringes from local pharmaceutical wholesalers.
- 1ml and 3ml syringes are available in small packs or single packs to avoid bulk buying and cost less than £1 each.
- Only the 5ml size oral syringe is currently on NI Drug Tariff.



## Vitamin D

The Department of Health (NI) issued updated [advice](#) to the public in 2017 on how much vitamin D they need and how to obtain it.

Some children aged up to four years and pregnant women will be entitled to free Healthy Start Vitamins (Healthy Start Vitamins are available via a voucher scheme see: [www.healthystart.nhs.uk](http://www.healthystart.nhs.uk)).

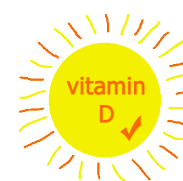
All other people should be **advised to purchase a vitamin D supplement** from their local community pharmacy, supermarket or other retail outlet. Vitamins should not be prescribed.

This advice relates to the general public and does not, for example, apply to those who are being treated for an underlying medical condition or deficiency with pharmacological doses as prescribed by their clinician.

**There are now many licensed vitamin D products available and should be chosen instead of nutritional supplements or 'specials' in patients requiring treatment doses.** Refer to vitamin D section of NI Formulary website for table of [licensed vitamin D products](#).

### Action for prescribers and pharmacists:

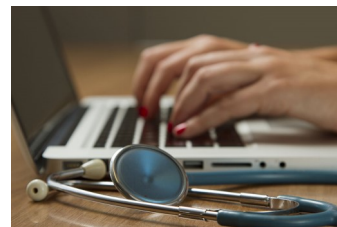
- A licensed product should be prescribed and dispensed where one is available.
- Avoid generic prescribing of vitamin D to ensure expensive 'specials' are not dispensed.
- Pharmacists are asked to order vitamin D preparations via usual pharmacy wholesalers, rather than placing an order for a 'special' as this is associated with higher costs.





## Actions for GP practices

- When clinically appropriate and available, licensed products should always be prescribed and dispensed in preference to unlicensed products / 'specials'.
- Ensure there is sufficient evidence / experience of using an unlicensed medicine to demonstrate its safety and efficacy.
- Take responsibility for prescribing the medicine and for overseeing the patient's care, monitoring, and any follow-up treatment.
- Make a clear, accurate and legible record of all medicines prescribed and, where you are not following common practice, your reasons for prescribing an unlicensed medicine.
- Review patients regularly who have 'specials' on repeat to ensure that they are still required, that the patient is benefiting from it, that a licensed product does not exist and that the dose / formulation is still appropriate for the patient:
  - Doses in a child may need to be changed as the child gets older
  - Check to see if the patient is receiving other medicines in solid dosage form, i.e. the patient is in fact able to swallow tablets.
- Refer to HSC Agreed list when prescribing oral liquid formulation for children.
- Refer to the ophthalmic list and, for items not on the list, confirm with secondary care to ensure that a transcription error has not occurred before prescribing.
- Refer to the BAD list and, for items not on the list, confirm with secondary care before prescribing.
- A licensed vitamin D preparation should be prescribed where one is available, and avoid generic prescribing of vitamin D.
- Given the potential for inadvertent prescribing of 'specials', practice based pharmacists may wish to audit prescribing to ensure that where a licensed product is available, it is specifically detailed on the prescription.



## Actions for community pharmacies

- Alert the GP to the unlicensed nature and cost of any prescribed 'special' before it is procured (GPs are often not aware from GP clinical systems that a product is a 'special') and advise on alternative licensed products where available.
- Pharmacists are encouraged to ensure that the Health Service secures good value from its expenditure, and pharmacists should bear this in mind in the procurement of 'specials'.
- The price of an individual 'special' can vary greatly from one manufacturer to another. Pharmacists should be aware of this when placing an order for a 'special'.
- If in doubt about ordering a 'special', contact a HSCB Pharmacy Advisor before ordering.
- Vitamin D nutritional supplements should be ordered via usual pharmacy wholesalers, rather than placing an order for a 'special' as this is associated with higher costs.
- A written Standard Operating Procedure (SOP) should be in place, detailing the steps involved in the ordering of 'specials' including risk assessments of the different options available.



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