

Q&A 294.2

Therapeutic options for patients unable to take solid oral dosage forms.

Prepared by UK Medicines Information ([UKMi](#)) pharmacists for NHS healthcare professionals
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Summary

- ◆ Some patients are unable to take medicines in solid oral dosage forms because they have swallowing difficulties or feeding tubes. The choice of medicine for these patients should be made on individual basis taking into account the patient's method of feeding, the practicalities of administration, product quality and cost.
- ◆ A stepwise approach is suggested to choose a suitable medicine:
 1. If possible, use a licensed medicine in a suitable formulation to meet the patient's needs (e.g. a dispersible tablet or licensed liquid medicine). Consider switching to a different agent in the same class, or to a different route of administration to allow a licensed medicine to be used.
 2. Consider using a licensed medicine in an unlicensed manner, for example by crushing/dispersing tablets or opening capsules. Not all medicines are suitable for use in this manner and it important to check beforehand. Take into account the patient/carer's ability to administer medicines in this way.
 3. In situations where the patient's needs cannot be met by licensed medicines, consider the use of special-order products ('specials').
- ◆ Licensed medicines should be used where possible. They are manufactured to specific standards and have been assessed for safety and efficacy.
- ◆ Special-order products are unlicensed and are not required to meet the same standards as licensed preparations. Prescribers assume greater liability when using them. They are considerably more expensive than licensed medicines.
- ◆ An appendix to this *Medicines Q&A* lists therapeutic options for adult patients unable to take solid oral dosage forms. A second appendix provides practical advice on the administration of medicines for these patients.
- ◆ An Academic Detail Aid highlights the key points of this *Medicines Q&A* (see appendix 3).

Background

Some adults are unable to swallow solid oral dosage forms because they have swallowing difficulties or feeding tubes. Children under the age of five years (and some older children) find a liquid formulation more acceptable than tablets or capsules. However, for long-term treatment it may be possible for a child to be taught to take tablets and capsules. [1]

This *Medicines Q&A* reviews the therapeutic options for patients unable to take solid oral dosage forms, and gives advice on how to choose the most appropriate preparation for a patient.

Answer

When choosing suitable preparations for a patient unable to take solid oral dosage forms, the prescriber must consider:

- ◆ Clinical appropriateness for the patient,
- ◆ Product quality and licensed status,
- ◆ Cost.

The first consideration should be to determine if a medicine is needed at all. Any unnecessary medicines should be stopped. If medication is required, consider agents with a prolonged therapeutic effect (but not modified or slow-release preparations) to reduce the frequency of dose administration. If a medicine is required a stepped approach is suggested to choose an appropriate preparation:

1. Licensed medicines administered as intended

Licensed medicines should be used where possible. They are associated with less risk and are less expensive than special-order products. Licensed medicines must meet quality standards for manufacture and be accompanied by appropriate product information and labelling. In order to be granted a licence, a medicine must show evidence of efficacy and safety. [2] In many cases a licensed medicine will be suitable to meet the patient's needs, for example a licensed liquid or dispersible tablets.

- ◆ Example: Metformin tablets can be replaced by metformin powder for oral solution.

It may be appropriate to switch to a different medicine.

- ◆ Example: Aspirin dispersible tablets may be a suitable alternative to clopidogrel tablets;
- ◆ Example: Fluoxetine liquid may be a suitable alternative to sertraline tablets.

Consider the use of dosage forms for administration via other routes such as transdermal patches or suppositories if appropriate.

- ◆ Example: Transdermal preparations of hormone replacement therapy may be preferred to oral preparations.

Adults who dislike swallowing large tablets or capsules can usually manage small tablets and capsules, or large tablets snapped in half, and, with encouragement, can manage most medicines. The use of costly special-order products for these patients is generally not justified. Community pharmacists may be able to suggest suitable preparations for their patients.

The prescriber should be aware of the route and method of administration of medicines they prescribe; information on the administration of medicines via feeding tubes or with food may not be included in a product's Summary of Product Characteristics or Patient Information Leaflet.

2. Licensed medicines administered in an unlicensed manner

If there is no suitable licensed formulation, consider using a licensed medicine in an unlicensed manner, for example by crushing/dispersing tablets or opening capsules immediately prior to administration, or by administering a solution for injection via a feeding tube. Not all medicines are suitable for administration this way. Prescribers should be aware if a medicine is to be used outside its licence and take responsibility for its use in this manner.

Consider the patient's method of feeding:

- ◆ Patients requiring liquid feeds may take oral liquid medicines, dispersible tablets or solid preparations dispersed in water prior to administration. For patients who require thickened fluids, liquids can be thickened with a small amount of a thickening agent such as *Thick and Easy* maize starch and maltodextrin powder.
- ◆ Patients able to tolerate a soft-food diet may be able to swallow crushed tablets or the contents of capsules administered with food.
- ◆ Patients with enteral feeding tubes can have oral medication administered via this route.

Consider also who will be administering the medicine (the patient themselves, a parent or carer), their manual dexterity and ability to follow instructions to administer the medicine correctly.

Appendix 2 provides practical information on crushing and dispersing tablets, opening capsules and giving medicines in soft food.

Not all tablets and capsules are suitable for dispersing, crushing or opening for administration in soft food or via feeding tubes and it is important to check beforehand. Appendix 1 lists options available in several therapeutic areas and provides specific examples for adult patients with swallowing difficulties or feeding tubes. Further information is available from reference texts [3, 4] and medicines information centres [5].

- ◆ Example: Bendroflumethiazide tablets can be dispersed in water;
- ◆ Example: Ramipril capsules can be opened and the contents dissolved in water or mixed with food.

As before, consider switching to a different agent within the same therapeutic class in order to use a licensed product.

- ◆ Example: Amlodipine tablets can be dispersed or crushed and mixed with water. They may be a suitable alternative to other dihydropyridine calcium channel blockers, none of which is available as a licensed liquid preparation. Amlodipine is suitable for once-daily administration.

Some parenteral medicines are suitable for administration orally or via feeding tubes. A *Medicines Q&A* provides examples. [6]

3. Special-order products

Medicines not commercially available in liquid formulations may be obtained as special-order liquids or extemporaneous preparations. Special-order products ('specials') and extemporaneous preparations are unlicensed and should only be considered for use when a patient's needs cannot be met by licensed medicines. [7-10] In many cases they are not required.

Manufacturers of special-order products must hold a Manufacturer's Specials Licence (MS) granted by the licensing authority and their manufacturing sites must be inspected for compliance with Good Manufacturing Practice. [11] Products made under a MS licence do not have a Marketing Authorisation and are considered unlicensed. These products can be identified by a MS number on their label.

Special-order medicines may be produced as batch-prepared products or individual bespoke preparations. A certificate of analysis should be available for any batch manufactured special-order product and is evidence that critical parameters have been confirmed by retrospective physical, chemical or microbiological assay of a sample of the final product. Bespoke special-order products should have a certificate of conformity, a signed statement by the manufacturer that they believe the product complies with the purchaser's specification.

Extemporaneous products can be made by pharmacists, or made by specials manufacturers outside of their MS licence. These products do not have a MS number on their label. There is no guarantee that the extemporaneous dispensing process meets Good Manufacturing Practice. [9]

Products made under licence by special-order manufacturers are preferred to extemporaneously prepared products. Batch-prepared special order products are preferred to bespoke preparations. [12]

The use of special-order or extemporaneous products may increase the risk to both patient and prescriber. These products are not assessed for safety or efficacy by the regulatory authorities and prescribers assume greater liability for their use.

Special-order liquids may have a short shelf-life compared with licensed preparations and may require fridge storage.

Special-order products are expensive, sometimes many times the cost of equivalent licensed medicines. Their cost is currently not regulated and it is hoped a tariff for some standardised specials will be introduced during 2011. [12, 13] Prescribers are often unaware of the high cost of special-order medicines they prescribe. [13]

- ◆ **Example: bendroflumethiazide**
 - Special-order bendroflumethiazide 2.5mg/5ml oral suspension is available as a batch-prepared product. It requires fridge storage. A 150ml bottle providing 30 doses of 2.5mg costs £66.
 - Bendroflumethiazide 2.5mg tablets can be dispersed in water. A box containing 28 doses of 2.5mg costs less than £1.
- ◆ **Example: sertraline**
 - Special-order sertraline 50mg/5ml oral suspension is available as a batch-prepared product. A 150ml bottle providing 30 doses of 50mg costs £105.
 - Fluoxetine 20mg/5ml is available as a licensed liquid preparation. Two 70ml bottles providing 28 doses of 20mg costs £10.

Other considerations

- ◆ The needs of patients and carers should be considered. It may not be practical for a patient to store or carry several bottles of liquid medicines. Some liquid medicines require fridge storage.
- ◆ NHS healthcare professionals have a duty to make the best use of public resources; cost as well as clinical suitability and product quality must be considered when choosing appropriate preparations. [14]
- ◆ The cost of special-order products can vary enormously between different suppliers. The Royal Pharmaceutical Society has prepared guidance for community pharmacists on the procurement and supply of special-order products. [9]
- ◆ Whichever product is selected, review the prescription regularly to ensure continued appropriateness; the patient's needs may have changed or an alternative treatment option may be available.

An Academic Detail Aid highlighting the key points of this *Medicines Q&A* is available at Appendix 3.

Limitations

The table of options (Appendix 1) may not be comprehensive and is the opinion of the author. Where different medicines are suggested, this does not imply therapeutic equivalence.

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Disclaimer

- ◆ Medicines Q&As are intended for healthcare professionals and reflect UK practice.
- ◆ Each Medicines Q&A relates only to the clinical scenario described.
- ◆ Medicines Q&As are believed to accurately reflect the medical literature at the time of writing.
- ◆ See [NeLM](#) for full disclaimer.

References

1. Paediatric Formulary Committee. BNF for Children 2010-11. Accessed at www.bnfc.org on 5/1/2011.
2. Medicines and Healthcare products Regulatory Agency. The supply of unlicensed relevant medicinal products for individual patients. MHRA Guidance Note No. 14. January 2008. Accessed at www.mhra.gov.uk/home/groups/is-lic/documents/publication/con007547.pdf on 5/1/2011.
3. White R and Bradnam V. Handbook of drug administration via enteral feeding tubes. Accessed via www.medicinescomplete.com on 11/1/2011.
4. Smyth J, editor. The NEWT Guidelines for administration of medication to patients with enteral feeding tubes or swallowing difficulties. Wrexham: North East Wales NHS Trust; 2010.
5. UK Medicines Information centres: contact details available at www.ukmi.nhs.uk/ukmi/directory/default.asp.
6. UKMi. Medicines Q&A 175.1. Which injections can be given enterally? July 2009 (partial revision April 2010). Accessed at www.nelm.nhs.uk/en/NeLM-Area/Evidence/Medicines-Q--A/Which-injections-can-be-given-enterally/ on 5/1/2011.
7. General Medical Council. Good practice in prescribing medicines. September 2008. Accessed at www.gmc-uk.org/static/documents/content/Good_Practice_in_Prescribing_Medicines_0911.pdf on 5/1/2011.
8. General Pharmaceutical Council. Standards for pharmacy owners and superintendent pharmacists of retail pharmacy businesses. September 2010. Accessed at www.pharmacyregulation.org/pdfs/premises/402779_owners_standards_090910_small.pdf on 11/1/2011.
9. Royal Pharmaceutical Society. Good practice guidance on the procurement and supply of pharmaceutical 'Specials'. June 2010. Accessed at <http://www.rpharms.com/support-pdfs/ppjune2010-specials.pdf> on 5/1/2011
10. Medicines and Healthcare products Regulatory Agency. Summary report for importation of unlicensed medicines 01 July 2010 - 30 September 2010. Approved December 2010. Appendix 1: Risk hierarchy for the use of unlicensed medicines. Accessed via www.mhra.gov.uk/Howweregulate/Medicines/Importingandexportingmedicines/Importingunlicensedmedicines/index.htm on 11/1/2011.
11. Medicines and Healthcare products Regulatory Agency. Notes for applicants and holders of a manufacturer's licence. MHRA Guidance Note No. 5. August 2006. Accessed at www.mhra.gov.uk/home/groups/is-lic/documents/publication/con007542.pdf on 5/1/2011.
12. Sims J. The Special Ones: a best practice guide for sourcing and dispensing specials. Chemist and Druggist online 26/11/2010. Accessed at www.chemistanddruggist.co.uk/c/portal/layout?p_l_id=259751&CMPI_SHARED_articleId=4438096&CMPI_SHARED_ImageArticleId=4438096&CMPI_SHARED_articleIdRelated=4438096&CMPI_SHARED_ToolsArticleId=4438096&CMPI_SHARED_CommentArticleId=4438096&articleTitle=The%20special%20ones on 11/1/2011.
13. Anon. The use of 'specials' in primary care. Drug and Therapeutics Bulletin 2010; 48(10): 110-112.
14. British Medical Association. Revisions to the GMS contract, 2006/7. Annex 8 – Excessive or inappropriate prescribing – guidance for health professionals on prescribing NHS medicines. February 2006. Accessed at www.bma.org.uk/employmentandcontracts/independent_contractors/general_medical_services_contract/revisionnGMSFeb20062.jsp?page=21 on 11/1/2011.

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Search strategy

In-house enquiries.

Prescribing data provided by PCTs in the North West.

Professional guidance: General Pharmaceutical Council, Royal Pharmaceutical Society, General Medical Council, British Medical Association, Nursing and Midwifery Council, Care Quality Commission.

Legislation: Medicines and Healthcare products Regulatory Agency.

Reimbursement: NHS Business Services Authority, Pharmaceutical Services Negotiating Committee.

Special-order manufacturers: personal communication.

Internet searches: search terms included special-order medicines, dysphagia, medicines administration, crushing, dispersing, unlicensed, feeding tubes, swallowing.

Appendix 1: Table of therapeutic options for adult patients unable to take solid oral dosage forms

- ◆ The following table lists therapeutic options for adult patients unable to swallow solid oral dosage forms. Information included can be used to choose medicines for patients with swallowing difficulties or feeding tubes.
- ◆ The choice of medicine should be made on individual basis taking into account the patient's method of feeding, the practicalities of administration, product quality and cost.
- ◆ The *Medicines Q&A* which this appendix accompanies reviews the therapeutic options for patients unable to take solid oral dosage forms, and gives advice on how to choose the most appropriate preparation. [1]

A step-wise approach is suggested:

1. If possible, use a licensed medicine in a suitable formulation to meet the patient's needs (e.g. a dispersible tablet or licensed liquid medicine). Consider switching to a different agent in the same class, or to a different route of administration to allow a licensed medicine to be used.
 2. Consider using a licensed medicine in an unlicensed manner, for example by crushing/dispersing tablets or opening capsules. Not all medicines are suitable for use in this manner and it important to check beforehand. Take into account the patient/carer's ability to administer medicines in this way.
 3. In situations where the patient's needs cannot be met by licensed medicines, consider the use of special-order products ('specials').
- ◆ The therapeutic drug classes chosen for inclusion in this table have been highlighted as having particular relevance to primary care, and include those where there has been a high spend on special-order medicines.
 - ◆ Where alternative agents are suggested, therapeutic equivalence is not implied. Patients will require monitoring and possibly dose titration when switching between different agents.
 - ◆ The inclusion of a special-order medicine in the table does not endorse its use. It is noted if special-order medicines are available as batch-prepared products or only as bespoke preparations, and if they have a short shelf-life or require fridge storage.
 - ◆ The prescriber should be aware of the licensed status, route and method of administration of medicines they prescribe. Prescribers assume greater liability for the use of unlicensed medicines and for the use of licensed medicines used in an unlicensed manner, than for licensed medicines used as intended.
 - ◆ Indicative prices are included in the table. Prices for licensed medicines are for generic preparations where available and reflect NHS costs in primary care. Three special-order manufacturers provided prices for inclusion in the table but may not be representative. The cost of special-order products is unregulated and can vary enormously between suppliers, typically in the range £50 to £700 for 150ml. Prices listed in the table do not include VAT, carriage or handling charges.

Where available, prices for batch-prepared products are listed. Batch-prepared products supplied with a certificate of conformity are preferred to bespoke preparations.

1. *Medicines Q&A 294.2*. Therapeutic options for patients unable to take solid oral dosage forms. January 2011. Available online at www.nelms.nhs.uk/en/NeLM-Area/Evidence/Medicines-Q--A/Therapeutic-options-for-patients-unable-to-take-solid-oral-dosage-forms/

Table of therapeutic options for adult patients unable to take solid oral dosage forms

BNF 1.3.5 Proton pump inhibitors

Licensed medicines in suitable formulations

Lansoprazole orodispersible tablets (*Zoton FasTabs*) can be allowed to disperse in the mouth then swallowed, or mixed with water to give a dispersion of small (0.33mm) granules for administration orally or via a feeding tube. [28 x 30mg: £6]

Omeprazole dispersible tablets (*Losec MUPS*) can be mixed with water to give a dispersion of small granules that can be given orally or first mixed with fruit juice, apple sauce or yoghurt; care must be taken not to crush or chew the granules. [28 x 20mg: £12]

Esomeprazole gastro-resistant granules for oral suspension are available. They are dispersed in water for administration orally or via a feeding tube. [28 x 10mg: £25]

H₂-receptor antagonists are available for patients in whom step-down therapy is appropriate: Ranitidine effervescent tablets [60 x 150mg: £17] and ranitidine 75mg/5ml oral solution [300ml: £19] are suitable for administration orally or via a feeding tube.

Licensed medicines used in an unlicensed manner

Omeprazole dispersible tablets (*Losec MUPS*) can be mixed with water to give a dispersion of small (0.5mm) granules. The granules have a tendency to block fine bore feeding tubes but can be mixed with water or 8.4% sodium bicarbonate for administration via wider feeding tubes.

Special-order medicines

Omeprazole 20mg/5ml oral solution is available as a batch-prepared product. It requires fridge storage. [150ml: £120 (one month shelf-life); £185 (two month shelf-life)]

BNF 2.2 Thiazide diuretics

Licensed medicines in suitable formulations

There are no suitable licensed formulations of bendroflumethiazide or other thiazide diuretics.

Loop diuretics are available as liquid preparations. They can be given via feeding tubes but may require dilution with water:

- Furosemide 20mg/5ml, 40mg/5ml and 50mg/5ml oral solutions [150ml: £14-20 depending on strength]
- Bumetanide 1mg/5ml oral liquid [150ml: £130]

Licensed medicines used in an unlicensed manner

Bendroflumethiazide tablets can be dispersed in water and given orally or via a feeding tube. [28 x 2.5mg: £1]

Indapamide immediate-release tablets can be dispersed in water for administration orally or via some feeding tubes, but absorption may be reduced if administered via tubes ending in the jejunum. Some indapamide immediate-release tablets are film-coated; they can be crushed and mixed with water before administration. [28 x 2.5mg: £2]

Special-order medicines

Bendroflumethiazide 2.5mg/5ml oral suspension is available as a batch-prepared product; it requires fridge storage. [150ml: £66]

BNF 2.5.5 Renin-angiotensin medicines

ACE inhibitors

Licensed medicines in suitable formulations

There are no suitable licensed formulations of any ACE inhibitor.

Licensed medicines used in an unlicensed manner

The following options are suitable for administration orally or via feeding tubes:

- Enalapril tablets can be crushed or dispersed in water for administration orally or mixed with food. The crushed tablets may have a bitter aftertaste. [28 tablets, any strength < £2]
- Lisinopril tablets can be dispersed in water. [28 tablets, any strength < £2]
- Perindopril tablets can be crushed or dispersed in water. [30 tablets, any strength (perindopril erbumine) < £2]
- Ramipril tablets can be dispersed in water. [28 tablets, any strength < £2]
- Ramipril capsules can be opened and the contents mixed with water or food. The capsule contents taste unpleasant. [28 capsules, any strength < £2]

Special-order medicines

Enalapril 5mg/5ml oral suspension is available as a bespoke special-order product. [150ml: £40 (one month shelf-life); £130 (two month shelf-life)]

Lisinopril 5mg/5ml oral solution is available as a bespoke special-order product. [150ml: £40 (one month shelf-life); £140 (three month shelf-life)]

Perindopril 4mg/5ml oral solution is available as a batch-prepared product; it requires fridge storage. [150ml: £90]

Ramipril 2.5mg/5ml oral solution is available as a batch-prepared product; it requires fridge storage. [150ml: £100]

Captopril 5mg/5ml and 25mg/5ml oral solutions are available as batch-prepared products; both require fridge storage. [150ml: £70-80, depending on strength] NB: Captopril is not suitable for once-daily administration.

Angiotensin II receptor antagonists

Licensed medicines in suitable formulations

Losartan 12.5mg/5ml oral suspension (supplied as powder and solvent) is available as a licensed preparation. Once reconstituted, it has a four-week shelf-life and requires fridge storage. [200ml: £54]

NB: ACE inhibitors are preferred for most patients; angiotensin II receptor antagonists are reserved for patients unable to tolerate ACE inhibitors.

Licensed medicines used in an unlicensed manner

The following options are suitable for administration orally or via feeding tubes. Irbesartan tablets disperse more readily than other preparations and are preferred for administration via feeding tubes.

- Candesartan tablets can be crushed and mixed with water. [28 tablets: £10-16 depending on strength]
- Irbesartan tablets can be dispersed in water. [28 tablets: £10-16 depending on strength]
- Losartan tablets can be crushed and mixed with water. [28 tablets: £2-7 depending on strength]
- Valsartan capsules can be opened and the contents mixed with water. [28 capsules: £14-18 depending on strength]

Special-order medicines

Losartan 12.5mg/5ml is available as a licensed oral suspension. If required, losartan 50mg/5ml oral suspension is available as a batch-prepared product, [150ml: £90]

Other angiotensin II receptor antagonists are available as bespoke special-order products.

BNF 2.6.2 Calcium channel antagonists

Amlodipine

Licensed medicines in suitable formulations

There are no suitable licensed formulations of amlodipine or other dihydropyridine calcium channel blockers.

Licensed medicines used in an unlicensed manner

Amlodipine tablets (besilate or maleate salts) can be dispersed or crushed and mixed with water for administration orally or via a feeding tube. [28 x 5mg or 10mg < £2]

Special-order medicines

Amlodipine 5mg/5ml oral solution is available as a batch-prepared product. It requires fridge storage. [150ml: £100]

BNF 2.8.2 Oral anticoagulants

Licensed medicines in suitable formulations

There are no suitable licensed formulations of warfarin or other oral anticoagulants.

Licensed medicines used in an unlicensed manner

Warfarin tablets can be dispersed or crushed and mixed with water for administration orally or via a feeding tube. [28 tablets any strength < £2]

Special-order medicines

Warfarin 1mg/ml oral suspension is available as a batch-prepared product. [150ml: £110]

BNF 2.9 Antiplatelet medicines

Licensed medicines in suitable formulations

There are no suitable licensed formulations of clopidogrel or modified-release dipyridamole.

Dispersible aspirin tablets should be considered for patients requiring antiplatelet monotherapy. They are suitable for administration orally or via a feeding tube. [28 x 75mg < £1]

Dipyridamole 50mg/5ml oral suspension is available [150ml: £40] and can be given orally or via a feeding tube. It is only licensed for use in patients with prosthetic heart valves in combination with oral anticoagulation. *NB: Evidence only supports the use of modified-release, not immediate-release, dipyridamole preparations for the prevention of vascular events.*

Licensed medicines used in an unlicensed manner

Clopidogrel tablets are film-coated but can be dispersed or crushed and mixed with water for administration orally or via a feeding tube. [28 x 75mg: £3]

Dipyridamole modified-release capsules (*Persantin Retard*) may be opened and the modified-release granules mixed with water. There is a risk that the granules could block a feeding tube. The granules must not be crushed. The granules may be given with soft food; care must be taken not to crush or chew the granules as this will damage the modified-release coating making this option unsuitable for patients with limited understanding or unable to follow instructions. [60 x 200mg: £9]

Dipyridamole immediate-release tablets (*Persantin*) can be crushed and mixed with water for administration orally or via a feeding tube. [84 x 100mg: £3] *NB: Evidence only supports the use of modified-release, not immediate-release, dipyridamole preparations for the prevention of vascular events.*

Special-order medicines

Clopidogrel 75mg/5ml oral suspension can be obtained as a batch-prepared product. [150ml: £85]

In view of the licensed dipyridamole 10mg/5ml suspension available, special-order dipyridamole preparations are unlikely to be required.

BNF 2.12: HMG CoA reductase inhibitors 'statins'

Licensed medicines in suitable formulations

Simvastatin 20mg/5ml [150ml: £100] and 40mg/5ml [150ml: £150] oral suspensions are available; they are suitable for administration orally or via a feeding tube.

Licensed medicines used in an unlicensed manner

Simvastatin tablets are film-coated but can be crushed and mixed with water for administration orally or via a feeding tube. [28 tablets, any strength < £3]

Pravastatin tablets can be crushed and dispersed in water for administration orally or via a feeding tube; they disperse more readily than simvastatin tablets. [28 tablets, any strength < £3]

Atorvastatin tablets are film-coated but can be crushed and dispersed in water for administration orally or via a feeding tube; they disperse more readily than simvastatin tablets. [28 tablets: £13-28 depending on strength]

Fluvastatin capsules can be opened and the contents mixed with water for administration orally or via a feeding tube. The 20mg capsules are small and may be fiddly to open. [28 capsules, £4-8 depending on strength]

Special-order medicines

Atorvastatin 20mg/5ml oral suspension is available as a bespoke special-order product. It has a shelf-life of 8 days and requires fridge storage. [35ml: £40]

BNF 4.1 Hypnotics

Chloral hydrate

Licensed medicines in suitable formulations

Chloral hydrate 143.3mg/5ml elixir (*Welldorm* elixir) is suitable for administration orally or via a feeding tube. [150ml: £9]

Other hypnotics may be preferred:

- Nitrazepam 2.5mg/5ml oral suspension is suitable for administration orally or via a feeding tube; for administration via feeding tubes that end in the jejunum, consider diluting the suspension with water to reduce the osmolarity. [150ml: £5]
- Temazepam 10mg/5ml oral solution is suitable for administration orally or via feeding tubes. [300ml: £33]

Licensed medicines used in an unlicensed manner

Zolpidem tablets can be dispersed or crushed and mixed with water for administration orally or via a feeding tube. [28 tablets, any strength, <£2]

Special-order medicines

NB: Chloral hydrate elixir is available as a licensed preparation (*Welldorm* elixir) and should be used in preference to a special-order product. *Welldorm* preparations are listed in the BNF under 'chloral betaine' but only the tablets contain the betaine salt.

Chloral hydrate oral solution (500ml/5ml, 'chloral mixture, BP 2000') is available as a batch-prepared product. [200ml: £18]

Chloral hydrate paediatric mixture (200mg/5ml, 'chloral elixir, paediatric, BP 2000') can be obtained as a bespoke special-order product. [200ml: £35]

Zopiclone

Licensed medicines in suitable formulations

There are no suitable licensed formulations of zopiclone.

Other hypnotics may be preferred:

- Nitrazepam 2.5mg/5ml oral suspension is suitable for administration orally or via a feeding tube; for administration via feeding tubes that end in the jejunum, consider diluting the suspension with water to reduce the osmolarity. [150ml: £5]
- Temazepam 10mg/5ml oral solution is suitable for administration orally or via feeding tubes. [300ml: £33]

Licensed medicines used in an unlicensed manner

Zopiclone tablets are not suitable for crushing or dispersing for administration via feeding tubes.

A suitable alternative may be zolpidem tablets, which can be dispersed or crushed and mixed with water for administration orally or via a feeding tube. [28 tablets, any strength, <£2]

Special-order medicines

Zopiclone 3.75mg/5ml oral suspension is available as a bespoke special-order product. It has a shelf-life of 14 days and requires fridge storage. [150ml: £105]

BNF 4.2 Atypical antipsychotics

Quetiapine

NB: There is a clear increased risk of stroke and a small increased risk of death when antipsychotic medicines (typical or atypical) are used in elderly patients with dementia.

Licensed medicines in suitable formulations

There are no suitable licensed formulations of quetiapine.

Other atypical antipsychotics are available and may be suitable for some patients:

- Amisulpride oral solution can be administered orally or via a feeding tube. [100mg/ml x 60ml: £34]
- Aripiprazole orodispersible tablets can be dispersed in water for administration orally. [28 tablets, either strength: £100]
- Aripiprazole oral solution is available. [1mg/ml x 150ml: £100]
- Olanzapine orodispersible tablets can be dispersed in water for administration orally or via a feeding tube. [28 tablets: £50-175 depending on strength]
- Risperidone liquid can be administered orally or via a feeding tube. [1mg/ml x 100ml: £57]
- Risperidone orodispersible tablets can be dispersed in water for administration orally or via a feeding tube. [28 tablets: £18-46 depending on strength]

Depot medication may be considered in some circumstances.

'Typical' antipsychotics may be suitable for some patients. The following licensed preparations are available and can be administered orally or via a feeding tube:

- Chlorpromazine 25mg/5ml and 100mg/5ml oral solutions [150ml: £2-5]
- Haloperidol 5mg/5ml and 10mg/5ml oral liquids [500ml: £35]
- Promazine 25mg/5ml and 50mg/5ml oral solutions [150ml: £5]
- Sulpiride 200mg/5ml oral solution [150ml: £25]
- Trifluoperazine 5mg/5ml oral solution (for administration via feeding tubes that end in the jejunum, consider diluting the suspension with an equal volume of water to reduce the osmolarity) [150ml = £10]

Licensed medicines used in an unlicensed manner

Quetiapine tablets can be crushed and mixed with water for administration via feeding tubes. The crushed tablets may be administered in soft food but taste bitter. [60 tablets: £35-170 depending on strength]

Special-order medicines

Quetiapine 25mg/5ml oral suspension can be obtained as a bespoke special-order product. [150ml: £130]

BNF 4.3.1 Tricyclic and related anti-depressants

Dosulepin

NB: NICE guidance on depression states that dosulepin should not be prescribed. It is associated with an increased risk of cardiac toxicity and toxicity in overdose.

Licensed medicines in suitable formulations

There are no suitable licensed formulations of dosulepin.

Other tricyclic antidepressants are available and may be preferred:

- Amitriptyline 25mg/5ml [150ml: £16] and 50mg/5ml [150ml: £18] oral solutions can be administered orally or via a feeding tube.
- Lofepamine 70mg/5ml oral suspension can be administered orally or via a feeding tube. [150ml: £22]

Licensed medicines used in an unlicensed manner

Dosulepin capsules can be opened and the contents mixed with water for administration orally or via a feeding tube; the capsule contents can be sprinkled on food but may have a local anaesthetic action. [28 x 25mg < £2]

Dosulepin tablets can be crushed but do not disperse in water easily; they are generally not considered suitable for administration via a feeding tube although some generic tablets have been administered after crushing once the tablet coating has dissolved. [28 x 75mg < £2]

Special-order medicines

Dosulepin 25mg/5ml [500ml: £35] and 75mg/5ml (500ml: £45) oral solutions are available as batch-prepared products.

BNF 4.3.3 Selective Serotonin Re-uptake Inhibitors (SSRIs)

Sertraline

Licensed medicines in suitable formulations

There are no suitable licensed formulations of sertraline.

Other SSRIs are available and may be administered orally:

- Fluoxetine 20mg/5ml oral liquid [70ml: £5]
- Citalopram 40mg/ml oral drops [15ml: £10]
- Escitalopram oral drops [10mg/ml x 28ml: £19; 20mg/ml x 15ml: £20]
- Paroxetine 10mg/5ml oral suspension [150ml: £9]

Licensed medicines used in an unlicensed manner

Fluoxetine 20mg/5ml oral liquid [70ml: £5] and paroxetine 10mg/5ml oral suspension [150ml: £9] can be administered via a feeding tube; both should be mixed with an equal volume of water first.

Sertraline tablets can be dispersed or crushed and mixed with water for administration orally or via a feeding tube. Crushed tablets can be mixed with food but have a bitter taste and may have a local anaesthetic effect. [28 tablets, either strength < £2]

Special-order medicines

Sertraline 50mg/5ml oral suspension is available as a batch-prepared product [150ml: £105]

BNF 4.8 Antiepileptic medicines

Clobazam

Licensed medicines in suitable formulations

There are no suitable licensed formulations of clobazam.

Licensed medicines used in an unlicensed manner

Clobazam tablets can be dispersed or crushed and mixed with water for administration orally or via a feeding tube but taste unpleasant. [30 x 10mg < £5]

Special-order medicines

Clobazam 5mg/5ml [150ml: £85] and 10mg/5ml [150ml: £125] oral solutions are available as batch-prepared products.

Clonazepam

Licensed medicines in suitable formulations

There are no suitable licensed formulations of clonazepam.

Licensed medicines used in an unlicensed manner

Clonazepam tablets can be dispersed in water for administration orally or via a feeding tube. [100 x 500mcg: £4; 100 x 2mg: £5]

Clonazepam injection can be administered orally or via a feeding tube. [100 x 1ml ampoule (1mg): £60]

Special-order medicines

Clonazepam 500mcg/5ml [150ml: £70] and 2mg/5ml [150ml: £90] oral solutions are available as batch-prepared products.

Gabapentin

Licensed medicines in suitable formulations

There are no suitable licensed formulations of gabapentin or pregabalin.

Licensed medicines used in an unlicensed manner

Gabapentin capsules can be opened and the contents mixed with water for administration orally or via a feeding tube. The capsule contents can be mixed with soft food or fruit juice; strong flavours may mask the unpleasant taste. Capsule contents should be taken immediately as the drug is rapidly hydrolysed. The 100mg capsules are small and may be fiddly to open. [100 capsules: £5-11 depending on strength]

Pregabalin capsules can be opened and the contents dissolved in water for administration orally or via a feeding tube. [100 capsules, any strength: £65]

Special-order medicines

Gabapentin 250mg/5ml oral solution is available as a batch-prepared product. [150ml: £60]

Phenobarbital

Licensed medicines in suitable formulations

Phenobarbital elixir 15mg/5ml is available but contains 38% alcohol. It is not considered suitable for use in children. It may be given orally or via a feeding tube for adults. [100ml:< £1]

Licensed medicines used in an unlicensed manner

Phenobarbital tablets may be crushed and mixed with water for administration orally or via a feeding tube. [28 tablets, all strengths < £1]

Special-order medicines

Phenobarbital 50mg/5ml oral solution (alcohol-free) is available as a batch-prepared product. [150ml: £85]

6.1 Drugs used in diabetes

Metformin

Licensed medicines in suitable formulations

Metformin powder for oral solution is available in 500mg and 1g sachets. The sachet contents should be mixed with 150ml water immediately before administration orally or via a feeding tube; smaller volumes have been used. [60 sachets: £7-13 depending on strength]

Metformin 500mg/5ml oral solution is available and can be given orally or via a feeding tube. [150ml: £80]

Licensed medicines used in an unlicensed manner

Metformin immediate-release tablets can be crushed and mixed with water for administration orally or via a feeding tube, but some tablets are difficult to crush. [84 x 500mg < £2; 56 x 850mg: £4] Modified-release metformin tablets must not be crushed.

Special-order medicines

In view of the licensed preparations available, special-order products are unlikely to be required.

6.3 Glucocorticoid therapy

Hydrocortisone

Licensed medicines in suitable formulations

There are no suitable licensed formulations of hydrocortisone.

Licensed medicines used in an unlicensed manner

Hydrocortisone tablets can be dispersed in water for administration orally or via a feeding tube. [30 tablets: £43-45 depending on strength]

Efcortisol (hydrocortisone sodium phosphate 100mg/ml) injection can be administered orally or enterally, but consider the phosphate content. [5 x 1ml: £5]

Corlan (hydrocortisone 2.5mg) oromucosal tablets may be swallowed. [20 tablets: £2]

Special-order medicines

Hydrocortisone 5mg/5ml [150ml: £50] and 10mg/5ml [150ml: £75] oral suspensions are available as batch-prepared products.

Bibliography

- Joint Formulary Committee. British National Formulary 60th edition. Accessed at www.bnf.org on 12/1/2011.
- MIMS: Monthly Index of Medical Specialities. Accessed at www.mims.co.uk on 12/1/2011.
- National Institute for health and Clinical Excellence. Clinical Guideline 90: Depression. October 2009. Accessed at www.nice.org.uk/nicemedia/pdf/CG90NICEguideline.pdf on 12/1/2011.
- Nova Laboratories Ltd. Personal communication: 12/1/2011.
- Paediatric Formulary Committee. BNF for Children 2010. Accessed at www.bnfc.org on 12/1/2011.
- Rosemont Pharmaceutical Ltd. Personal communication: 5/1/2011 and 12/1/2011.
- Rosemont Pharmaceuticals Ltd. Retail licensed and specials price list. Downloaded from www.rosemontpharma.com on 5/1/2011.
- Smyth J, editor. The NEWT Guidelines for administration of medication to patients with enteral feeding tubes or swallowing difficulties. Wrexham: North East Wales NHS Trust; 2010.
- The Specials Laboratory Ltd. Personal communication: 12/1/2011.
- UKMi. Medicines Q&A 175.1. Which injections can be given enterally? July 2009 (partial revision April 2010). Accessed at www.nelm.nhs.uk/en/NeLM-Area/Evidence/Medicines-Q--A/Which-injections-can-be-given-enterally/ on 5/1/2011.
- White R and Bradnam V. Handbook of drug administration via enteral feeding tubes. Accessed via www.medicinescomplete.com on 11/1/2011.

Appendix 2: Administering medicines to patients unable to take solid oral dosage forms

In all cases, first establish that a medicine is suitable for administration in the intended manner. Consult standard reference texts or contact your medicines management team or medicines information centre for advice. [1, 2, 3]

Care staff may only administer medicines in an unlicensed manner on the instruction of the prescriber. A written direction to crush or disperse tablets or to open capsules should be documented in the patient's care plan.

- **Crushing or dispersing tablets**

Many immediate-release tablets will disperse sufficiently in water to be suitable for administration via an enteral feeding tube without the need for crushing. [1] Modified-release tablets are not suitable for crushing or dispersing.

For medicines that are suitable for crushing, crush using a tablet crusher, a pestle and mortar or between two metal spoons. Only crush medicines one at a time; do not crush all the patient's medicines together. Crushing or dispersing should only be performed immediately before administration.

- **Opening capsules**

Some hard gelatin capsules can be opened and their contents mixed with water or administered with food. Some capsules may be too small to manipulate. Capsules should only be opened immediately before administration.

- **Administering medicines in liquids or soft food**

Crushed medicines or capsule contents may be given with a small amount of cold liquid or soft food such as a teaspoon of yoghurt or jam. A small amount should be used to ensure the full dose is taken; if taken with a meal, the medicine should be added to the first mouthful of food.

Crushed tablets or capsule contents may taste very bitter; it can be helpful to mask the taste for patients taking these medicines orally by using strong flavours such as jam or blackcurrant cordial. Medicines should not be mixed or administered in a baby's feeding bottle. [4]

Medicines should only be administered in food with the patient's knowledge and consent. Hiding medication in food is considered 'covert administration' and is only condoned in certain circumstances. [5]

- **Administering medicines via feeding tubes**

Feeding tubes should be flushed with water before and after each medicine is administered. If the medicine is viscous, flushing or dilution with water may be required during administration. For patients who are fluid-restricted, the volume of water used for flushing needs to be considered. Medicines should not be added to enteral feeds.

When administering crushed tablets or opened capsules via a feeding tube, mix the powder with 15-30ml water. Draw into a 50ml oral syringe and administer. If you have used a mortar or tablet crusher, rinse this with water and administer the rinsings also.

Suggested protocol for administering medicines via a feeding tube: [2]

1. Stop the feed (leaving a feeding break if necessary).
2. Flush the tube with 30ml water.
3. Prepare the first medicine for administration, and administer it.
4. Flush with 10ml water.
5. Repeat stages 3 and 4 with subsequent medicines.
6. Flush with 30ml water.
7. Re-start the feed (leaving a feeding break if necessary).

The administration of medicines via feeding tubes by care workers in care homes and those providing domiciliary care should only be performed by those with the competency and skills required. [6]
Procedures should be in place to ensure care workers who agree to give medicines via feeding tubes receive appropriate training.

References

1. White R and Bradnam V. Handbook of drug administration via enteral feeding tubes. Accessed via www.medicinescomplete.com on 13/1/2011.
2. Smyth J, editor. The NEWT Guidelines for administration of medication to patients with enteral feeding tubes or swallowing difficulties. Wrexham: North East Wales NHS Trust; 2010.
3. UK Medicines Information centres: contact details available at www.ukmi.nhs.uk/ukmi/directory/default.asp
4. Paediatric Formulary Committee. BNF for Children 2010. Accessed at www.bnfc.org on 13/1/2011.
5. Nursing and Midwifery Council. Covert administration of medicines – disguising medicine in food and drink. November 2007. Accessed at www.nmc-uk.org/Nurses-and-midwives/Advice-by-topic/A/Advice/Covert-administration-of-medicines/ on 13/1/2011.
6. Care Quality Commission. Guidance about compliance: Essentials standards of quality and safety. March 2010. Accessed at www.cqc.org.uk/db/documents/Essential_standards_of_quality_and_safety_March_2010_FINAL.pdf on 13/1/2011.

Appendix 3: Academic Detail Aid

An Academic Detail Aid has been published to highlight the main points of this *Medicines Q&A*.

Academic detailing aims to change the practice of healthcare professionals, often prescribers. The process involves face-to-face education of practitioners, usually by clinical pharmacists, in the practitioner's clinical setting. [1]

One of the principles of academic detailing is to use concise visual materials, or 'detail aids' that summarise the key messages and may be provided to the prescriber.

References

1. Cutts C and LaCaze A. What tricks and techniques can be used to influence prescribing? *Prescribing and Medicines Management* 2003; 5: 12-14.

A stepwise approach is suggested:

STEP 1

Use a licensed medicine in a suitable formulation.

For example:

- Licensed liquid preparation
- Soluble tablets
- Powders or granules for suspension

In order to use a licensed medicine, consider switching to a different agent in the same class, or to a different route of administration.

For example, consider:

- Fluoxetine liquid (licensed preparation) as an alternative to sertraline tablets
- Aspirin dispersible tablets instead of clopidogrel tablets.
- HRT patches instead of tablets

Consider the patient's method of feeding:

Patients on liquid feeds may take oral liquid medicines, dispersible tablets or solid preparations dispersed in water. For patients on thickened fluids, liquid medicines can be mixed with products like *Thick and Easy*.

Patients on soft-food diets may be able to swallow crushed tablets or the contents of capsules given with food.

Patients with enteral feeding tubes may have oral medicines given by this route.

Why licensed status matters

To be granted a licence a medicine must meet quality standards and be shown to be safe and effective. Licensed medicines usually come with a patient information leaflet and are considered the safest choice.

Special-order medicines are unlicensed and are not required to meet the same standards as licensed medicines. Prescribers take greater responsibility when using them.

In many cases a licensed preparation will be available that meets the patient's needs.

Cost

Special-order medicines are often considerably more expensive than licensed medicines. They may have short shelf-lives compared with licensed alternatives and may need fridge storage.

For example, bendroflumethiazide liquid is 60 times more expensive than tablets:

- 28 doses of 2.5mg tablets costs about £1
- 30 doses of 2.5mg/5ml liquid (150ml) costs more than £65.

Bendroflumethiazide tablets can be dispersed in water for administration orally or via feeding tubes.

STEP 2

Consider using a licensed medicine in an unlicensed manner, for example by dispersing tablets in water or by opening capsules.

For example:

- Ramipril capsules can be opened and the contents mixed with water.
- Bendroflumethiazide tablets can be dispersed in water.

Both examples are suitable for administration orally or via a feeding tube.

Not all medicines are suitable for administration in this way and it is important to check beforehand. See over for where to get advice.

As before, consider switching to a different agent or route of administration in order to use a licensed product.

Is it needed?

If the patient is taking medicines that aren't needed or aren't working, stop or change them.

Care staff should only give licensed medicines in an unlicensed way if there is a written direction in the patient's care plan.

Practical directions are overleaf.

STEP 3

In situations where there is no suitable licensed option, consider using a 'special'.

Special-order ('special') liquid medicines are unlicensed and expensive. They should only be prescribed if there is no licensed medicine that meets the patient's needs.

**Licensed medicines should be used where possible.
Special-order medicines are unlicensed and expensive and should only be prescribed if necessary.**

Practical directions

Always check beforehand if a tablet is suitable for dispersing or crushing, or if a capsule is suitable for opening.

• Crushing or dispersing tablets

Many immediate-release tablets can be dispersed in water without crushing; some medicines need to be crushed first. Some tablets (e.g. modified-release) are not suitable for crushing.

For medicines that are suitable for crushing, crush using a tablet crusher, a pestle and mortar or between two metal spoons.

Only crush medicines one at a time; do not crush all the patient's medicines together. Crushing or dispersing should only be performed immediately before administration.

• Opening capsules

Some hard gelatin capsules can be opened and their contents mixed with water or administered with food. Some capsules are too small to manipulate. Capsules should only be opened immediately before administration.

• Giving medicines in liquids or soft food

Some capsule contents or crushed tablets can be given with a small amount of cold liquid or cold soft food such as a teaspoon of yoghurt or jam. Use a small amount of food to ensure the full dose is taken; if taken with a meal, add medicine to the first mouthful of food.

Crushed tablets or capsule contents may taste very bitter to patients taking them orally. Mask the taste by giving with strong flavours such as blackcurrant.

Medicines should only be administered in food with the patient's knowledge and consent. Hiding medicines in food is considered 'covert administration' and is only condoned in certain circumstances.

• Giving medicines via feeding tubes

Feeding tubes should be flushed with water before and after each medicine is administered. If a liquid medicine is thick or syrupy, dilution may be required. Some patients are fluid restricted and that needs to be taken into account.

When administering crushed tablets or opened capsules via a feeding tube, add the powder to 15-30ml water and mix well. Draw into a 50ml oral syringe and administer. If you have used a mortar or tablet crusher, rinse this with water and administer the rinsings also.

Suggested protocol for administering medicines via feeding tubes:

1. Stop the feed (leaving a feeding break if necessary).
2. Flush the tube with 30ml water.
3. Prepare the first medicine for administration, and give it.
4. Flush with 10ml water.
5. Repeat stages 3 and 4 with subsequent medicines.
6. Flush with 30ml water.
7. Re-start the feeding (leaving a feeding break if necessary).

Care staff may only administer medicines in an unlicensed manner on the instruction of the prescriber.

A written direction to crush or disperse tablets or to open capsules should be documented in the patient's care plan.

Where can I get advice?

• Medicines Management and Medicines Information pharmacists

For advice on choosing appropriate dosage forms or to check if tablets or capsules can be dispersed, crushed or opened and dispersed, contact your Medicines Management team or UKMi medicines information centre.

Contact details for UKMi medicines information centres are available at www.ukmi.nhs.uk. Click on the map then search for your local or regional centre.

• Medicines Q&A

This leaflet accompanies a *Medicines Q&A* document which provides further information and lists options available in several therapeutic areas for adult patients with swallowing difficulties or feeding tubes. Access it online via the link at the bottom of the page.

• Reference texts

Details of two respected texts are at the bottom of the page.

Only prescribe special-order medicines if there is no suitable licensed medicine available that meets the patient's needs.

It may be appropriate to use a licensed medicine in an unlicensed way.

References:

- UKMi. Medicines Q&A 294.2: Therapeutic options for patients unable to take solid oral dosage forms. January 2011. Available online at: www.nelm.nhs.uk/en/NeLM-Area/Evidence/Medicines-Q--A/Therapeutic-options-for-patients-unable-to-take-solid-oral-dosage-forms/
- White R and Bradnam V. Handbook of drug administration via enteral feeding tubes, 2nd edition. Pharmaceutical Press; 2010.
- Smyth J. The NEWT Guidelines for administration of medication to patients with enteral feeding tubes or swallowing difficulties, 2nd edition. Wrexham: North East Wales NHS Trust; 2010.

Date of preparation: January 2011