NHS Grampian

Guidance For Switching Oral Anti-Seizure Medication To Other Routes Of Administration By Healthcare Professionals Working Within NHS Grampian

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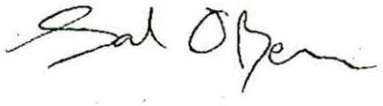		

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Policy Statement:

It is the responsibility of all staff to ensure that they are working to the most up to date and relevant guideline, policies, protocols and procedures.

Version 2

Executive Sign-Off

This document has been endorsed by the Director of Pharmacy and Medicines Management

Signature: 

Replaces: NHSG/Guide/Oral_AntiSeizMeds/MGPG1311, Version 1

Document application: NHS Grampian

Revision History:

Revision Date	Summary of Changes (Descriptive summary of the changes made)	Changes Made (Identify page numbers and section heading)
June 2024	New section	Page 3, Section 2
June 2024	Pregnancy prevention programme and therapeutic drug monitoring information added.	Page 3, Section 3
June 2024	Minor grammar/phrasing changes.	Page 4, Section 4
June 2024	Detail added to carbamazepine, eslicarbazepine added, licensing information added to levetiracetam.	Page 6, Table 2
June 2024	Minor updates in line with local enteral guidance.	Section 6
June 2024	Licensing information added to cannabidiol, eslicarbazepine added, brand-specific information removed from gabapentin, detail added to carbamazepine, clobazam, clonazepam, levetiracetam, phenytoin, topiramate, vigabatrin.	Page 13, Table 3
June 2024	Valproate and topiramate pregnancy prevention programmes noted.	Page 6,Table 2 and Page 13, Table 3
June 2024	Added lamotrigine rectal administration, levetiracetam paediatric infusion volume information, phenytoin Infatab information, paediatric information for phenytoin injection, fenfluramine, valproate rectal information.	Page 6,Table 2
June 2024	Added phenytoin Infatab information, fenfluramine, additional carbamazepine information, paediatric clonazepam and phenobarbital information, stiripentol bioequivalence information.	Page 13, Table 3

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1. Introduction

Anti-seizure medications are considered critical medicines and doses should not be delayed or omitted. Therefore, if the oral route is unavailable, other routes of administration should be considered.

Where no other routes of administration are available (due to lack of access or unavailability of a suitable formulation) and the indication is epilepsy, advice should be sought from neurology regarding management of the patient.

This document has been produced based on the most up-to-date information available. Specific factors relating to an individual patient may dictate a different approach. This document is not a substitute for professional clinical judgement. Where there are any concerns, or individual patient advice is required, please contact your Clinical Pharmacist, or the Grampian Medicines Information Centre on 01224 552316.

2. Status Epilepticus And/Or Prolonged Seizures

There is separate guidance for the treatment of status epilepticus and/or prolonged seizures for adult patients within the hospital setting, available on Grampian Guidance at the following link: NHS Grampian Status Epilepticus Guideline

Potential treatments and routes of administration for these treatments, are covered in the above document.

3. General Information

The indication for the anti-seizure medication should be determined in all cases. Anti-seizure medicines can be used to treat other conditions.

Crushing and/or dispersing of tablets or the opening of capsules is rarely covered by the product licence and licensed routes of administration should be explored in the first instance. However, there may be no other option for some patients. Only prescribers can authorise the unlicensed use of medicines. Authorisation by the prescriber should be obtained (ideally in writing) prior to any adjustment in how an oral dosage is administered. The MHRA hierarchy should be considered while making decisions about medication, however this should not be seen as a barrier to timely and appropriate clinical care.

Sodium valproate and topiramate are now subject to Pregnancy Prevention Programmes.

Therapeutic drug monitoring can be required for some anti-seizure medications - NHS Grampian Guideline For Therapeutic Drug Monitoring (TDM) In Adults

4. Medicines And Healthcare Products Regulatory Agency (MHRA)/ Commission On Human Medicines (CHM) Advice: 'Antiepileptic Drugs: Updated Advice On Switching Between Different Manufacturers' Products' (November 2017)

The CHM reviewed spontaneous adverse reactions received by the MHRA and publications that reported potential harm arising from switching of antiepileptic drugs in patients previously stabilised on a branded product to a generic. The CHM concluded that reports of loss of seizure control and/or worsening of side-effects around the time of switching between products could be explained as chance associations, but that a causal role of switching could not be ruled out in all cases.

The following guidance was issued to help minimise risk:

1. Different antiepileptic drugs vary considerably in their characteristics, which influences the risk of whether switching between different manufacturers' products of a particular drug may cause adverse effects or loss of seizure control;

2. Antiepileptic drugs have been divided into three risk-based categories to help healthcare professionals decide whether it is necessary to maintain continuity of supply of a specific manufacturer's product. These categories are listed below;

3. When it is necessary for a patient to be maintained on a specific manufacturer's product (e.g. when using carbamazepine for the management of epilepsy) this should be prescribed either by specifying a brand name, or by using the generic drug name and name of the manufacturer (otherwise known as the Marketing Authorisation Holder);

4. This advice relates only to antiepileptic drug use for treatment of epilepsy; it does not apply to their use in other indications (e.g. mood stabilisation, neuropathic pain);

5. Report on a Yellow Card any suspected adverse reactions to antiepileptic drugs, including any adverse effect that could be attributed to a change in formulation or manufacturer;

6. Dispensing pharmacists should ensure the continuity of supply of a particular product when the prescription specifies it. If the prescribed product is unavailable, it may be necessary to dispense a product from a different manufacturer to maintain continuity of treatment of that antiepileptic drug. Such cases should be discussed and agreed with both the prescriber and patient (or carer);

7. Usual dispensing practice can be followed when a specific product is not stated, as per the MHRA statement. However, it would be best practice to confirm the indication for medications, particularly those in Category 1, prior to prescribing generically or accepting a generic prescription, due to the potential risk to the patient.

4.1 Anti-seizure medication risk-based categories

Note: Medicines that have come to market since the publication of the MHRA statement will not be classified below (e.g. cenobamate, stiripentol). Therefore, clinical judgement will be required for these medications.

Table 1. Risk-based categories for anti-seizure medication

Category	Medications	Advice for prescribing
Category 1	Carbamazepine, phenobarbital, phenytoin, primidone.	For these medications, prescribers are advised to ensure that their patient is maintained on a specific manufacturer's product.
Category 2	Clobazam, clonazepam, eslicarbazepine acetate, lamotrigine, oxcarbazepine, perampanel, rufinamide, topiramate, valproate, zonisamide.	For these medications, the need for continued supply of a particular manufacturer's product should be based on clinical judgement and consultation with the patient and/or carer taking into account factors such as seizure frequency, treatment history, and potential implications to the patient of having a breakthrough seizure. Non-clinical factors as for Category 3 drugs should also be considered.
Category 3	Brivaracetam, ethosuximide, gabapentin, lacosamide, levetiracetam, pregabalin, tiagabine, vigabatrin.	For these medications, it is usually unnecessary to ensure that patients are maintained on a specific manufacturer's product as therapeutic equivalence can be assumed, however, other factors are important when considering whether switching is appropriate. Differences between alternative products (e.g. product name, packaging, appearance, and taste) may be perceived negatively by patients and/or carers, and may lead to dissatisfaction, anxiety, confusion, dosing errors, and reduced adherence. In addition, difficulties for patients with co-morbid autism, mental health problems, or learning disability should also be considered.

For further advice, please contact Pharmacy (Clinical Pharmacist or Medicines Information within core hours, on call Pharmacist out-of-hours).

5. Guidance For Switching Anti-Seizure Medications From The Oral Route To The Intravenous Or Rectal Route

Table 2. Oral to intravenous or rectal route

IV = intravenous, N/A = not applicable (not available via these routes)

Medicine	ORAL → IV CONVERSION (total daily dose equivalence)	ORAL → IV FREQUENCY	ORAL → IV EXAMPLE	COMMENTS	ORAL → Rectal
Brivaracetam	Same dose	Same frequency	50mg twice daily oral → 50mg twice daily IV	SPC states that there is no experience of IV use >4 days – overall duration at physician's discretion	N/A
Cannabidiol (Epidyolex only)	N/A	N/A	N/A	N/A	N/A
Carbamazepine	N/A	N/A	N/A	N/A	Carbamazepine 100mg tablet or liquid is equivalent to carbamazepine 125mg suppository. Maximum dose of 1g in four divided doses. Absorption of higher doses is not consistent. Licensed for use for up to 7 days. Manufacturer advises that longer term use may carry a risk of rectal irritation.
Cenobamate	N/A	N/A	N/A	N/A	N/A

Medicine	ORAL → IV CONVERSION (total daily dose equivalence)	ORAL → IV FREQUENCY	ORAL → IV EXAMPLE	COMMENTS	ORAL → Rectal
Clobazam	N/A	N/A	N/A	N/A	N/A
Clonazepam	N/A	N/A	N/A	N/A	N/A
Eslicarbazepine	N/A	N/A	N/A	N/A	N/A
Ethosuximide	N/A	N/A	N/A	N/A	N/A
Fenfluramine	N/A	N/A	N/A	N/A	N/A
Gabapentin	N/A	N/A	N/A	N/A	N/A
Lacosamide	Same dose	Same frequency	100mg twice daily oral → 100mg twice daily IV	There is experience of IV use for up to 5 days, but overall duration is at physician's discretion.	N/A
Lamotrigine	N/A	N/A	N/A	If patient has not received lamotrigine for more than 5 days, re-titration of dose will be required.	Seek specialist advice. Lamotrigine dispersible tablets have been administered rectally for maintenance doses (unlicensed). Use same dose as oral route. Dissolve in a small volume of water before administration.

Medicine	ORAL → IV CONVERSION (total daily dose equivalence)	ORAL → IV FREQUENCY	ORAL → IV EXAMPLE	COMMENTS	ORAL → Rectal
Levetiracetam	Same dose	Same frequency	500mg twice daily oral → 500mg twice daily IV	SPC states no experience of IV use >4 days, but overall duration is at physician's discretion. Smaller infusion volumes may be used for paediatric patients – see Paediatric Medusa.	N/A
Oxcarbazepine	N/A	N/A	N/A	N/A	N/A
Perampanel	N/A	N/A	N/A	N/A	N/A
Phenobarbital	Same dose	Same frequency	100mg at night oral → 100mg at night IV	Almost bioequivalent. IV route gives a marginal dose increase - monitor response.	N/A

Medicine	ORAL → IV CONVERSION (total daily dose equivalence)	ORAL → IV FREQUENCY	ORAL → IV EXAMPLE	COMMENTS	ORAL → Rectal
Phenytoin Capsules or Tablets	Same dose	Increase (3-4 times daily)	300mg once daily oral → 100mg three times daily IV	Therapeutic drug monitoring required. Consider taking pre-dose trough level before re-dosing. Steady state achieved after 5-7 days. Monitor ECG & BP. Injection may contain propylene glycol and ethanol; use with caution in paediatric patients.	N/A
Phenytoin Liquid or Infatabs	90:100	Increase (3-4 times daily)	270mg once daily oral → 100mg three times daily IV	Therapeutic drug monitoring required. Consider taking pre-dose trough level before re-dosing. Steady state achieved after 5-7 days. Monitor ECG & BP. See note on use in paediatrics above.	N/A

Medicine	ORAL → IV CONVERSION (total daily dose equivalence)	ORAL → IV FREQUENCY	ORAL → IV EXAMPLE	COMMENTS	ORAL → Rectal
Pregabalin	N/A	N/A	N/A	N/A	N/A
Primidone	N/A	N/A	N/A	N/A	N/A
Rufinamide	N/A	N/A	N/A	N/A	N/A
Sodium valproate EC/Liquid	Same dose	Same frequency	500mg three times daily oral → 500mg three times daily IV	Note: Use is subject to Pregnancy Prevention Programme, as per MHRA guidance	Seek specialist advice. The liquid has been used rectally. It should be retained for at least 15 minutes.
Sodium valproate M/R (Chrono)	Same dose	Increase (3 times daily)	750mg morning and night oral → 500mg three times daily	Note: Use is subject to Pregnancy Prevention Programme, as per MHRA guidance	Seek specialist advice. The liquid has been used rectally. It should be retained for at least 15 minutes.
Stiripentol	N/A	N/A	N/A	N/A	N/A
Topiramate	N/A	N/A	N/A	Note: Use is subject to Pregnancy Prevention Programme, as per MHRA guidance	N/A

Medicine	ORAL → IV CONVERSION (total daily dose equivalence)	ORAL → IV FREQUENCY	ORAL → IV EXAMPLE	COMMENTS	ORAL → Rectal
Vigabatrin	N/A	N/A	N/A	N/A	Seek specialist advice. Has been administered rectally in children using granules. Given at the same dose as oral administration. Sachets are dissolved in a small amount of water prior to administration. Granules are not licensed for rectal use.
Zonisamide	N/A	N/A	N/A	N/A	N/A

6. Guidance For Switching Anti-Seizure Medications From The Oral Route To Nasogastric (NG), Percutaneous Endoscopic Gastrostomy (PEG) Or Jejunal Administration

Tubes may terminate in the stomach or the jejunum, and they may enter via the nose or through the abdominal wall. It is usually possible to give medicines via these enteral tubes, but it can be difficult to find guidance on the best approach. Important considerations include the diameter of the tube (and therefore risk of blockage), the suitability of the formulation used, whether the stability of the medication might be affected by the acid environment of the stomach, or whether absorption might be affected by bypassing the stomach in the case of jejunal tubes.

General recommendations for drug administration via enteral tubes:

- Use enteral syringes at all times, not injection syringes.
- For tubes terminating in the stomach, tap water is acceptable. For tubes terminating in the jejunum, sterile water should be used.
- Stop feed and/or flush enteral tube with 15-30mL of water prior to drug administration. Check if a prolonged break in feeding is advised prior to administration of specific drugs.
- If able, ensure the patient is sitting up at an angle of at least 30 degrees to avoid reflux of medication or water. Note that this may not be possible for some patients such as those with spinal injuries.
- Give medication via enteral tube as directed by the guidance within the table below.
- If more than one medicine is being administered, flush with at least 10mL of water between each medication.
- After administration of the last medication, flush tube well with 15-30mL of water after the dose.
- Restart feed if a prolonged break in feed is not advised.

Practical advice for patient/carer/healthcare professional administering medicines:

- Do not crush modified release preparations. These might be indicated by ‘MR’, ‘SR’ or ‘XL’ in the name. If you are not certain, confirm with Pharmacy.
- When tablets are crushed, a powder is formed and this can be unintentionally inhaled by staff members when breathing. Ensure protective equipment such as gloves and masks are worn when crushing tablets to reduce exposure of staff members to this powder.
- Particular care must be taken to avoid exposure to antimicrobial, cytotoxic, steroid or hormonal preparations in the crushed/powder form. If you are unsure of the nature of a medicine, check with pharmacy.
- If a tablet can be dispersed, this would ideally be carried out in a closed system, such as the barrel of an enteral syringe. To do this, remove the plunger and place the tablet in the barrel of a 50mL enteral syringe. Replace the plunger and draw up 10-15mL of water. Cap the syringe and allow the tablet to disperse, agitating if necessary. Shake well, remove the cap and administer the required dose via the feeding tube. Flush with water as usual, and dispose of the syringe in the appropriate waste stream.

Table 3. Oral to enteral route

NG = nasogastric, PEG = percutaneous endoscopic gastrostomy

Medicine	Form	Instructions	Feed Directions	Additional Information
Brivaracetam	Oral Solution	Solution can be given undiluted, but may be diluted with an equal volume of water if required.	A prolonged break in feeding is not required before/after administration.	The solution is licensed for NG and PEG administration. If administered via jejunal tube, monitor for loss of efficacy or increased side effects.
Cannabidiol (Epidyolex only)	Oral solution	Solution can be given undiluted.	A prolonged break in feeding is not required before/after administration, but give in a consistent manner.	The solution is licensed for administration via silicone NG and PEG tubes. If administered via jejunal tube, monitor for loss of efficacy or increased side effects.

Medicine	Form	Instructions	Feed Directions	Additional Information
Carbamazepine	Liquid	Dilute with an equal volume of water. There may be resistance when administered via enteral feeding tube due to high viscosity of liquid.	A prolonged break in feeding is not required before/after administration, but give in a consistent manner. An alteration in carbamazepine absorption should be considered in any patient who commences or discontinues enteral feeds. Drug level monitoring should be carried out as necessary.	400mg modified release (MR) twice daily is equivalent to 200mg liquid four times daily. The liquid produces higher peak plasma concentrations which may be associated with an increase in adverse effects. Enteral feeding may slightly delay and reduce absorption of the liquid preparation, which may help to reduce side-effects such as mild drowsiness and lightheadedness. Contains sorbitol. Doses above 800mg/day may cause bloating due to the sorbitol content of the liquid. If administered via jejunal tube, monitor for loss of efficacy or increased side effects.
Cenobamate	Tablets	No information. Discuss with Pharmacy.		

Medicine	Form	Instructions	Feed Directions	Additional Information
Clobazam	Tablets	The tablets can be dispersed in water for administration. They disperse in one to five minutes. Clobazam is very hard to suspend, therefore take care to ensure the whole dose is administered. Flush well.	A prolonged break in feeding is not required before/after administration.	There is no information on enteral administration of the oral suspension. If administered via jejunal tube, monitor for loss of efficacy or increased side effects.

Medicine	Form	Instructions	Feed Directions	Additional Information
Clonazepam	Oral Solution	Use an oral solution licensed for administration via enteral feeding tubes (non-PVC tubes only). Flush well with three separate flushes of 5mL water, as the solution is oily.	A prolonged break in feeding is not required before/after administration.	Use the tablets for jejunal administration. If administered via jejunal tube, monitor for loss of efficacy or increased side effects. Some brands of liquid contain a high alcohol content. For paediatrics, tablets are preferred. If using the liquid, confirm suitability with a clinical pharmacist prior to prescribing.
	Tablets	The tablets can be dispersed in at least 30mL of water (volume required to prevent binding to the tube) for administration. They disperse in less than two minutes.		
Eslicarbazepine	Tablets/suspension	No information. Discuss with Pharmacy.		
Ethosuximide	Syrup	Syrup can be diluted with water immediately before administration if necessary to reduce viscosity.	A prolonged break in feeding is not required.	If administered via jejunal tube, monitor for loss of efficacy or increased side effects.

Medicine	Form	Instructions	Feed Directions	Additional Information
Fenfluramine	Oral solution	Solution can be given undiluted. Flush the tube three times after the dose is administered.	A prolonged break in feeding is not required before/after administration.	If administered via jejunal tube, monitor for loss of efficacy or increased side effects.
Gabapentin	Oral solution	Give undiluted	A prolonged break in feeding is not required before/after administration.	Use a liquid that is licensed for NG or PEG administration, if available. If administered via jejunal tube, use the capsules and monitor for loss of efficacy or increased side effects.
	Capsules	Dissolve contents in water and give immediately.		
Lacosamide	Syrup	Syrup can be diluted with water immediately before administration if necessary to reduce viscosity.	A prolonged break in feeding is not required before/after administration.	If administered intrajejunally, monitor for loss of efficacy or increased side effects.
Lamotrigine	Dispersible Tablets	Disperse in 10-15mL of water immediately prior to administration.	A prolonged break in feeding is not required before/after administration.	Monitor closely for changes in efficacy or increased side effects.

Medicine	Form	Instructions	Feed Directions	Additional Information
Levetiracetam	Granules	Suspend the granules by shaking in at least 10mL of water for at least 2 minutes. After the dose, flush twice with 10mL of water each time.	A prolonged break in feeding is not required before/after administration.	The granules (Desitrend) are licensed for tube administration and should be used if available. Can also be administered intrajejunally. Monitor closely for changes in efficacy or increased side effects.
	Oral solution	Solution can be given undiluted.		
	Tablets	Crush and disperse with water. Flush well.		
Oxcarbazepine	Oral Suspension	The suspension can be diluted with water to aid administration.	A prolonged break in feeding is not required before/after administration.	If administered intrajejunally, monitor for loss of efficacy or increased side effects.
Perampanel	Tablets/suspension	Limited information available. Discuss with pharmacy.		

Medicine	Form	Instructions	Feed Directions	Additional Information
Phenobarbital	Elixir	Elixir can be given undiluted.	A prolonged break in feeding is not required before/after administration.	The elixir contains 38% alcohol. For paediatric patients, use an unlicensed, ethanol-free 50mg/mL liquid. The licensed liquid is unsuitable for children. If administering via jejunal tube, consider diluting the liquid formulation to reduce osmolarity.
	Tablets	The tablets may be crushed and mixed with 15-30mL of water for administration.		

Medicine	Form	Instructions	Feed Directions	Additional Information
Phenytoin	Oral Suspension (Phenytoin base)	Shake well and mix with an equal volume of water. Flush with 30-60mL of water.	Withhold feeds for 2 hours before and 2 hours after each dose. Patient response and levels should be monitored carefully, especially after any changes in the feeding regimen, as the dosage may require adjustment.	When converting between capsules and suspension, a dose conversion is required. 100mg phenytoin sodium (capsules) = 90mg phenytoin base (suspension). Infatabs can be converted to the suspension at the same dose; a dose conversion is not required. **Only give enterally if there are no other routes available, and no other suitable treatment options**. Absorption is poor intrajejunally. Monitor patient and plasma levels closely and dilute suspension to avoid GI adverse effects.
	Capsules (Phenytoin sodium)	Open and disperse the powder in 10mL of water. Leave for 5 minutes and stir to form a fine dispersion. Flush with 30-60mL of water.		
Pregabalin	Oral Solution	Can be given undiluted.	A prolonged break in feeding is not required before/after administration.	Flush well. Can also be administered via jejunal tube. Monitor for increased GI adverse effects.
	Capsules	Open and disperse contents in 15-30mL of water.		

Medicine	Form	Instructions	Feed Directions	Additional Information
Primidone	Tablets	The tablets can be crushed and dispersed in 15-30mL of water for administration. The drug is poorly soluble so flush tube thoroughly.	A prolonged break in feeding is not required before/after administration.	If administered intrajejunally, monitor for loss of efficacy or increased side effects.
Rufinamide	Oral Suspension	Suspension can be given undiluted.	A prolonged break in feeding is not required before/after administration.	Suspension is licensed for administration via enteral feeding tubes. Rufinamide should be taken with food. If administered intrajejunally, monitor for loss of efficacy or increased side effects.

Medicine	Form	Instructions	Feed Directions	Additional Information
Sodium valproate	Oral Liquid	Dilute with an equal volume of water immediately prior to administration.	A prolonged break in feeding is not required before/after administration.	Do **not** crush modified release products. If converting from modified release preparations, give the same total daily dose, but divided into more frequent doses. If administered via jejunal tube, use dispersed tablets or dilute the liquid 3-4 times with water. Liquid contains sorbitol. Monitor for loss of efficacy or increased side effects. Note**:** Use is subject to Pregnancy Prevention Programme, as per MHRA guidance
	Epilim Crushable Tablets	Crush and disperse in 10mL of water.		
Stiripentol	Capsules/sachets	No information. Discuss with pharmacy.		The capsule and sachet formulations are not bioequivalent.

Medicine	Form	Instructions	Feed Directions	Additional Information
Topiramate	Tablets	The tablets can be crushed and dispersed in 15-30mL of water for administration.	A prolonged break in feeding is not required before/after administration.	It is not recommended to open capsules and sprinkle the contents into water as the beads readily stick to tubing causing blockage. Topiramate is probably absorbed in the upper gastrointestinal tract, therefore absorption and clinical effectiveness may be altered if administered through an enteral tube which terminates in the jejunum. If jejunal administration is essential, monitor for loss of efficacy or increased side effects. Note: Use is subject to Pregnancy Prevention Programme, as per MHRA guidance

Medicine	Form	Instructions	Feed Directions	Additional Information
Vigabatrin	Soluble Tablets	Dissolve in 5-10mL if water for administration.	A prolonged break in feeding is not required before/after administration.	The soluble tablets are not licensed for use in adults. The sachets have been administered in a much smaller volume (10mL) without blockage. There is no information on jejunal administration. If administered intrajejunally, monitor for loss of efficacy or increased side effects.
	Sachets	Dissolve the sachet in 100mL water for administration.		
	Tablets	The tablets can be crushed and dispersed in water for administration.		
Zonisamide	Oral Suspension	Shake well before use. The suspension can be given undiluted, or diluted with an equal volume of water. The tube must be flushed three times with 5mL of water after each dose.	A prolonged break in feeding is not required before/after administration.	The suspension is licensed for enteral administration. There is no information on jejunal administration. If administered intrajejunally, monitor for loss of efficacy or increased side effects.
	Capsules	The capsules can be opened and the contents dispersed in water or apple juice for administration.		

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8. Responsibilities For Implementation

Organisational:	Chief Executive and Management Teams
Corporate:	Senior Managers
Departmental:	Heads of Service/Clinical Leads
Area:	Line Managers
Hospital/Interface services:	Group Clinical Directors
Operational Management Unit:	Unit Operational Managers