

Choosing medicines for patients unable to take solid oral dosage forms

Selecting suitable formulations for adult patients with swallowing difficulties or feeding tubes.



IMPORTANT MESSAGE: Licensed medicines should be used where possible.

Special-order medicines are unlicensed and expensive and should only be used if there is no licensed alternative.

A stepwise approach is suggested:

STEP 1

Review the need for each medication.

Stop medicines that aren't needed or aren't working.

How do I know if a medicine is unlicensed?

If a medicine or form of a medicine is not listed in the BNF then it is likely to be unlicensed. The BNF does list some unlicensed products or uses of medicines but it clearly identifies these.

GP clinical systems also identify some 'specials' and ScriptSwitch will 'flag up' commonly used 'specials'.

A licensed medicine will been issued have а Marketing Authorisation (MA) number by the MHRA following а rigorous assessment process. This number must be displayed on the pack. An unlicensed medicine will not have an MA number on the pack.

ESCALATING COSTS IN WIRRAL

'Specials' are often considerably more expensive than licensed medicines and the cost of 'specials' in Wirral has **trebled** in the last 3 years. Unlicensed medicines should only be used when there is no suitable licensed alternative. However, ePACT data has shown that in some cases 'specials' have been prescribed when there is a licensed alternative available. The top liquid 'special', by cost, prescribed on Wirral last year was **OMEPRAZOLE LIQUID 20mg/5ml**, with £49,443 being spent. The cost for the year if omeprazole dispersible tablets had been used would have been £1,772 and if lansoprazole orodispersible tablets had been used, just £457.

STEP 2

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.

Care staff may 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

Use a licensed medicine in an unlicensed manner, for example by crushing / 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 the above 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 overleaf for where to get advice.

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

Why licensed status matters

Special-order medicines ('specials') are unlicensed and are not required to meet the same standards as licensed medicines.

Clinical and legal responsibility for the use of unlicensed medicines rests with the prescriber. Therefore, careful thought should be taken before prescribing an unlicensed preparation and the prescriber should be able to justify and feel competent in using medicines.

STEP 4

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

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



Choosing medicines for patients unable to take solid oral dosage forms



Practical directions

Always check beforehand if a tablet is suitable for dispersing / crushing, or a capsule suitable for opening. (See the 'where can I get advice?' section).

Crushing / dispersing tablets

Many immediate-release tablets can be dispersed in water without crushing; some medicines need crushing 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 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 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.

Administering medicines via feeding tubes

Medicines should be administered one at a time and the feeding tube should be flushed with water before and after each medicine is administered.

Some patients may be fluid restricted and this will need to be taken into account. Please consult the patient's dietitian for advice on fluid requirements.

The NHS Wirral Standard Operating Procedure for administration of medicines via enteral feeding tubes should be followed.

It is found at the following link:

http://www.wirral.nhs.uk/document_uploads/Policies_and_Procedures_Nursing/NP_MM15-SOPMedicinesviaEnteralFeedingTubes.pdf

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.

Where can I get advice?

 NHS Wirral Guidance on Unlicensed and 'Off-label' Medicines is available at the link below:

http://nww.wirralhealth.nhs.uk/document_uploads/Medicines_Management/WirralSpecialsMar11.pdf

- This document gives advice on choosing therapeutic alternatives for patients unable to swallow solid dosage forms and recommends if tablets or capsules can be dispersed, crushed or opened for the most commonly prescribed 'specials' on Wirral (by cost).
- If the medicine required is not listed in this guidance please contact NHS Wirral Medicines Management Team on:

0151 643 5338

References

Details of a useful UKMI Medicines Q&A and 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.

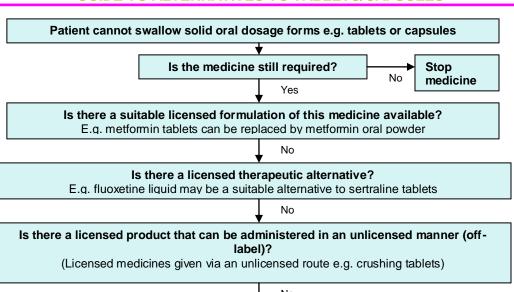
It may be appropriate to use a licensed medicine in an unlicensed way.

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 and PEC approval: Sept 2010 (updated March 2011)



GP contacts community pharmacy supplying the medication to inform them they are aware of unlicensed status of the medicine and to ensure there is no suitable licensed alternative

Consider the use of a medicine not licensed in the UK

Other factors to take into account:

- Expiry date of product (may affect the quantity supplied per prescription)
- How long it may take to obtain a supply
- The expected cost

N.B. Wirral Medicines Management Team (0151 643 5338) and the community pharmacy can be contacted at any earlier point in this process to ensure there are no alternative licensed therapeutic options

GP and community pharmacy record rationale for using a 'special'

GP prescribes the medicine

Ensure all relevant information is on the prescription for the pharmacist to dispense the correct medicine/ formulation.

If a pharmacist receives a prescription for a newly prescribed 'special' without having first been contacted by the GP, the GP should then be contacted to ensure they are aware of unlicensed status of medicine and to ensure there is no licensed alternative that will meet the patient's needs

GP reviews need for special on regular basis to ensure it is still appropriate

The pharmacist should also periodically reconfirm with prescriber that the ongoing use of an unlicensed product is appropriate

GP receives discharge letter from secondary or tertiary care asking them to prescribe an unlicensed medicine

- Information on discharge letter and fax from hospital pharmacy department is complete
- There is no suitable licensed alternative
- GP is familiar with medicine
- GP is willing to accept clinical and legal responsibility for prescribing

Information on discharge letter or letter from hospital pharmacy department is incomplete

GP should obtain complete information:

- Contact Wirral Medicines Management Team on 0151 643 5338
- Discuss with patient/carer
- Review product and labelling information given to patient from hospital
- Contact the original prescriber if necessary

GP is unfamiliar with medicine

GP should obtain complete information:

- Review letter from prescriber
- Contact Wirral Medicines Management Team on 0151 643 5338
- Discuss with patient/carer
- Review product and labelling information given to patient from hospital
- Contact the original prescriber if necessary

GP contacts community pharmacy supplying the medication to inform them they are aware of unlicensed status of the medicine and to ensure there is no suitable licensed alternative

Other factors to take into account:

- Expiry date of product (may affect the quantity supplied per prescription)
- How long it may take to obtain a supply
- The expected cost
- Where the hospital supply came from to ensure continuity of care where possible

GP and community pharmacy record rationale for using a 'special'

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Therapeutic alternatives for commonly prescribed 'specials' on Wirral



Special	Therapeutic alternatives for adult patients
Amitriptyline Liquid 10mg/5ml	Licensed medicines in suitable formulations
	Amitriptyline oral solution 25mg/5ml and 50mg/5ml are available. Oral syringes can be used to measure smaller doses.
Amlodipine Liquid 5mg/5ml	Licensed medicines in suitable formulations:
	There are no suitable licensed formulations of amlodipine
	Licensed medicines used in an unlicensed manner
	Amlodipine tablets can be crushed and dispersed in 10ml water for administration orally or via feeding tubes
Bendroflumethiazide Liquid 2.5mg/5ml	Licensed medicines in suitable formulations:
	There are no suitable licensed formulations of bendroflumethiazide or other thiazide diuretics.
	Licensed medicines used in an unlicensed manner
	Bendroflumethiazide tablets can be dispersed in 10ml water and given orally or via a feeding tube.
Clonazepam Liquid 500mcg/5ml and	Licensed medicines in suitable formulations
2mg/5ml	There are no suitable licensed formulations of clonazepam.
	Licensed medicines used in an unlicensed manner
	Clonazepam tablets can be dispersed in 10ml water for administration orally or via a feeding tube.
Omeprazole Liquid 20mg/5ml and	Licensed medicines in suitable formulations
40mg/5ml	Lansoprazole orodispersible tablets can be allowed to disperse in the mouth then swallowed, or mixed with 10ml water to give a
	dispersion of small (0.33mm) granules for administration orally or via a feeding tube.
	Omeprazole dispersible tablets 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.
	Licensed medicines used in an unlicensed manner
	Omeprazole dispersible tablets can be mixed with water to give a dispersion of small (0.5mm) granules. The granules have a tendency
Paracetamol Liquid 500mg/5ml	to block fine bore feeding tubes but can be mixed with water or 8.4% sodium bicarbonate for administration via wider feeding tubes. Licensed medicines in suitable formulations
Paracetamor Liquid 300mg/3mm	
Phenobarbital Liquid 50mg/5ml (alcohol	Paracetamol soluble tablets and paracetamol 120mg/5ml and 250mg/5ml oral suspensions available.
	Licensed medicines in suitable formulations
free)	Phenobarbital elixir 15mg/5ml is available. It contains 38% alcohol so may not be considered suitable for children. It may
	be given via a feeding tube for adults. Licensed medicines used in an unlicensed manner
Danain will invide for a figure	Phenobarbital tablets may be crushed and mixed with 10ml water.
Ramipril Liquid 5mg/5ml	Licensed medicines in suitable formulations There are no suitable licensed formulations of ACE inhibitors available.
	Licensed medicines used in an unlicensed manner
	Ramipril capsules can be opened and the contents mixed with 15ml water or food.
Controling Liquid FormulEngl	Ramipril tablets can be dispersed in 10ml water Licensed medicines in suitable formulations
Sertraline Liquid 50mg/5ml	
	There are no suitable licensed formulations of sertraline but other SSRIs are available in suitable licensed formulations:
	Fluoxetine 20mg/5ml oral liquid Citalopram 40mg/ml oral drops
	Escitalopram oral drops 10mg/ml and 20mg/ml
	Paroxetine 10mg/5ml oral suspension
	Licensed medicines used in an unlicensed manner
	Sertraline tablets can be crushed but do not disperse readily in water. They will disintegrate if shaken in 10ml water for a
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