

Therapeutic options for patients unable to take solid oral dosage forms Guidance for prescribers and pharmacists

Summary

Some patients are unable to take medication in solid oral dosage forms due to dysphagia or neuro-logical conditions. A stepwise approach is suggested to choose a suitable alternative:

- 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).
 - 2 If there is no suitable licensed formulation, consider using a licensed medicine in an unlicensed manner, for example by crushing tablets or opening capsules. This would be preferable to using an unlicensed product. It should be understood that the prescriber's responsibility and potential liability are increased when prescribing outside of the licensed indications.
 - 3 In order to use a licensed medicine, consider switching to a different therapeutic agent in the same class, or to a different route of administration. In most cases a suitable licensed preparation will be available to meet the patient's needs.
 - 4 In the few situations where the patient's needs cannot be met by licensed medicines, the use of a special-order product ('special') may be considered. These are made in GMP inspected facilities but are otherwise un-assessed.
 - 5 Products that are unlicensed in the country of origin, and which are not classed as medicines in the country of origin (but are in the UK) should be avoided whenever possible. For example, melatonin products from the USA, where melatonin products are classed as supplements, not pharmaceuticals.
- ◆ 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.
 - ◆ The administration requirements should be added to the prescription directions and the instructions added to the label on dispensing.
 - ◆ Appendix 1 to this protocol lists therapeutic options for patients unable to take solid oral dosage forms. Appendix 2 provides practical advice on the administration of medicines in these patients.

Important

If the person crushing and administering oral dose forms is pregnant or could be pregnant, a pharmacist should be consulted for advice before proceeding as some medication could be toxic to the mother or baby.

Points to consider

- ◆ 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. [1]
- ◆ The needs of patients and carers should be considered; it may not be practical for a patient to carry several bottles of liquid medicines with them on a daily basis. Some liquid medicines require fridge storage and often have a short shelf-life.
- ◆ The cost of special-order products can vary enormously between different suppliers. Pharmacists have a professional duty to ensure that these medicines are competitively priced. The RPSGB is preparing guidance for community pharmacists on the procurement of special-order products. [2]
- ◆ 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. [3]
- ◆ Dermatological pharmaceutical special-order products with formulations which are more than two years old may have been superseded by commercially available licensed products which were not available at the time of prescribing.
- ◆ The continuing need for an unlicensed special-order product should be regularly reviewed. A swallowing difficulty may have been resolved and the patient can return to solid oral dosage forms.

Recommendations

1. Licensed medicines administered as intended

Licensed medicines should be used where possible. They are associated with less risk and are less costly 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. [4] In most 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 oral powder.

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.

2. Licensed medicines administered in a unlicensed manner

If there is no suitable licensed formulation, consider using a licensed medicine in an unlicensed manner, for example by crushing tablets or opening capsules prior to administration, or by administering a solution for injection via a feeding tube. Prescribers should be aware if a medicine is to be used outside its licence and take responsibility for its use in this manner.

The administration requirements should be added to the prescription directions and the instructions added to the label on dispensing.

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 products such as Thick and Easy® or Nutilis®.
- ◆ 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 their oral medication administered via this route.

Not all tablets and capsules are suitable for crushing or opening for administration in soft food or via feeding tubes and it is important to check beforehand. Appendix 1 contains a table of therapeutic options for patients with swallowing difficulties or feeding tubes. Further information is available from reference texts [5, 6] and medicines information centres [7].

- ◆ Example: Bendroflumethiazide tablets can be dispersed in water;
- ◆ Example: Ramipril capsules can be opened and the contents dissolved in water or administered on 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 crushed and dispersed in water. They may be a suitable alternative to other dihydropyridine calcium channel blockers, none of which is available as a licensed liquid preparation or as a solid form that can be crushed, dispersed or opened. Amlodipine is suitable for once-daily administration.

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

3. Special-order products

Special-order products (or 'specials') are unlicensed and should only be considered for use when a patient's needs cannot be met by licensed medicines. [8, 9] In most cases special-order products are not required.

Special-order medicines may be produced as batch-prepared products or individual bespoke preparations. Manufacturers of batch-prepared specials must hold a Manufacturer's Specials Licence (MS) granted by the licensing authority. Their manufacturing sites are inspected for compliance with Good Manufacturing Practice (GMP). Although there is some reassurance around the quality of manufacture, special-order products have not been assessed for safety and efficacy by regulatory authorities and the products themselves are unlicensed. Batch-prepared products made by these manufacturers will have a MS number on the label. [10]

Bespoke special-order products are extemporaneously prepared products made for an individual patient and are prepared under the supervision of a pharmacist. Special-order manufacturers who prepare bespoke preparations must not make reference to their MS number regarding these preparations. **Extemporaneous dispensing (by a pharmacist or specials manufacturer) should only be undertaken if there is no licensed product or batch-prepared special available.** [11, 12]

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

Special-order products are expensive, sometimes many times the cost of equivalent licensed medicines. They may have a short shelf-life compared with licensed preparations and may require fridge storage.

The least acceptable products are those that are unlicensed in the country of origin, and which are not classed as medicines in the country of origin (but are in the UK). Hence, for example, the use of melatonin products from the USA, where melatonin products are classed as supplements, not pharmaceuticals and may not be made to expected standards of pharmaceutical GMP should be avoided whenever possible. [13]

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

Drug	Preparation	Comments
Alendronate	No liquid formulation available. Tablets should not be crushed	Alternative—Strontium ranelate sachets
Allopurinol	Tablets disperse in water	If via feeding tube, give after feed
Amlodipine	5mg and 10mg tablets disperse in water	Take immediately as light sensitive
Atorvastatin	Crush and disperse tablets in water	Flush feeding tubes well after dosing
Bendroflumethiazide	Tablets disperse in water	
Bisoprolol	Crush tablets and disperse in water	
Candesartan	Tablets do not disperse readily	Consider switching to irbesartan
Carbimazole	Tablets disperse in water	
Citalopram	Oral drops are available but are not bio-equivalent to the tablets.	8mg (4 drops) of liquid may be considered therapeutically equivalent to a 10mg tablet.
Clonazepam	Tablets disperse in water	
Clopidogrel	Plavix® tablets can be crushed and dispersed in water	
Co-beneldopa (Madopar®)	Dispersible tablets 62.5mg, 125mg	Switch to dispersible tablets which have faster onset of action compared to modified release capsules. Dose and frequency may need adjustment. Madopar® capsules should not be opened.
Co-careldopa (Sinemet®)	Tablets disperse in water	CR formulations should not be crushed and are not suitable for administration via feeding tubes. Dose and frequency may need adjusting when changing from other forms
Cyclizine	Crush tablets and disperse in water by shaking for 5 minutes	Give immediately as light sensitive or consider alternative anti-emetic.
Diltiazem	Capsules may be opened and granules administered without crushing	Modified release tablets should not be crushed except for 60mg generic preparations
Dipyridamole	Suspension 50mg/5ml	Sugar free. Dose adjustment required when switching from modified release capsules
Donepezil	Crush tablets and disperse in water	
Doxazosin	Crush tablets and disperse in sterile water, not tap water	Do not crush modified release (XL) tablets
Enalapril	Tablets disperse slowly in water with stirring	
Entacapone	Tablets disperse in water	Tablets can be crushed and given in jam, honey or orange juice
Ferrous sulphate	Use ferrous fumerate syrup	Dose adjustment required – check BNF
Fludrocortisone	Tablets disperse in water	Flush feeding tubes well after administration
Gabapentin	Open capsules and disperse contents in water	Add fruit juice to mask unpleasant taste. Can sprinkle capsules contents onto food. Use immediately as drug is rapidly hydrolysed.
Galantamine	Solution 4mg/1ml	
Gliclazide	Tablets disperse in water	Monitor blood glucose – risk of increased absorption. Do not crush MR preparations
Irbesartan	Tablets disperse in water	
Isosorbide mononitrate	Tablets disperse in water	Increased absorption may lead to increased side-effects. Do not crush modified release preparations. Consider switch to GTN patches

Drug	Preparation	Comments
Levothyroxine	Solution 25mcg/5ml, 50mcg/5ml, 100mcg/5ml	Sugar free (Evotrox®)
Lisinopril	Tablets slowly disperse in water	
Lofepamine	Suspension 70mg/5ml	Sugar free (Lomont®)
Lorazepam	Crush tablets and disperse in water	Wyeth brand can be given sublingually
Losartan	Crush tablets and disperse in water	Consider switching to irbesartan
Melatonin	Capsules can be opened and mixed with water	Do not crush modified release preparations
Metformin	Oral powder 500mg and 1g sachets	Oral solution 500mg/5ml also available
Midazolam	Buccal liquid 10mg/ml	Prescribe as Epistatus®
Multivitamins	Oral drops	Abidec® or Dalivit®
Naproxen		Consider switching to diclofenac dispersible tablets
Omeprazole	MUPS tablets 10mg, 20mg	Alternatively switch to lansoprazole FasTab® in patients with swallowing difficulties. PEG tube – place MUP tablet in syringe, fill with 10ml water and 5ml air. Shake for 2 min to disperse tablet. Granules may block tubes finer than 8Fr. Do not crush MUPS
Olanzapine	Use Zyprexa Velotabs® 5mg, 10mg, 15mg and 20mg	For 2.5mg dose, halve the 5mg velotab
Perindopril	Tablets disperse in water	
Phenytoin	Suspension 30mg/5ml, 90mg/5ml	Phenytoin suspension and capsules are not equivalent. 90mg suspension is approx. equivalent to 100mg tablets or capsules
Pravastatin	Crush and disperse in water	
Quetiapine	Crush and disperse in water	
Quinine sulphate	Crush and disperse in water	Large volume (200ml) of water needed. Sugar coating should dissolve.
Ramipril	Crush tablets and disperse in water	Capsules can be opened and contents dispersed in water – unpleasant taste
Sertraline	Crush and disperse in water	
Simvastatin	Crush tablets and administer in water	Use immediately as light sensitive
Spiroolcatone	Suspension 5mg/5ml, 10mg/5ml, 25mg/5ml, 50mg/5ml and 100mg/5ml	Prescribe as Rosemont brand
Thiamine	Crush and administer in water	
Topiramate	Sprinkle capsules 15mg, 25mg, 50mg	Sprinkle caps not suitable for feeding tubes, crush and disperse tablets in water
Venlafaxine	Efexor® tablets can be crushed and dispersed in water	
Warfarin	Tablets disperse in water	
Zopiclone		Tablets must not be crushed, change to alternative hypnotic
Zolpidem	Crush and disperse in water	

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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 must be documented in the patient's care plan. [4]

• **Crushing or dispersing tablets**

A large proportion of 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.

For medicines that are suitable for crushing, crush using a pestle and mortar, a tablet crusher or between two metal spoons. Only crush medicines one tablet at a time; do not crush all the patient's medicines together. Crushing or dispersal 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 soft food**

Crushed medicines or capsule contents may be administered with a small amount of cold soft food such as a teaspoon of yoghurt or jam. A small amount should be used to ensure the full dose is taken.

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. [5]

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. [6]

• **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. [1]

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: [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 feeding (leaving a feeding break if necessary).

The administration of medicines via feeding tubes is considered a level 3 skill for care workers in care homes and those providing domiciliary care. [7, 8] Care workers who agree to give medicines via feeding tubes must receive training from a healthcare professional and there must be a written record of this training. [9]

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