

Guidance on Unlicensed and 'Off-label' Medicines

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GLOSSARY OF TERMS

Certificate of Analysis: For products produced in batches a certificate of analysis confirms that levels of active ingredients have been retrospectively confirmed by testing a sample of the final product.

A certificate of analysis should:

- State the laboratory / organisation issuing it
- Be authorised by an appropriately qualified person with signature
- Be specific to the batch concerned (state the batch number which matches that of the medicine supplied)
- Clearly indicate who performed the tests and the date
- State the specification against which the tests were performed
- State the test results (actual result or 'complies')

Certificate of Conformity: A certificate of conformity states that the batch of medicine supplied is in conformance with its release specification, i.e. that the final product conforms to the specification supplied by the pharmacist. It will not contain any test results and may not be signed or bear a batch number relating to the batch of the product supplied.

Extemporaneously Prepared Medicines

These are unlicensed medicines made in a pharmacy under the direct supervision of a pharmacist.

Manufacturers Specials Licence: This is a license issued by the Medicines and Healthcare products Regulatory Agency (MHRA) to organisations wishing to place unlicensed medicines on the market in the UK.

Off-label use: 'Off-label' use of medicines is when UK licensed medicines are used outside of their licence.

Specials: A 'special' is a medicine made to satisfy an individual patient's special need. These are unlicensed medicines which have been specially prepared by the holder of a Manufacturers Specials License.

Unlicensed Medicines: These are medicines which do not have a UK Marketing Authorisation (MA) number issued by the regulatory authority, the Medicines and Healthcare products Regulatory Authority (MHRA) or a European Marketing Authorisation issued by the European Medicines Agency (EMA) for use in the UK.

Sections 9, 10 and 11: These are section of the Medicines Act 1968 describing the exemption from the need to hold a manufacturers license by doctors (Section 9), pharmacists (Section 10) and nurses (Section 11) when preparing medicinal products.

INTRODUCTION

This document provides guidance on the clinical, prescribing and supply responsibilities of prescribers and pharmacists with regard to the use of unlicensed medicines and 'off-label' use of licensed medicines in primary care throughout Wirral.

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. 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.

Monographs have been provided in appendix 1 as a useful reference source for licensed alternatives when adult patients are unable to swallow solid oral dose formulations.

How much do 'special' preparations cost?

The costs associated with 'specials' will always be higher than that of licensed medicines as they are low quantity, bespoke items. However, unlike the manufacture of licensed medicines, there is no regulation on pricing of 'specials'. This means that manufacturers may invoice community pharmacies for any amount of money and the Prescription Pricing Division is required to reimburse that amount. Prices can therefore, vary greatly, e.g. for omeprazole 20mg/5ml, prices varied from £79.52 - £1,245.75 for 150ml and prices for simvastatin liquid 40mg/5ml varied from £81.54 - £570.45 for 140ml. It is hoped a tariff for some standardised specials will be introduced during 2011.

What are the top 15 unlicensed liquid 'specials' prescribed on Wirral?

Special	Total Cost for 12 months (ePACT April 09 to March 10)
Omeprazole Liquid 20mg/5ml	£49,443
Clonazepam Liquid 500mcg/5ml	£31,054
Simvastatin Liquid 20mg/5ml	£28,210
Chloral Hydrate Liquid 500mg/5ml	£21,956
Midazolam Oromucosal Liquid 10mg/1ml	£16,398
Melatonin Liquid 5mg/5ml	£14,890
Clobazam Liquid 10mg/5ml	£14,237
Simvastatin Liquid 40mg/5ml	£13,411
Phenobarbital Liquid 50mg/5ml	£12,990
Sertraline HCl Liquid 50mg/5ml	£11,973
Paracetamol Liquid 500mg/5ml	£11,883
Clobazam Liquid 5mg/5ml	£8,835
Warfarin Sodium Liquid 5mg/5ml	£8,683
Amitriptyline HCl Liquid 10mg/5ml	£8,012
Amlodipine Liquid 5mg/5ml	£7,688



Indicates items where alternative licensed products are available

WHY THIS GUIDANCE IS IMPORTANT FOR GPs

- Prescribing unlicensed medicines increases the prescriber's professional responsibility and potential liability.
- Unlicensed medicines or 'specials' do not undergo the same rigorous quality control checks as unlicensed medicines.
- Generic drugs which are cheap as solid oral dose forms often become extremely expensive when compounded into special formula liquids e.g. bendroflumethiazide liquid is 75 times more expensive than the tablets.
- The General Medical Council provides good practice guidance for prescribing unlicensed medicines (see page 11).

WHY THIS GUIDANCE IS IMPORTANT FOR COMMUNITY PHARMACIES

- Unlicensed medicines or 'specials' do not undergo the same rigorous quality control checks as unlicensed medicines
- Supplying unlicensed medicines increases the pharmacist's professional responsibility and potential liability.
- The pharmacist is responsible for the quality of the unlicensed medicine they supply to the patient.
- The Royal Pharmaceutical Society of Great Britain has produced good practice guidance on the procurement and supply of pharmaceutical specials (see page 19).

SCOPE

The most commonly required unlicensed medicines are liquid forms of solid medications and therefore, this is the main focus of this document.

The principles behind choosing therapeutic alternatives for children who have problems swallowing solid oral dosage forms should generally follow a similar process but there may be some exceptions. For further information please see 'Prescribing for children' p 12.

BACKGROUND

The Medicines Act 1968 states that medicines may only be marketed in the UK for use in patients if they have been given a licence by the appropriate regulatory body. Following a rigorous assessment process, every marketed medicinal product in the UK is issued a Marketing Authorisation (MA) number by the Medicines and Healthcare products Regulatory Authority (MHRA) or by the European Medicines Agency (EMA). The MA must be displayed on the pack and provides a guarantee of quality, safety and efficacy.

A Marketing Authorisation defines a medicine's terms of use. It includes a Summary of Product Characteristics (SPC) which outlines, among other things, the indication(s), recommended dose(s), contraindications, and special warnings and precautions for use on which the licence is based. Additionally, post marketing surveillance of newly licensed products allows feedback from clinicians and patients about any adverse events from treatment thus identifying less common clinical effects.

Most patient needs can be met with commercially available licensed medicines and appliances. However, a special need for an unlicensed medicine may arise in a range of circumstances. For example¹:

- There is no equivalent licensed medicine available in the UK to meet the special need of the patient
- A licensed medicine is available but not in a suitable formulation / presentation (e.g. oral liquids needed for patients unable to swallow solid oral dosage forms – see appendix 1 for suggested alternatives.)
- The equivalent licensed medicine is likely to be unavailable for a significant period (e.g. because the manufacturer is experiencing difficulties)
- For commercial reasons either the licence for a product has been relinquished or is maintained but without the product being marketed.

UK Regulations² exempt from the need for a marketing authorisation a relevant medicinal product which is provided to fulfil a "special need" and in response to a bona fide unsolicited order, formulated in accordance with the specification of a doctor or dentist registered in the UK and for use by his individual patients on his direct personal responsibility.

The MHRA guidance note 14 requires that **a pharmaceutical special medicine should ONLY be used where there is no suitable licensed alternative**³. Specials will be monitored by NHS Wirral Medicines Management Team on a quarterly basis.

NB: If a medicine or form of a medicine is not listed in the British National Formulary (BNF) then it is likely to be unlicensed. The BNF does list some unlicensed products or uses of medicines but it clearly identifies these. The GP Clinical Systems appear to include a number of 'specials'. However, they usually identify that these medicines are unlicensed. ScriptSwitch will also flag up commonly used 'specials' and suggest licensed alternatives where available.

To manufacture 'specials' in the UK an MHRA Manufacturer's 'Specials' Licence (MS) is required. This guarantees the sourcing of ingredients, product development packaging and labelling as well as the manufacturing and ex-factory supply processes are all to regulatory standards. There has, however, been no formal assessment of product safety or efficacy. A 'special' is therefore an unlicensed medicine and the MS number must be printed on the label.

It is not uncommon for manufacturers holding an MS to make small quantities of medicine under the supervision of a pharmacist (i.e. under the exemptions allowed by section 10 of the Medicines Act 1968). There is no guarantee that this extemporaneous dispensing process has been subject to any formal quality assurance and an MS number will not be printed on the label.

Clinical responsibility and legal liability for the use of unlicensed medicines or off-label use of licensed medicines rests with the prescriber. Therefore, careful thought should be taken before prescribing an unlicensed preparation over a licensed one and the prescriber should be able to justify and feel competent in using such medicines.

Every pharmacist, when making a supply of any medicinal product, assumes a duty of care to the patient. If a product without a marketing authorisation is supplied or a product is supplied outside its marketing authorisation indications and an adverse reaction is suffered, the supplying pharmacist may assume some liability with the doctor who prescribed it⁴.

DETERMINING THE NEED FOR 'SPECIALS'

Before deciding if a 'special' is necessary for a particular patient, the following steps should be considered: (Please also see flow chart on page 10).

Step 1. Review the need for each medicine

Discontinue any medicines that are no longer required.

Step 2. Consider using a licensed medicine administered as intended⁵

Licensed medicines should be used where possible. They are associated with less risk and are less expensive than special-order products. In most cases a licensed medicine will be suitable to meet the patient's needs e.g. metformin tablets can be replaced by metformin oral powder.

It may be appropriate to switch to a different medicine e.g. 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 e.g. 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 and, with encouragement, can manage most medicines. The use of costly special-order products for these patients is generally not justified.

Step 3. Consider using a licensed medicine administered in an unlicensed manner⁵

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.

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. Modified release tablets are formulated to release the drug slowly over time, therefore, as a general rule these are not suitable to be crushed as this will affect the pharmacokinetic profile of the drug. Other examples of medications that should not be crushed or manipulated include cytotoxic medications so as to avoid environmental contamination and exposure of the carer or patient to the medicine.

When prescribing medicines in this manner full dose directions need to be included on the prescription (if applicable) e.g. *"disperse one tablet in water and take once in the morning"* or *"crush one tablet, mix with water and take..."*

Appendix 1 lists therapeutic options available for commonly prescribed 'specials' on Wirral. Further information is available from reference texts^{6,7} and NHS Wirral Medicines Management Team on 0151 643 5338. Please refer to the patient and carer information leaflet for 'Special preparation of medicines' for advice on how to prepare medicines for administration in an unlicensed manner (appendix 2).

Patients on sip feeds or liquidized diets 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* maize starch and maltodextrin powder.

- **Administering medicines in liquids or soft food⁵**

Some crushed medicines or capsule contents may be administered 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.

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 - they should be administered one at a time. They should also not be administered in a baby's feeding bottle.

Medicines should only be administered in food with the patient's knowledge and consent. For further information regarding consent please refer to the NHS Wirral policy for consent to examination and treatment. Hiding medication in food is considered 'covert administration' and is only condoned in certain circumstances. Please refer to the Nursing and Midwifery Council statement on covert administration of medicines: Disguising medicine in food and drink⁸ for further information.

- **Administering medicines via feeding tubes**

Patients with feeding tubes in place may be able to have their medicines administered via the feeding tube. Medicines should be administered one at a time and the feeding tube should be flushed with water before and after each medicine is administered⁵. The volume of water to be used will be defined by the dietitian on a patient specific basis. Some patients may be fluid restricted and the volume of water used for flushing will therefore need to be considered. Please consult the patient's dietitian for advice on fluid requirements.

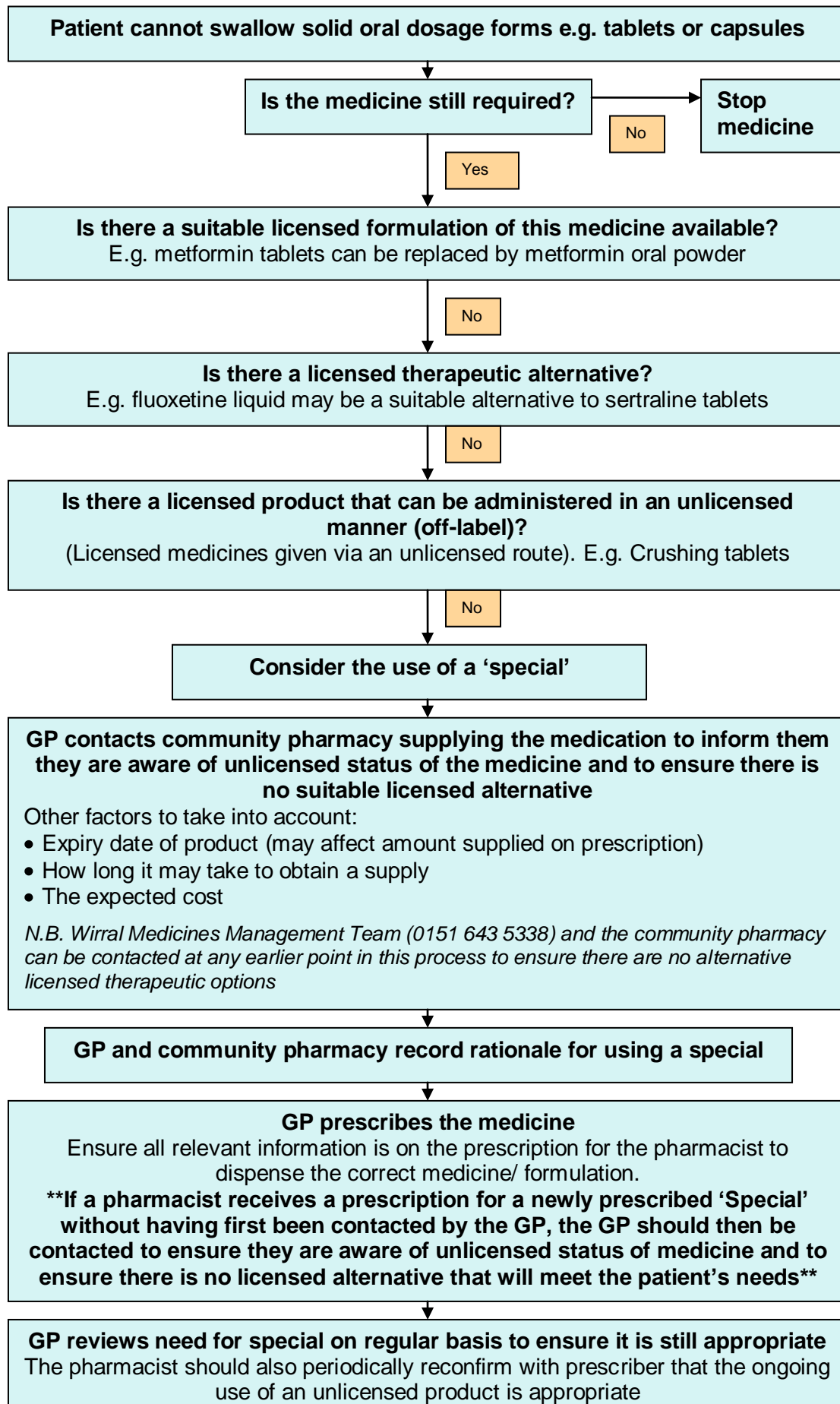
The NHS Wirral Standard Operating Procedure for administration of medicines via enteral feeding tubes should be followed:

http://www.wirral.nhs.uk/document_uploads/Policies_and_Procedures_Nursing/NPM_M15-SOPMedicinesviaEnteralFeedingTubes.pdf

Step 4. 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.

GUIDE TO ALTERNATIVES TO TABLETS/CAPSULES



ROLES AND RESPONSIBILITIES OF PRESCRIBERS OF PHARMACEUTICAL SPECIALS

The MHRA guidance note 14 requires that a **pharmaceutical special medicine should ONLY be used where there is no suitable licensed alternative**³.

It is the prescriber's responsibility to decide whether the patient has special pharmaceutical needs which a licensed product cannot meet.

In 'Good Practice in Prescribing Medicines'⁹, the General Medical Council states that the prescriber must:

- a) be satisfied that an alternative, licensed medicine would not meet the patient's needs
- b) be satisfied that there is a sufficient evidence base and/or experience of using the medicine to demonstrate its safety and efficacy
- c) take responsibility for prescribing the unlicensed medicine and for overseeing the patient's care, including monitoring and any follow up treatment
- d) record the medicine prescribed and, where you are not following common practice, the reasons for choosing this medicine in the patient's notes.

It is important to remember that the prescribers of pharmaceutical 'specials' are directly responsible for the prescribing of these products and that they will be liable for adverse effects or harm resulting from the use of that product.

GPs should review all their patients that are currently prescribed 'specials' to ensure they are still appropriate. It is also important to continually review requirements as circumstances may change, e.g. the swallowing difficulty may have resolved so liquid medicines are no longer appropriate. Both the GP and pharmacist should make a record of this assessment. The Medicines Management Team can advise on suitable alternatives if the medicine is not included in this guidance.

The first time a special is prescribed in primary care the prescriber should contact the community pharmacy who will supply the medication. This is to ensure that the community pharmacist knows the prescriber is aware of the unlicensed status of the medication and to ensure there is no licensed suitable alternative.

Other factors to discuss with the community pharmacy include:

- Expiry date of product
- How long it may take to obtain a supply
- The expected cost

Sourcing pharmaceutical specials from a variety of manufacturers will result in variability in formulation and hence efficacy, bioavailability and excipients. If the patient has had the special before, information about previous supplies can improve continuity of care.

Prescribing for Children

'Off-label' and unlicensed prescribing is widespread in paediatrics. Many children require medicines not specifically licensed for paediatric use. The British National Formulary for Children (BNFC)¹⁰ includes advice involving the use of unlicensed medicines or licensed medicines for unlicensed ('off-label') uses. Such advice reflects careful consideration of the options available to manage a given condition and the weight of evidence and experience of the unlicensed intervention.

The same stepwise approach of determining the need for specials should be applied when prescribing for children. The BNFC states that in many cases it is preferable to give a licensed product by an unlicensed route (e.g. an injection given by mouth) than to prepare a special formulation. When tablets or capsules are cut, dispersed, or used for preparing liquids immediately before administration, it is important to confirm uniform dispersal of the active ingredient, especially if only a portion of the solid content (e.g. a tablet segment) is used or if only an aliquot of the liquid is to be administered.

However, there may be certain circumstances when a licensed medicine used in an unlicensed manner may not be appropriate e.g. because of the excipients in the product and an unlicensed special may be chosen instead. One example of this would be Phenobarbital elixir 15mg/5ml which is a licensed product. However, it contains 38% alcohol and the unlicensed special Phenobarbital liquid 50mg/5ml (alcohol free) may be considered more appropriate in children.

Prescribing unlicensed medicines or medicines outside the recommendations of their marketing authorisation for children is associated with the same increased clinical responsibility and legal liability as adults.

Appendix 1 only covers examples of alternatives for adult patients. For advice related to children, please contact the Medicines Management Team.

Patient and Carer Information¹¹

It is best practice to give patients, or those authorising treatment on their behalf, sufficient information about the proposed treatment, including known serious or common adverse reactions, to enable them to make an informed decision. Where current practice supports the use of a medicine outside the terms of its licence, it may not be necessary to draw attention to the licence when seeking consent. However, it is good practice to give as much information as patients or carers require or which they may see as relevant.

It is also best practice that you explain the reasons for prescribing a medicine 'off-label' or prescribing an unlicensed medicine where there is little evidence to support its use, or where the use of a medicine is innovative. The Patient Information Leaflet in appendix 3 can be used to help explain the situation.

If the patient needs to crush or disperse tablets in water or open capsules there is a leaflet in appendix 2 which details how to prepare medication in this way. For further advice on prescribing for patients with professional carers please see page 17.

Reporting Adverse Drug Reactions

It is the responsibility of the prescriber to report serious suspected adverse drug reactions (ADRs) to the MHRA via the 'yellow card scheme' - <http://yellowcard.mhra.gov.uk>.

Non Medical Prescribers

Following amendments to the Medicines for Human Use Regulations 2009, independent nurse or pharmacist non-medical prescribers are now permitted to prescribe unlicensed medicines¹². However, non-medical prescribers should only prescribe unlicensed medicines in justifiable exceptional and approved circumstances for example, justified by current best practice (e.g. national NHS guidance)¹³.

Record Keeping

It is recommended that the prescriber documents:

- The rationale behind using a special
- The assessments to determine if a special is still required
- The supplier if known (in case patient changes community pharmacies)
- The expiry date if it is less than 1 month as this will mean that either more than 1 bottle/container will need to be prescribed on a prescription for a month's supply or the treatment duration should be specified instead of the quantity (e.g. 28 days).

Documentation will help if more than one GP will be prescribing the special or if queries arise over the quantity prescribed.

INITIATION IN SECONDARY OR TERTIARY CARE

Often initiation of 'specials' takes place in secondary or tertiary care. When this occurs the agreement of the patient's GP to continue prescribing should be sought prior to transferring responsibility for ongoing care back to primary care.

The GP must be informed of the unlicensed status of the proposed treatment. They must be fully aware of the risks involved and willing to accept clinical and legal responsibility for prescribing. GPs are under no obligation to become involved, if they consider it to be inappropriate or feel unable to take on clinical responsibility.

Requests to prescribe unlicensed pharmaceutical specials by a third party, e.g. secondary care, do not diminish the responsibility of the prescribing GP.

Shared care guidelines may be available which describe where clinical and prescribing responsibility rests between Consultants and GPs. These protocols outline details of the indication, doses, contraindications and monitoring arrangements. These are not rigid guidelines and on occasions, Consultants and GPs may agree to work outside of this guidance. As always, the doctor who prescribes the medication has the clinical responsibility for the drug and the consequences of its use.

Before, deciding whether to take on the clinical responsibility of prescribing an unlicensed medicine, prescribers should take into account the clinical risk involved. If a prescriber would like to discuss the clinical risk involved with prescribing a particular unlicensed medicine please contact the Medicines Management Team on 0151 643 5338.

The following questions should also be considered:

- Is the patient being seen on a regular basis by the hospital, in which case they could continue to supply the patient with the medicine at each appointment? (NB. The expiry date of the medicine will need to be taken into consideration).
- Is the patient only seen once a year by the hospital, in which case, practically it may be more appropriate for the patient's GP to prescribe?
- If the patient's GP does not prescribe the medicine, is this likely to increase the number of hospital appointments that the patient needs, which will impact on hospital activity costs within practice based commissioning budgets?

If a request is made to the GP to prescribe an unlicensed medicine by secondary or tertiary care the algorithm on p16 should be followed.

Discharge Letter Information

The discharge letter should include the following details regarding the unlicensed medicine:

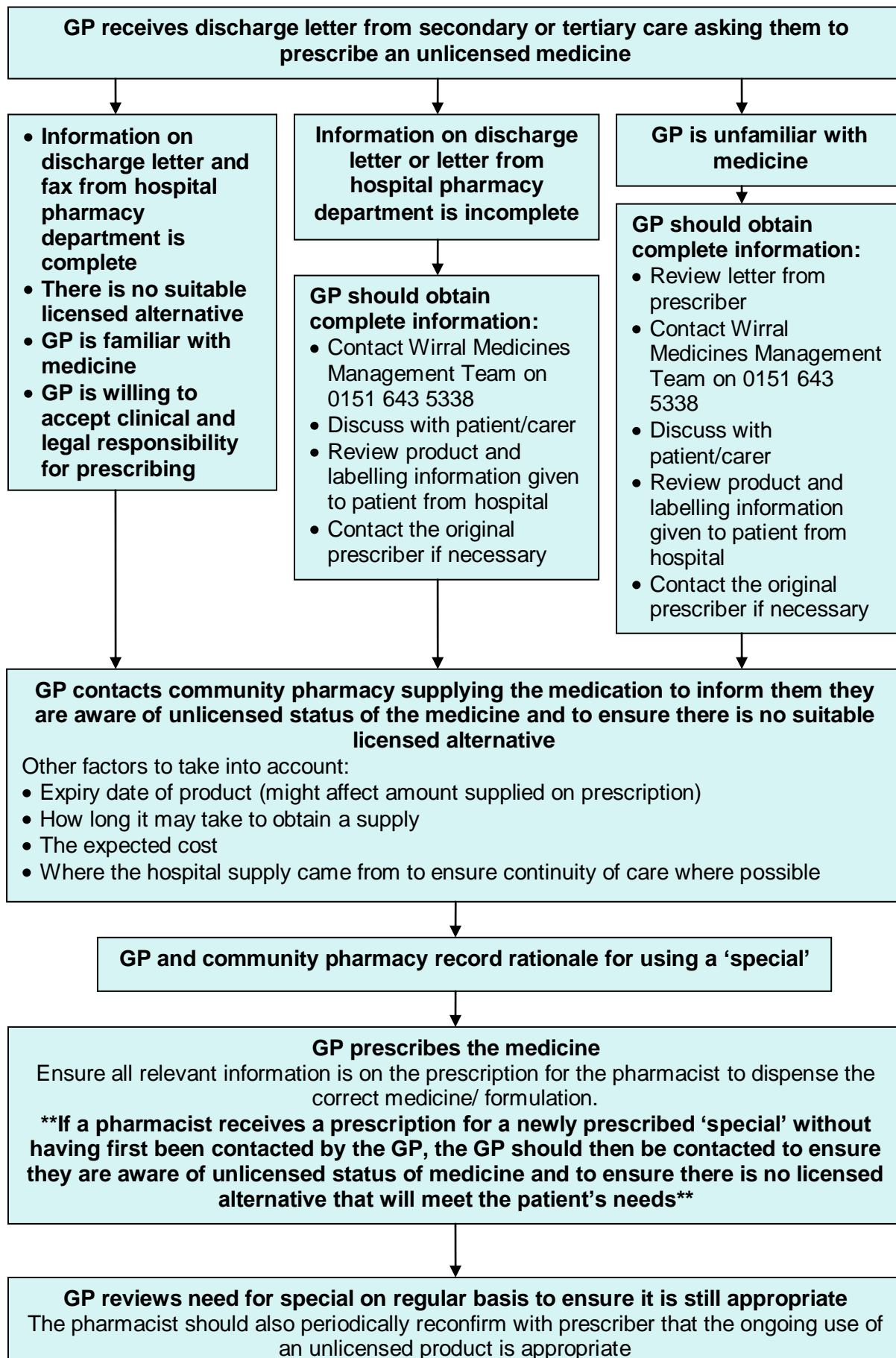
- A statement indicating the unlicensed status of the medicine
- Indication
- Duration of treatment
- Drug name, strength, dose and frequency
- Dosage form e.g. tablet, capsule, liquid
- Specific formulation needs e.g. alcohol-free for liquids
- Confirmation that information regarding source of supply of the unlicensed medicine has been provided to the patient

Please contact NHS Wirral Medicines Management Team on 0151 643 5338 if it is unclear why an unlicensed medicine is being prescribed or if any further information is required. The Medicines Management Team will then liaise with the hospital and discuss the specific patient circumstances with the clinicians or pharmacists involved. As work in the area of 'specials' continues we will keep records of problems arising and implement solutions to prevent the same issues recurring.

In order to ensure consistent clinical response, in particular for medicines with a narrow therapeutic window, the same formulation and supplier should be used where possible. If a patient is initiated on an unlicensed preparation by Wirral University Teaching Hospital NHS Foundation Trust, that is to be continued in primary care, the hospital pharmacy department will provide this information to the patient*. The patient will be asked to take this information to their GP and the community pharmacy who will be continuing to supply the 'special'.

*The Wirral University Teaching Hospital NHS Foundation Trust Unlicensed Medicines Policy (which includes details of the above procedure) is to go to a future Wirral Drug and Therapeutics Committee meeting for approval. In the meantime if there is insufficient information provided by the hospital please contact the NHS Wirral Medicines Management Team.

REQUESTS FROM SECONDARY OR TERTIARY CARE



PATIENTS WITH PROFESSIONAL CARERS: Advice for prescribers and care workers in community and residential homes

If a person is experiencing difficulty swallowing medicines then the care worker should report it to their manager who should contact the person's GP. Care staff may only administer medicines in an unlicensed manner on the written instruction of the prescriber. A written direction to crush or disperse tablets or to open capsules must be documented in the person's care plan¹⁴. As per a licensed medicine the person must agree to have the care worker administer medication and consent should be documented in the person's care plan.

It is suggested that the GP include the following information when writing instructions for the care home:

- Patient's name and date of birth
- Drug name, strength, dose and frequency
- Dosage form e.g. capsules or tablets
- How the medicine is to be administered i.e. capsule opened and mixed with water or tablet crushed and then mixed with water
- The volume of water needed to disperse each drug (if the drug is not listed in appendix 1 please contact NHS Wirral Medicines Management Team for advice on 0151 643 5338)
- A reminder that each medicine should be prepared and administered separately

The written instruction should then be signed and dated and faxed to the care home or domiciliary care organisation's office so it can be placed in the patient's care plan straight away. The information leaflet 'Special preparation of medicines - information for patients and carers' in appendix 2 could also be given.

N.B tablet crushers are available to buy from pharmacies and usually cost approximately £3.00.

When you write a prescription for medicines to be taken in this manner full dose directions need to be included on the prescription (if applicable) e.g. "*disperse one tablet in water and take once in the morning*" or "*crush one tablet, mix with water and take...*". These instructions should then also be reproduced on the MAR chart from the community pharmacy.

Guidelines of the Nursing and Midwifery council state that nurses may crush tablets upon pharmacist advice. However, any advice obtained from a pharmacist that potentially requires changes to the prescription must be discussed with the prescriber, to ensure the prescriber accepts responsibility for administration of a medicine outside the terms of its marketing authorisation.

It is important to check that the patient does not have any medical conditions or problems that may preclude this administration guidance, e.g. fluid restriction. Specific advice may need to be sought for these individual patients from the Medicines Management Team at NHS Wirral on the above number or the patient's dietitian for advice regarding fluid requirements.

ROLES AND RESPONSIBILITIES OF PHARMACISTS

To maintain *good practice* and adhere to the code of ethics and standards of practice¹⁷, all pharmacists have a professional responsibility to ensure that¹⁸:

- Patients receive medication that is safe, effective, appropriate for their condition and their circumstances, with minimal risk.
- A 'special' is prescribed and supplied *only* when there is no available licensed medicine which fully meets the patient's clinical needs.
- The appropriateness of continued prescription of a 'special' is reviewed and that continued supply is justified by continued special clinical need.
- Any 'special' product supplied is *fit for purpose* – is of the appropriate quality and clinically appropriate for the individual patient.
- They understand their legal responsibilities when supplying 'specials'.
- They minimise legal risk to patients and themselves: the expectation is that pharmacists will supply an unlicensed product only by exception and with the full knowledge of the prescriber and the patient. This requirement is detailed in MHRA guidance note 14³.

Therefore, the first time a special is prescribed for a patient the need for a 'special' should be determined (see p8) and the pharmacist should ensure that prescriber is aware of the unlicensed status of the medicine.

If the prescriber has not provided details of the rationale for prescribing a 'special' then the community pharmacy should contact them to discuss alternatives and to ensure a 'special' is appropriate.

This consultation should be recorded on the patient's medication record (PMR) for reference for future supplies of this 'special'.

Indemnity Insurance

There have been some issues raised around pharmacists' professional indemnity insurance. Some insurers will not cover recommending alternatives to unlicensed specials where such recommendations result in the integrity of the licensed medicinal product being compromised e.g. by crushing, dispersing or breaking open (capsules) or which otherwise interfere with products in any other way except in exceptional or emergency circumstances.

The pharmacist still has a professional responsibility to contact the prescriber to ensure they are aware they are prescribing an unlicensed product and **this does not stop the pharmacist recommending licensed alternatives to unlicensed specials**. Pharmacists can also recommend crushing or dispersing a tablet or opening a capsule as long as they are using their professional judgement and acting in the patient's best interests, e.g. if crushing a tablet is more acceptable for the patient than carrying around large volumes of a special liquid or if the special is going to take a long time to order in. As with every recommendation the pharmacist must be able to justify their decision. Pharmacists should contact their indemnity insurers for clarification if they are unsure.

GUIDANCE FOR PHARMACISTS AND DISPENSERS WHEN SOURCING A PHARMACEUTICAL SPECIAL

The Royal Pharmaceutical Society of Great Britain recommends that pharmacists write a Standard Operating Procedure (SOP) detailing the steps involved in the ordering of 'specials' including risk assessments of the different options available¹⁸.

Unlicensed medicines may be obtained:

- From the holder of a Manufacturer's 'Specials' Licence, either a commercial company or an NHS hospital
- By importation from within the European Economic Area (EEA) from the holder of a Wholesale Dealer's Licence valid for import and handling unlicensed relevant medicinal products¹⁹
- By importation from outside the EEA from the holder of a Manufacturer's 'Specials' Licence valid for import¹⁹

When importing products it is preferable to import a product licensed in Europe, USA, Canada, Australia or in another MHRA recognised authority.

Medicines may also be prepared extemporaneously against a prescription under a pharmacist's direct supervision.

Previously pharmaceutical specials manufacturers were not allowed to advertise unlicensed products which, meant that it was often difficult to find out information about pharmaceutical 'Specials'. However, on 19 August 2010, The Medicines for Human Use (Advanced Therapy Medicinal Products and Miscellaneous Amendments) Regulations 2010 amended the legislation to allow price lists for unlicensed medicines to be published and shared.

Specials manufacturers are being encouraged to publish price lists where practical; however, it is recognised that because of the bespoke nature of some special products, it may not be possible for all unlicensed medicines to be included in manufacturer price lists.

Safety and Quality Considerations

To ensure quality of the product, a certificate of analysis or a certificate of conformity should be asked for with every product.

Whether a 'special' is made under section 10 or under an MS, the pharmacist who supplies the product to the patient remains legally accountable for its quality, regardless of who made it and how. Therefore, pharmacists should not assume any aspect of quality and should take all reasonable steps to assure it.

Pharmacists should agree with the supplier exactly what they require, including strength, formulation, excipients, where relevant, such as sugar free or alcohol free formulations. Where feasible the agreed formulation should be confirmed to the manufacturer in a written order.

Pharmacists should ensure that the product:

- Is of a suitable standard
- Comes with a **certificate of analysis** or a **certificate of conformity** (see glossary).
- Is pharmaceutically appropriate and suitable for the patient e.g. check strength, formulation and excipient details on the certificate, and where available, on the label
- Has evidence to support the labelled shelf life of the product

Choosing a Suitable Supplier

An MHRA licensed 'specials' supplier is preferred (details can be found at www.mhra.gov.uk/pharmaceuticalindustry/manufacturingandwholesaling/index.htm). Details of NHS hospital manufacturing departments are listed in the BNF.

The manufacturer should be chosen on the basis they:

- Give the best balance of validated shelf-life, presentation, supply and cost.
- Possess a specials manufacturing license (MS)
- Use Good Manufacturing Practice (GMP) processes.
- Label and package the product in accordance with latest guidelines.
- Provide supporting governance documentation of quality (described above).
- Deliver within a suitable time period.
- Have a proven supply record.

The Cost Effectiveness of the Medicine

The code of ethics states that pharmacists should make the best use of the resources available to them¹⁷. The Society encourages all pharmacists to ensure that the NHS secures good value from its expenditure, and recommends that pharmacists should bear this in mind in procurement of specials¹⁸. Ideally this can be achieved by obtaining several quotes and using the one which represents the best balance of quality and cost effectiveness.

The Society acknowledges that a supply chain involving one or more third parties is potentially associated with additional risk and cost¹⁸. Therefore, where possible, pharmacists should order specials direct from manufacturers rather than using intermediaries.

The Society also recommends that pharmacists regularly check that their chosen supplier is offering the best all round service, taking into account quality, promptness of supply and value for money¹⁸.

Previous Supplies

When dispensing a repeat supply, or if the patient has had the product previously from elsewhere, aim to continue to use the same supplier if possible to ensure product consistency. This will improve the likelihood of clinical equivalence and continuity of care.

Expiry Dates of Pharmaceutical ‘Specials’

Pharmaceutical specials manufacturers do not necessarily perform stability testing on their products measuring potency and stability over time. The expiry date is therefore reduced to a short period of time compared to a licensed product. This can result in treatment becoming very expensive with high levels of waste over time.

If the shelf life / expiry date does not allow for the initial supply to cover the full intended duration of treatment, this should be drawn to the patient’s attention and appropriate arrangements for further supplies should be made.

Patient Information

Pharmacists are likely to be the last point of contact with the patient prior to the unlicensed medicine being administered. It is the responsibility of the pharmacist to remind the patient that the medicine is unlicensed and ensure they are fully informed about the medicine including its unlicensed status.

The Royal Pharmaceutical Society of Great Britain fact sheet on the use of unlicensed medicines in pharmacy⁴ advises that a pharmacist should bring to the attention of the patient that the product does not have a marketing authorisation. This should be done without undermining the patient’s confidence in either the prescriber or the prescribed medicine⁴. An example of a patient information leaflet that could be used to support this is shown in Appendix 3.

Where the product has a patient information leaflet, the pharmacist should provide this to the patient. If written information is not available then verbal advice should be given¹⁸.

If a GP has written a prescription for medicines to be taken in an unlicensed manner and full dose instructions are included on the prescription (if applicable) e.g. *“disperse one tablet in water and take once in the morning”* or *“crush one tablet, mix with water and take...”* these instructions should be reproduced on the medication label, and also on the MAR chart if one is required.

Record Keeping

The MHRA has specific requirements around record keeping for all ‘specials’, including those that are imported. In addition, pharmacists should also comply with the RPSGB guidelines on record keeping for unlicensed medicines (<http://www.rpsgb.org/pdfs/factsheet5.pdf>)⁴

It is recommended to maintain the following records¹⁸:

To be kept for a minimum of 5 years
A record of the purchase and supply of a ‘special’ and the specification of the product agreed with the supplier should be documented.
Documentation to verify the specifications i.e. certificate of analysis or a certificate of conformity from the manufacturer, should be obtained on delivery and must include the batch number and expiry details of the product; kept on file in the pharmacy.
Patient details, such as name and address linked to the special should also be maintained to provide an adequate audit trail.
The source of the product i.e. manufacturer details
The quantity of each sale or supply
The batch number and expiry date of the product (listed on the certificate of analysis or certificate of conformity)
If the product is in response to a prescription, the records must also include the patient’s details, prescription details and the date of dispensing.
The date on which the product was supplied (as may differ from the date of manufacture)

It is also recommended to keep a record of the risk assessment and reasons for the decision to purchase and supply a ‘special’.

Reporting Adverse Drug Reactions

Pharmacists and prescribers should report serious suspected adverse drug reactions (ADRs) to the MHRA via the ‘**yellow card scheme**’ - <http://yellowcard.mhra.gov.uk>

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Appendix 1.

COMMONLY PRESCRIBED SPECIALS ON WIRRAL – ALTERNATIVE THERAPEUTIC OPTIONS

Please note: Every effort has been made to ensure the information in this document is current and correct, however data for individual drugs may have changed. Where there is any doubt, information should be checked against manufacturers' recommendations, published literature or other specialist sources.

Where alternative agents are suggested, therapeutic equivalence is not implied. Patients will require monitoring and possibly dose titration when switching to a different agent. This appendix only covers examples of alternatives for **adult** patients. Please contact the Medicines Management Team on 0151 643 5338 for advice related to children or medicines not listed below.

If a patient has an enteral feeding tube please follow the NHS Wirral Standard operating procedure for administration of medicines via enteral feeding tubes, which is found at the following link:

http://www.wirral.nhs.uk/document_uploads/Policies_and_Procedures_Nursing/NPM_M15-SOPMedicinesviaEnteralFeedingTubes.pdf

SPECIAL	THERAPEUTIC ALTERNATIVES
Amitriptyline Liquid 10mg/5ml	Licensed medicines in suitable formulations Amitriptyline oral solution 25mg/5ml and 50mg/5ml are both available. Oral syringes can be used to measure smaller doses
Amlodipine Liquid	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
Bendroflume thiazide Liquid	Licensed medicines in suitable formulations There are no suitable licensed formulations of bendroflumethiazide or other thiazide diuretics. Loop diuretics are available as liquid preparations: Furosemide 20mg/5ml, 40mg/5ml and 50mg/5ml oral solutions are available. Bumetanide 1mg/5ml oral liquid is available Licensed medicines used in an unlicensed manner Bendroflumethiazide tablets can be dispersed in 10ml water and given orally or via a feeding tube.
Chloral Hydrate Liquid 500mg/5ml	Licensed medicines in suitable formulations Chloral Hydrate 143.3mg/5ml (Welldorm elixir) is available N.B. Welldorm preparations are listed in the BNF under 'cloral betaine' but only the tablets contain the betaine salt. Other hypnotics are available and may be preferred: Nitrazepam 2.5mg/5ml suspension Temazepam 10mg/5ml oral solution

	<p>Licensed medicines used in an unlicensed manner Zolpidem tablets can be crushed and mixed with 10ml water for administration orally or via a feeding tube. Nitrazepam tablets can be crushed and mixed with 10ml water for administration orally or via a feeding tube</p>
Clobazam Liquid	<p>Licensed medicines in suitable formulations There are no suitable licensed formulations of clobazam.</p> <p>Licensed medicines used in an unlicensed manner Clobazam tablets can be dispersed in 10ml water for administration orally or via a feeding tube</p>
Clonazepam Liquid	<p>Licensed medicines in suitable formulations There are no suitable licensed formulations of clonazepam.</p> <p>Licensed medicines used in an unlicensed manner Clonazepam tablets can be dispersed in 10ml water for administration orally or via a feeding tube. Clonazepam injection can be administered orally or via a feeding tube. For further information contact the Medicines Management Team.</p>
Co-dydramol Liquid	<p>Licensed medicines in suitable formulations Paracetamol soluble tablets are available Paracetamol 120mg/5ml and 250mg/5ml oral suspensions are available. Dihydrocodeine 10mg/5ml oral solution is available Co-codamol (paracetamol 500mg and codeine 30mg) effervescent tablets are available</p>
Diazepam oral solution 2.5mg/5ml	<p>Licensed medicines in suitable formulations Diazepam oral solution 2mg/5ml available Diazepam strong oral solution 5mg/5ml available (not prescribable on the NHS) Diazepam rectal tubes and suppositories also available</p>
Dipyridamole Liquid 100mg/5ml	<p>Licensed medicines in suitable formulations There are no suitable licensed formulations of 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. Dipyridamole 50mg/5ml oral suspension is available 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. <i>NB: Evidence only supports the use of modified-release, not immediate-release, dipyridamole preparations for the prevention of vascular events.</i></p> <p>Licensed medicines used in an unlicensed manner Dipyridamole modified-release capsules may be opened and the modified-release granules mixed with 15ml 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</p>

	<p>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.</p> <p>Dipyridamole immediate-release tablets can be crushed and mixed with 10ml water. (See NB above)</p>
Gliclazide Liquid	<p>Licensed medicines in suitable formulations There are no suitable licensed formulations of gliclazide available.</p> <p>Licensed medicines used in an unlicensed manner Immediate release gliclazide tablets can be crushed and dispersed in 10ml water. MR preparations of gliclazide should not be crushed.</p>
Haloperidol Liquid 1mg/5ml	<p>Licensed medicines in suitable formulations Haloperidol 1mg/ml and 2mg/ml oral liquids. Oral syringes can be used to measure smaller doses.</p>
Lisinopril Liquid	<p>Licensed medicines in suitable formulations There are no suitable licensed formulations of ACE inhibitors available</p> <p>Licensed medicines used in an unlicensed manner Lisinopril tablets can be dispersed in 10ml water.</p>
Melatonin Liquid	<p>Licensed medicines in suitable formulations There are no suitable licensed formulations of melatonin</p>
Methotrexate Liquid	<p>Licensed medicines in suitable formulations There are no suitable licensed formulations of methotrexate available</p> <p>Licensed medicines used in an unlicensed manner Methotrexate tablets will disperse in water. However, it is preferable to use a 'special' liquid in this instance as it is a cytotoxic drug.</p>
Midazolam Oromucosal Liquid	<p>Licensed medicines in suitable formulations There are no suitable licensed formulations of midazolam.</p> <p>Therapeutic alternatives Diazepam rectal tubes</p> <p>Licensed medicines used in an unlicensed manner Hypnovel[®] (midazolam) ampoules (unlicensed route but able to be administered buccally or intranasally). For further information contact the Medicines Management Team.</p> <p>Special order medicines Midazolam buccal liquid 10mg/ml e.g. Epistatus[®] or Suptamid[®]</p>
Nitrazepam Liquid 5mg/5ml	<p>Licensed medicines in suitable formulations Nitrazepam 2.5mg/5ml oral suspension is available</p>
Omeprazole Liquid	<p>Licensed medicines in suitable formulations 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</p>

	<p>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.</p> <p>H2-receptor antagonists are available for patients in whom step-down therapy is appropriate: Ranitidine effervescent tablets Ranitidine 75mg/5ml oral solution sugar free</p> <p>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 to block fine bore feeding tubes but can be mixed with water or 8.4% sodium bicarbonate for administration via wider feeding tubes.</p>
Paracetamol Liquid 500mg/5ml	<p>Licensed medicines in suitable formulations Paracetamol soluble tablets Paracetamol 120mg/5ml and 250mg/5ml oral suspensions</p>
Phenobarbital Liquid 50mg/5ml (alcohol free)	<p>Licensed medicines in suitable formulations 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.</p> <p>Licensed medicines used in an unlicensed manner Phenobarbital tablets may be crushed and mixed with 10ml water</p>
Quetiapine Liquid	<p>Licensed medicines in suitable formulations There are no suitable licensed preparations of quetiapine. Other atypical antipsychotics are available and may be suitable for some patients: Amisulpride 100mg/ml solution Aripiprazole orodispersible tablets Aripiprazole 1mg/ml oral solution Olanzapine orodispersible tablets Risperidone orodispersible tablets Risperidone 1mg/ml liquid</p> <p>Depot medication may be considered in some circumstances.</p> <p>‘Typical’ antipsychotics may be suitable for some patients. The following licensed preparations are available: Chlorpromazine 25mg/5ml and 100mg/5ml oral solutions Haloperidol 1mg/ml and 2mg/ml oral liquids Promazine 25mg/5ml and 50mg/5ml oral solutions Sulpride 200mg/5ml oral solution Trifluoperazine 1mg/5ml syrup and 5mg/5ml oral solution</p> <p>Licensed medicines used in an unlicensed manner Quetiapine tablets can be crushed and mixed with 10ml water or added to soft food but taste bitter</p>
Ramipril Liquid	<p>Licensed medicines in suitable formulations There are no suitable licensed formulations of ACE inhibitors available</p>

	<p>Licensed medicines used in an unlicensed manner Ramipril capsules can be opened and the contents mixed with 15ml water or food. Ramipril tablets can be dispersed in 10ml water</p>
Sertraline Liquid	<p>Licensed medicines in suitable formulations There are no suitable licensed formulations of sertraline. 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</p> <p>Licensed medicines used in an unlicensed manner Fluoxetine 20mg/5ml oral liquid and paroxetine 10mg/5ml oral suspension 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.</p>
Simvastatin Liquid	<p>Licensed medicines in suitable formulations Simvastatin oral suspensions: 20mg/5ml and 40mg/5ml x 150ml; they are suitable for administration orally or via a feeding tube.</p> <p>Licensed medicines used in an unlicensed manner Simvastatin tablets are film coated but can be crushed and dispersed in 10ml water for administration orally or via a feeding tube. Pravastatin tablets can be dispersed in 10ml water for administration orally or via a feeding tube. They are more readily dispersible than simvastatin tablets. Atorvastatin tablets are film coated but can be dispersed in 10ml water for administration orally or via a feeding tube.</p>
Spirolactone Liquid	<p>Licensed medicines in suitable formulations There are no suitable licensed formulations of spironolactone available</p> <p>Licensed medicines used in an unlicensed manner Spirolactone tablets can be crushed and dispersed in 10ml water</p>
Warfarin Sodium Liquid	<p>Licensed medicines in suitable formulations There are no suitable licensed formulations of warfarin or other oral anticoagulants.</p> <p>Licensed medicines used in an unlicensed manner Warfarin tablets can be crushed and suspended in 10ml water for administration orally or via a feeding tube.</p>

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Appendix 2

SPECIAL PREPARATION OF MEDICINES – INFORMATION FOR PATIENTS AND CARERS

HOW TO CRUSH TABLETS AND MIX WITH WATER AND HOW TO OPEN THE CONTENTS OF CAPSULES AND MIX WITH WATER
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This leaflet has been given to you as your pharmacist or doctor has advised that it is appropriate to crush or mix some of your tablets with water or open capsules and mix the contents with water.

Not all tablets may be crushed or dispersed in water, and not all capsules may be opened and the contents mixed with water. This is because it may affect the way a medicine is absorbed. Therefore, you should only do it on the advice of a healthcare professional. This leaflet is to show you how to prepare the medicines.

TABLETS

If you have been advised that it is suitable to crush your tablets the following method is suggested:

Crush the tablet using a pestle and mortar, a tablet crusher (available to buy from pharmacies) or between two metal spoons. Only crush medicines one tablet at a time; do not crush all the medicines together. Crushing or mixing the tablet with water should only be performed immediately before taking.

How to crush tablets and mix with water

1. Crush the tablet (either using a pestle and mortar, a tablet crusher or between 2 metal spoons) to form a fine powder
2. Place the fine powder into a plastic medicine pot
3. Add 15 ml of water
4. Mix thoroughly, ensuring that there are no large particles of tablet and take
5. Add another 15ml of water to the medicine pot
6. Stir to ensure that any remaining drug is rinsed from the container and take

How to mix tablets with water

Some tablets do not need to be crushed before mixing with water. If you have been advised to just mix the tablet with water the following method may be used:

1. Place the tablet into a plastic medicine pot
2. Add 10ml of water and allow the tablet to disperse (mix with the water)
3. Take the medication
4. Add another 10ml of water to the medicine pot
5. Stir to ensure that any remaining drug is rinsed from the container and take.

CAPSULES

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.

How to mix the contents of capsules with water

1. Open the capsule and pour the contents into a plastic medicine pot
2. Add 15ml of water
3. Stir to mix the powder in the water
4. Take the medication
5. Add a further 15ml to the medicine pot
6. Stir to ensure that any powder remaining in the pot is mixed with water and take.

TAKING MEDICINES IN SOFT FOOD

Crushed medicines or capsule contents may be taken 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.

If you are a carer looking after someone it is important that medicines are only administered in food with the person's knowledge and consent. For further information please speak to your doctor or pharmacist.

TUBE FEEDING AND MEDICINES

You will have been told what type of water to use. The volumes suggested in this leaflet are just a guide, and your specific amount may vary as directed by your dietitian.

How to take the medicines

If you can still swallow your medicines, you should take them this way. If you need to give your medicines via your feeding tube, you should follow these instructions. Consult your dietitian on volume of water to be taken as flushes.

1. Switch off the feed if it is running.
2. Flush the tube as directed by your dietitian
3. Prepare your medicine as instructed e.g. crush tablet and disperse in water. (This should be done one medicine at a time, unless you have been told otherwise).
4. Give medicine down feeding tube.
5. Draw up a minimum of 10ml of water into the same syringe and flush down feeding tube.
6. Repeat from step 3 if giving more than one medicine.
7. Finally flush tube as directed.
8. Re-start feed if necessary. You may need to allow some time for the medicine to work (your pharmacist or nutrition nurse will discuss this with you).

Appendix 3.

PATIENT INFORMATION LEAFLET - UNLICENSED MEDICINES

What is this leaflet about?

In the UK most medicines are 'licensed' but some are not. This leaflet explains why medicines are 'licensed' and why some useful medicines do not have licences.

You will have been given this leaflet by your doctor or pharmacist because the medicine prescribed for you is not 'licensed' or is being used for a reason not covered by the licence. We want to reassure you that we have thought very carefully about the best medicine for you and to answer any questions you may have.

Why are medicines 'licensed'?

Medicines that are sold in the UK have received a 'Marketing Authorisation' number (product licence) from the Medicines and Healthcare products Regulatory Authority (MHRA). This means that the medicine works for the illnesses to be treated, does not have too many side effects or risks and has been made to a high standard.

Why don't all medicines have a licence?

There are several reasons why some medicines are used for illnesses or conditions not covered by their licence and why some medicines have no licence at all.

Medicines are usually only licensed for conditions that have been tested in clinical trials. Sometimes the clinical trial (and product licence) is for one illness but doctors find that the medicine works very well for another illness.

Some medicines have no licence at all. These may be some liquid medicines that people with swallowing difficulties can take easily or medicines used for rare illnesses. It may be too expensive or there may not be enough people with the illness to have a clinical trial.

Why have I been given an unlicensed medicine?

The doctor who is treating you has recommended an unlicensed medicine because there is no suitable licensed alternative to treat your condition. As your medicine is not licensed the leaflet may not talk about your particular illness or condition or it may say that the medicine should not be used for your age.

Should I be worried about taking these medicines?

The doctors looking after you will have carefully thought about prescribing the best medicine for you. If you are still worried after reading this leaflet, please talk to your doctor or pharmacist.

What else do I need to know?

Sometimes it may take your pharmacist longer to get hold of unlicensed medicines. Therefore, you will probably need to allow one or two weeks for the pharmacist to obtain a further supply for you. It is important that you do not let your supply run out before going to the GP.

Where can I get further advice?

Please speak to your doctor or pharmacist