

Advice for Health Professionals: Choosing medicines for patients unable to swallow solid oral dosage forms

Northern Ireland (NI) Regional Medicines and Poisons
Information Service
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Patients Unable to Take Solid Oral Dosage Forms

Clinical Evaluation and Medication Review:

For patients unable to take medicines in solid oral dosage forms because they have swallowing difficulties (dysphagia) or feeding tubes in place, the choice of medicine for these patients should be made on an individual basis taking into account the patient's method of feeding, the practicalities of administration, product quality and cost.

Health professionals should always ask the patient or carer whether they have difficulty swallowing medication and assess the reason for this.

Speech and Language Therapists can assess, diagnose and treat swallowing difficulties. They can offer advice on appropriate and safe textures of food and liquids. They can discuss requirements for consideration of liquid forms of medication.

Community pharmacists should assess the suitability of medication formulations for individual patients, and discuss swallowing difficulties to the prescriber.

All prescribers should ensure that known swallowing difficulties or the presence of an enteral feeding tube are taken into consideration when prescribing medication.

A full medication review should be carried out to rationalise drug therapy where possible.

Referral to Speech and Language Therapy may be necessary for patients presenting with swallowing difficulties and this may indicate a further requirement for pharmaceutical advice on suitable alternatives to solid oral medicines. It is important to note that people can have difficulty swallowing liquids safely and therefore liquid medications may not always be a suitable alternative.

In all cases, first establish that a medicine is suitable for administration in the intended manner by seeking advice from your local community pharmacist. If further information is required, contact either your local NI HSC Medicines Information (MI) centre or local HSCB office; contact details at end of document.

The medication chart should be rewritten to reflect a change in route of administration if medicine is being administered via an enteral feeding tube or if a licensed form of a medicine is to be manipulated.

It is recognised that the use of an unlicensed route of administration or a manipulated form of a medicine is sometimes necessary in order to provide the optimum treatment for a patient. When a prescriber prescribes a manipulated medicine or administration of a medicine via an unlicensed route, they are professionally accountable for their judgement in so doing, and may be called upon to justify their actions. Prescribers should satisfy themselves that they would obtain a professional body of support for their practice in relation to the use of the medicine and seek to obtain patient consent.

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.

When patients move across care sectors any changes to a dosage formulation should be noted, with information clearly transferred to subsequent prescribers and health professionals.

Management of Identified Patients

A stepped approach to choosing a suitable medicine is suggested.¹

Step 1: If possible, use a **licensed medicine** in a suitable formulation to meet the patient's needs e.g. a dispersible tablet or granules/powders or a licensed liquid medicine. Consider, when clinically appropriate, switching to a different agent in the same class, or to a different route of administration or to a different medicine, to allow a licensed medicine to be used.

Step 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. Take into account the patient/carer's ability to administer medicines in this way.

Step 3: In situations where the patient's needs cannot be met by steps 1 and 2 consider using a **liquid 'special' (unlicensed)** from a 'specials' manufacturer or a **liquid extemporaneous medicine (unlicensed)**.

Consider the patient's method of feeding when considering medicine choice:

- Patients requiring liquid feeds may take oral liquid medicines, dispersible tablets or granule/powder formulations.
- Solid oral preparations dispersed in water (immediately) prior to administration may be considered in some patients requiring liquid feeds.
- For patients who require thickened fluids, some liquid medicines may have to be thickened, when there is no suitable alternative, with a small amount of a thickening agent (e.g. *Thick and Easy* or *Nutilis* or other similar thickening product). Always seek advice from a Medicines Information department before thickening a liquid medicine as there may be potential medicines-thickening agent/medicines-food interactions or other contraindications; information may be limited and a multidisciplinary discussion may be required to reach a practical decision.
- Patients able to tolerate a soft-food diet may be able to swallow crushed tablets or the contents of capsules administered with food. Always seek advice from a pharmacist as there may be medicine-food interactions; information may be limited and a multidisciplinary discussion may be required to reach a practical decision to resolve medicines administration issues.
- Patients with enteral feeding tubes can have oral medication administered via this route. Choice of formulation should take into account the patient and their environment.
- Consider who will be administering the medicine; the patient themselves, a parent or carer, and their manual dexterity and ability to follow instructions to administer the medicine correctly.

Pharmaceutical Issues when crushing, opening or splitting solid oral dose forms

It is important to recognise the potential consequences of manipulating a medicinal product. Changing the way in which a dosage form is presented can alter its absorption characteristics, result in medicines instability, produce local irritant effects, cause failure to reach the site of action, may produce occupational health and safety issues, and could result in a preparation with an unacceptable taste.

Most of these considerations apply equally to 'specials' and extemporaneous preparations as well as to splitting and crushing of tablets and opening of capsules.

Whilst it may be possible to crush, open or split uncoated tablets, film coated tablets, sugar coated tablets or immediate-release capsules, consideration must be given to any cytotoxic, teratogenic, stability, irritancy and bitterness issues associated with the dosage form.³

Pharmacists should consider:

- The stability of the product once opened to the environment.
- Alteration of a solid-dose oral formulation should be considered under Control of Substances Hazardous to Health (COSHH) regulations since there may be an increased exposure to chemical components, potential hypersensitivity to the product or its constituents.
- The safety of the person preparing or administering the product.
- If dose preparation could be accurately repeated.
- The amount and type of diluent and/or thickening agents that would be used.
- Whether the results would be unpalatable to patients.²

Administering Medicines to patients unable to take solid oral dosage forms

Prescribers should seek advice from a pharmacist.

A pharmacist can ascertain if alternative formulations of the medication in question are available, for example:

- soluble tablets or oro-dispersible tablets
- transdermal patches
- buccal or sublingual tablets
- suppositories
- intranasal sprays/drops
- injectables

Changing to a liquid or dispersible oral formulation

Changing the formulation of a product may alter its bioavailability, efficacy and/or side-effect profile.

- Do not assume that the dose of a liquid/dispersible formulation will be the same as the solid oral form of a particular product.
- Check dose equivalence when switching from a sustained-release to a standard release form of a medicine, dose frequency will need to be adjusted accordingly; evaluate efficacy and side effects frequently.
- Dispersible tablets may not give an even solution when dispersed in water so part dosing using this method is potentially inaccurate.
- Some medicines are available as unlicensed liquid 'specials' or extemporaneous preparations, which are formulated to meet the requirements of a doctor for specific use by an individual patient: dose uniformity or reproducibility may not have been tested for extemporaneous preparations, or some 'specials'.²
- Medicines that are licensed in other countries, but are unlicensed in the UK can also be considered as an option or as an alternative to a 'special'. Refer to the steps above to ensure that an imported medicine would be appropriate in the management of an individual patient.

Altering a solid-dose oral medication

Altering a solid-dose formulation should only occur:

- **After appropriate advice has been sought from a pharmacist.**
- **Consent is obtained from the prescriber.**

Certain types of drug should never be altered due to the changes these actions impose on the pharmacokinetics and pharmacodynamics and bioavailability of the drug resulting in under dosing or adverse effects. The outcome of such pharmacological changes can be accentuated in older people due to age-related differences in pharmacokinetics. Such changes may be particularly important for drugs that have narrow therapeutic windows e.g. phenytoin, digoxin, carbamazepine, theophylline, or sodium valproate.² A variety of oral solid dosage forms should not be crushed or chewed prior to administration because of their formulation, these include: slow release or modified release formulations, medications formulated for sublingual or buccal absorption, or those designed to exert a local effect in the mouth (e.g. lozenges).

Crushing or dispersing tablets and opening capsules

- Many immediate-release tablets will disperse sufficiently in water to be suitable for administration via an enteral feeding tube without the need for crushing.
- Modified-release tablets are not suitable for crushing or dispersing. Modified release formulations should not be altered because the medicine is designed to be released over a prolonged period and any manipulation may damage the slow release mechanism and subsequently the patient may receive a full dose quicker than expected.²
- Most enteric coated tablets should not be altered. A coating may be added to protect the stomach; if the formulation is altered, co-administer a suitable gastro-protective product. Or, the coating is designed to deliver the drug beyond the stomach so crushing may result in the medicine not reaching the intended target. Crushing enteric coated tablets may result in the drug being released too early, destroyed by stomach acid, or irritating the stomach lining.²
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Drug irritation and other adverse effects:

Some drugs are formulated or coated to minimise the risk of oesophageal or stomach irritation or ulceration. If tablets are crushed or capsules are opened this may increase the risk for adverse effects from some medicines including: nitrofurantoin, potassium chloride, alendronate, NSAIDs. Sertraline is known to have an anaesthetic effect on the tongue; patients may become aware of this effect if a formulation of sertraline is given in a powdered form.³

- Most film and sugar coated tablets should not be altered. They may be coated to disguise poor tasting medicine or to avoid rapid degradation of the drug. Some may be coated as the medicament may cause irritation to skin.² Examples of unpleasant tasting medicines: cefuroxime axetil, ciprofloxacin, docusate, pseudoephedrine and praziquantel.³
- It is best to avoid crushing hormonal, cytotoxic, teratogenic, steroidal or antibiotic medicines. Drug particles may be dispersed in the air when crushed and so expose health professional or carer to health risks.²
- Some medicines can cause irritation if powder is aerosolised and inhaled or comes into contact with the eyes, skin, or other mucous membranes e.g. alendronate, diflunisal, finasteride, isotretinoin, mycophenolate, piroxicam.³

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.¹

Some hard gelatin capsules can be opened and their contents mixed with water or administered with food. Capsules should only be opened immediately before administration. Note: some capsules may be too small to manipulate.¹

Blister packs and medicine bottles often contain a silica gel desiccant to help protect the medicine. The silica gel desiccant is not to be swallowed and therefore should not be crushed.

Administering medicines in liquids or soft food

Crushed medicines or capsule contents may be given with a small amount of cool liquid or soft food such as a teaspoon of yoghurt or jam. Consider each individual medicine carefully prior to recommending administration in this way and ensure consent is obtained from the prescriber.

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 or other flavoured cordials. Grapefruit juice and cranberry juice should be avoided due to potential interactions with medicines.

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.

Administering medications through enteral feeding tubes

Medication management of patients with percutaneous endoscopic gastrostomy (PEG), percutaneous endoscopic jejunostomy (PEJ) or nasogastric (NG) tubing requires careful consideration since most products are not licensed for administration via this route.² NG tubes are the smallest bore diameter whilst PEG and PEJ are usually wider bore so there is less risk of medicines blocking the tubing.

Prescribers should seek advice from a pharmacist and/or a Medicines Information Centre before prescribing drugs to be administered via a feeding tube.

Medical considerations:

- The medication needs of patients should be reviewed if they are switched to enteral feeding, as certain medications may no longer be required.
- Ensure that there is a functional and accessible gastrointestinal tract.
- Assess risk of tube blockage: medicines -tube or medicines -food interactions.
- Interactions between medicines may occur if more than one medicine is administered at a time.
- As the formulation is altered, the activity of the product may be altered and variability may occur in the dose administered: monitor.²

Recommendations for administration of medicines through enteral feeding tubes:

- Administration of medicines through a feeding tube should only be carried out by suitably trained staff, under an agreed written policy, and the practice should be documented.
- Medicines should not be added to enteral feeds.
- Medicine-enteral feed interactions should also be considered.
- Select a medicine formulation that is appropriate for tube administration - some immediate release medicines can be dispersed and administered in a small volume of water.
- If the medicine is viscous, flushing or dilution with water may be required during administration.
- Ensure that the feed and medicine regimens are practical e.g. where possible use a once daily dosing preparation (not sustained release) to reduce the number of manipulations.
- For medicines that need to be given on an empty stomach, the feed should be stopped for the appropriate duration before and after the medication is administered.
- If more than one medicine is required, give separately and flush between administrations. A smaller volume for flushing may need to be considered for patients who are fluid restricted but this increases the risk of tube blockage.
- Increase monitoring for clinical efficacy and adverse events.²
- Medicines administration via a PEJ may reduce the bioavailability of a drug intended to be absorbed elsewhere in the GI tract.

Suggested protocol for administering medicines via a feeding tube:

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 at least 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. Procedures should be in place to ensure care workers who agree to give medicines via feeding tubes receive appropriate training.¹

This is adapted from: UKMi. Medicines Q&A 294.3. What are the therapeutic options for patients unable to take solid oral dosage forms? 02 July 2013.

Further Information

Standard reference texts include:

- **The NEWT Guidelines** for the administration of medication to patients with enteral feeding tubes or swallowing difficulties. This book provides drug-specific information to pharmacists and other health professionals providing or administering medications to patients with swallowing problems. It also provides general information on the legal aspects of altering licensed medicine formulations, how to prepare solid dose formulations for administration to patients with swallowing problems, and contains formulae for the extemporaneous preparation of suspensions. Available at www.newtguidelines.com (subscription required).
- **The Handbook of Drug Administration via Enteral Feeding Tubes**, Vicky Bradnam and Rebecca White, ISBN: 9780857111623, Pharmaceutical Press, 3rd Revised Edition. This book provides the background knowledge to inform clinical decisions and contains guidance on the safe administration of specific drugs and formulations. Contents include: tube flushing, restoring and maintaining patency, drug therapy review, medication formulation choice, unlicensed medication use, health and safety and interactions. Available via www.medicinescomplete.com (subscription required).
- The BNF for children **BNFC** <http://www.bnfc.nice.org.uk> also gives information on unlicensed uses e.g. Amlodipine: tablets may be dispersed in water. BNF for Children 2016-2017 (BNFC), Paediatric Formulary Committee, ISBN: 9780857111364, Pharmaceutical Press.

National Guidelines:

The British Association for Parenteral and Enteral Nutrition (BAPEN) provide a practical guide for administering drugs via enteral feeding tubes under the For professional > Publications and Resources Section>Other Resources: http://www.bapen.org.uk/pdfs/d_and_e/de_pract_guide.pdf (registration may be required).

Advice/Referral

Individual manufacturer's medicine information departments may also be able to provide advice on their products. Pharmaceutical company contact information is available in the BNF and also via: <https://www.medicines.org.uk/emc/browse-companies>

Regional Northern Ireland Contact Information:

For advice on choosing an appropriate dosage form or manipulating a medicine contact your local community pharmacist. If further information is required, contact either your local NI HSC Medicines Information (MI) Centre or local HSCB office; contact details below.

Regional contact information for **Belfast HSC Trust** and regional community primary/care:

Belfast Regional MI: **028 950 40558**

Or e-mail non urgent enquiries to MedicineInfo@belfasttrust.hscni.net

Local Medicines Information Departments for **all other** NI Trusts:

South Eastern MI: 028 9056 1445

Southern MI: 028 3861 2709

Northern MI: 028 9442 4278

Western MI: 028 7161 1462

Regional Pharmacy and HSC Medicines Management Team:

Belfast Office: 028 9536 3926

South Eastern Office: 028 9147 5133

Southern Office: 028 3741 0041

Northern Office: 028 9536 2835

Western Office: 028 7186 0086

Appendix

Signposting to the full UKMi *Medicines* Q&As:

UK Medicines Information (UKMi) medicines Q&As can be accessed in full via the SPS website.

<https://www.sps.nhs.uk>

The Q&A summary can be accessed by clicking on each of the hyperlinks provided.

The full document will open by further clicking on word next to the title.

Q&A 294.3 22 August 2013: What are the therapeutic options for patients unable to take solid oral dosage forms?

<https://www.sps.nhs.uk/articles/what-are-the-therapeutic-options-for-patients-unable-to-take-solid-oral-dosage-forms/>

- ✚ **Appendix 2: What are the therapeutic options for adult patients unable to take solid oral dosage forms? This includes** Practical information on crushing and dispersing tablets, opening capsules and giving medicines in soft food: UKMi *Medicines* Q&A 294.3 22 August 2013 - Appendix 3.

- ✚ **Appendix 3:** Provides advice on crushing tablets or opening capsules in a care home setting. Crushing tablets or opening capsules in a care home setting: UKMi *Medicines* Q&A 339.4 December 2016 - Appendix 4 Q&A 339.4 01 December 2016: **Crushing tablets or opening capsules in a care home setting.** <https://www.sps.nhs.uk/articles/crushing-tablets-or-opening-capsules-in-a-care-home-setting/>

- ✚ **Appendix 4:** Some parenteral medicines are suitable for administration orally or via feeding tubes: UKMi *Medicines* Q&A 155.3 11 March 2016 provides examples Appendix 5.

Q&A 175.4 11 March 2016: Which injections can be given enterally?

<https://www.sps.nhs.uk/articles/which-injections-can-be-given-enterally/>

Q&A January 2018: Which medicines require extra care when switching between liquid and tablet/capsule formulations?

Others Resources

Prescribing Specials: Five Guiding principles for Prescribers NPC July 2011. Held on file at RMPIS.

(Previously available at www.npc.nhs.uk - now decommissioned)

National Patient Safety Agency (NPSA) Alert 19 - promoting safer measurement and administration of liquid medicines via oral and other enteral routes.

Recommendations for Implementation in Northern Ireland; Appendix 2

Policy for the use of oral/enteral syringes in the safer measurement and administration of liquid medicines via oral and other enteral routes in secondary care (Developed by the Northern Ireland Medicines Governance Team December 2003, Updated September 2007) <http://www.medicinesgovernance.hscni.net/secondary-care/safety-documents/policies/>

Local Guidelines:

Guidelines and Audit Implementation Network GAIN and current related guidance:

<http://www.gain-ni.org/>

Regional Trust Unlicensed Medicines Policy – can be accessed by Trust staff through the Northern Ireland Trust/s intranet sites.

Definition/ Glossary of Terms

Dysphagia: the medical term for a difficulty swallowing.

Formulations that can be crushed/chewed: tablets described as crushable, or chewable

Enteric Coating: a polymer coating applied to tablets to delay the release of drugs that are inactivated by the stomach contents or irritate the stomach or require release elsewhere within the gastrointestinal tract e.g. the tablet remains intact in the stomach but dissolves to release drug in the small intestine.

Modified release (MR): tablets or capsules that have a method of formulation to prolong the release of the drug over a longer period of time. Also known as extended release (ER) or slow release (SR) and usually have the letters MR, ER, SR or XL, LA, SR, MR, EC or CR in the name.

Solid oral dosage form: tablet or capsule (buccal or dispersible tablets are not considered solid)

SPC: Summary of Product Characteristics.

Tablet or capsule manipulation/altering a solid-dose oral formulation: Crushing a tablet, dispersing a tablet in water that is not designed to be soluble, opening a capsule, sucking or chewing a medication that is not designed to be sucked or chewed

Unlicensed medicines: medicines without a Marketing Authorisation from MHRA.¹⁰

Unlicensed medicines may be obtained from:

- A pharmaceutical manufacturer 'specials'
- Imported by a specialist importer
- Manufactured by a commercial or hospital MHRA licensed manufacturing unit 'specials'
- Prepared extemporaneously against a prescription.

'Specials':

A pharmaceutical 'special' as defined by law is a medicine made to satisfy the needs of an individual patient. They are specially prepared unlicensed medicines, made according to many different formulations by different companies as batch products or as bespoke products (the exact contents can differ every time) and often have no safety, stability or efficacy testing.

The MHRA refers to 'specials' as 'unlicensed relevant medicinal products placed on the market in order to meet the special needs of an individual patient'.¹⁰

Extemporaneously prepared medicines:

Unlicensed medicines made in a pharmacy under a pharmacist's direct supervision. These preparations are not defined in law as 'specials' and are exempt from the usual requirements of the Medicines Act 1968 for quality, safety and efficacy (sometimes referred to as 'Section 10-exemptions')¹⁰.

'Off-label' or 'off-licence' use:

'Off-label' medicines are medicines with a UK or EU marketing authorisation, which are prescribed for an unlicensed indication, or age group or in unlicensed dosages or via a different route (i.e. out with the terms of the marketing authorisation).

It is recognised that the use of an off-label medicine is sometimes necessary in order to provide the optimum treatment for a patient. The use of medicines 'off-label' is often necessary and is common in many areas of medicine, for example palliative care, paediatrics, intensive care and psychiatry.

Swallowing Difficulties

