

# Lincolnshire Prescribing and Clinical Effectiveness Bulletin

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## What's new this month?

- The price of nefopam 30mg tablets is escalating rapidly and now constitutes a significant financial risk within Lincolnshire primary care. New initiations of nefopam should be kept to a minimum and existing patients should be reviewed and alternatives considered (see page 3).
- *Symbicort pMDI* is a new lower cost metered dose inhaler alternative to *Symbicort Turbohaler 200/6*. The product has been approved for inclusion in the *Lincolnshire Joint Formulary*, but product switching is not advocated (see page 5).
- Despite the recent price reduction of tiotropium bromide monohydrate 2.5 microgram per puff (*Spiriva Respimat*), prescribers are not advised to switch patients from the *Spiriva Handihaler* to the *Respimat* device due to: (1) Patient and clinician preference for the *Spiriva Handihaler* due to its ease of use; and (2) Patent expiry of tiotropium in March 2016 and the imminent launch of a lower cost generic alternative to the *Handihaler* later in the year (see page 5).
- Fosfomycin trometamol 3g granules for oral solution (*Monuril*) are significantly lower in cost than the alternative fosfomycin 3g product and should be prescribed preferentially. *Monuril* is approved for use through the *Lincolnshire Joint Formulary*; designation AMBER prescribed on the advice of a microbiologist only. It should always be prescribed by brand to avoid inadvertent dispensing of the high-cost alternative product. Fosfomycin trometamol 3g granules for oral solution from Concordia International are prohibitively expensive and should no longer be prescribed; designation RED-RED (see page 7).
- Loteprednol 0.5% eye drops (*Lotemax*) are designated RED for the treatment of postoperative inflammation following ocular surgery. As the maximum treatment duration for this condition is 14 days, all of the post-operative treatment will be provided by ULH. Treatment for uveitis is longer term; it will be initiated by ULH ophthalmology with the expectation that the GP will prescribe any further supply necessary; designation AMBER following ophthalmologist initiation (see page 8).
- Budesonide 9mg sustained release gastro-resistant MMX tablet (*Cortiment*) is approved for use for the induction of remission in mild to moderate active ulcerative colitis where mesalazine is not sufficient. It should be prescribed second line as an alternative to prednisolone. It is prescribed in eight week courses that will be supplied in their entirety by ULH. It is designated RED and approved for inclusion in the *Lincolnshire Joint Formulary* (see page 9).

## CONTENTS

Page 3	<b>Review: Escalating cost of Nefopam 30mg tablets</b>
Page 5	<b>Rapid Drug Assessment: Budesonide 200microgram/formoterol 6microgram per actuation metered dose inhaler (Symbicort pMDI)</b>
Page 6	<b>Rapid Cost Comparison: Tiotropium bromide monohydrate 2.5microgram per actuation (Spiriva Respimat) price reduction</b>
Page 8	<b>Rapid Cost Comparison: Fosfomycin 3g granules (Monuril)</b>
Page 8	<b>Rapid Drug Assessment: Loteprednol etabonate 0.5% eye drops (Lotemax)</b>
Page 9	<b>Rapid Drug Assessment: Budesonide 9mg multimatrix tablets (Cortiment)</b>
Page 10	<b>NICE Technology Appraisal 404: Degarelix for treating advanced hormone-dependent prostate cancer (August 2016)</b>

## SUMMARY OF PACEF DECISIONS: SEPTEMBER 2016 UPDATE

Device, Dressing or Drug	Indication(s)	Traffic Light and Joint Formulary Status
Budesonide 9mg sustained release gastro-resistant multimatrix tablets (Cortiment) (Ferring)	For the induction of remission in mild to moderate active ulcerative colitis where mesalazine is not sufficient.	RED Approved for inclusion in the <i>Lincolnshire Joint Formulary</i> . Eight week courses will be prescribed in their entirety by ULH gastroenterology.
Budesonide/formoterol 200microgram/6microgram per actuation metered dose inhaler (Symbicort pMDI) (AstraZeneca)	Symptomatic treatment of COPD with a post-bronchodilator FEV1 <70% predicted and a history of exacerbations despite regular bronchodilator therapy.	GREEN Approved for inclusion in the <i>Lincolnshire Joint Formulary</i> .
Degarelix (Firmagon) 80mg and 120mg injection (Ferring Pharmaceuticals Ltd)	For the treatment of adult male patients with advanced hormone-dependent prostate cancer.	AMBER Included in the <i>Lincolnshire Joint Formulary</i> .
Fosfomycin trometamol 3g granules for oral solution (Monuril) (Profile Pharma Ltd)	For the treatment of acute lower uncomplicated urinary tract infections, caused by pathogens sensitive to fosfomycin in adult and adolescent females.  For prophylaxis in diagnostic and surgical transurethral procedures.	AMBER on the advice of a microbiologist only.  Approved for inclusion in the <i>Lincolnshire Joint Formulary</i> .  Always prescribe by brand name.
Fosfomycin trometamol 3g granules for oral solution (Concordia International)	For the treatment of acute lower uncomplicated urinary tract infections, caused by pathogens sensitive to fosfomycin in adult and adolescent females.  For periprocedural prophylaxis in diagnostic and surgical transurethral procedures.	RED-RED  Removed from the <i>Lincolnshire Joint Formulary</i> on the grounds of cost. A lower cost equivalent <i>Monuril</i> is now available.
Loteprednol 0.5% eye drops (Lotemax) (Bausch & Lomb)	For the treatment of postoperative inflammation following ocular surgery (licensed )  For the treatment of uveitis (unlicensed).	RED Approved for inclusion on the <i>Lincolnshire Joint Formulary</i> . All prescribing will be by ULH ophthalmology.  AMBER initiation by an ophthalmologist. Approved for inclusion on the <i>Lincolnshire Joint Formulary</i> .
Nefopam 30mg tablets	For use in acute and chronic pain including post-operative, dental, musculoskeletal, acute traumatic and cancer pain.	RED-RED Removed from the <i>Lincolnshire Joint Formulary</i> . New initiation is not recommended. Should only be prescribed if paracetamol, NSAIDs and opioids are insufficiently effective or inappropriate. Not listed as a recommended treatment on the <i>Pain Ladder for Chronic Non-</i>

		<i>Malignant Pain.</i>  AMBER without shared care within the context of ULH guidance on <i>Pain Management in Chronic Kidney Disease</i>
Tiotropium bromide 18 microgram per capsule ( <i>Spiriva Handihaler</i> ) (Boehringer Ingelheim)	For the maintenance treatment of COPD.	GREEN Included in the <i>Lincolnshire Joint Formulary</i> .
Tiotropium bromide monohydrate 2.5 microgram per puff ( <i>Spiriva Respimat</i> ) (Boehringer Ingelheim)	For the maintenance treatment of COPD.  Add-on maintenance treatment for asthma in patients receiving inhaled corticosteroids ( $\geq$ 800 microgram budesonide/day or equivalent) and long-acting beta2 agonists with $\geq$ 1 severe exacerbation in previous year.	GREEN Included in the <i>Lincolnshire Joint Formulary</i> . Now significantly lower cost than <i>Spiriva Handihaler</i> .

This *Bulletin* has been created specifically to convey details of decisions taken at the Prescribing and Clinical Effectiveness Forum (PACEF) to all stakeholders across the Lincolnshire Healthcare Community in both primary and secondary care. Back issues of the *PACE Bulletin* and other PACEF publications are available through the PACEF website (<http://lincolnshire-pacef.nhs.uk>). Electronic copies of the *PACE Bulletin* are circulated to a wide readership via email. If you are not currently on our distribution list and wish to receive regular copies of PACEF publications please contact Sandra France on [sandra.france@ardengemcsu.nhs.uk](mailto:sandra.france@ardengemcsu.nhs.uk).

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**RED-RED:** This signifies that a product is **not recommended** for prescribing in **either** primary or secondary care. All new products are classified as RED-RED pending assessment by PACEF.  
**RED:** This signifies that a product has been approved for use within secondary care, tertiary care or a primary care hosted specialist service only and **should not be routinely prescribed in primary care**. RED drugs may be used within ULHT or LPFT subject to approval for use within each Trust. ULHT and LPFT reserve the right to determine whether or not RED drugs will be used within their Trusts. RED classification does not automatically signify that a drug will be available within secondary/tertiary care.  
**AMBER:** This signifies that a drug has been approved for use in primary care **subject to specialist initiation; a shared care guideline (SCG) may also be required**. The main purpose of the SCG will be to clearly define both specialist and GP responsibilities. Not all AMBER drugs that require SCGs are currently covered by formal documents; PACEF are working to rectify this.  
**GREEN:** This signifies a product that is **approved for initiation in either primary or secondary care**.

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## **REVIEW: ESCALATING COST OF NEFOPAM 30MG TABLETS**

**The price of nefopam 30mg tablets is escalating rapidly and now constitutes a significant financial risk within Lincolnshire primary care. New initiations of nefopam should be kept to a minimum and existing patients should be reviewed and alternatives considered.**

Nefopam is a centrally acting, non-opioid analgesic licensed for use in acute and chronic pain, including post-operative, dental, musculoskeletal, acute traumatic and cancer pain. Historically, it has been used for persistent pain unresponsive to other non-opioid analgesics. A Cochrane review of nefopam failed to find trial evidence of sufficient quality or quantity to recommend its use for chronic pain or acute post-operative pain. Limited evidence of benefit in on-going inflammatory pain associated with rheumatoid arthritis was off-set by disbenefit linked to a poor adverse event profile.

Nefopam is associated with both antimuscarinic and antihistaminergic side effects including nausea, sweating, dizziness, vomiting, hallucinations, confusion, urinary retention,

headache, insomnia, tachycardia, palpitations, convulsions and anaphylaxis. A Cochrane meta-analysis showed that 27% of patients report nausea, sweating, insomnia, pruritis and/or malaise when the drug is used for 4 consecutive weeks. Tachycardia is relatively common (Number Needed to Harm = 7), making nefopam a poor choice in patients with ischaemic heart disease.

Nefopam is extensively metabolised with less than 5% of a dose excreted unchanged in the urine. This means that dosage adjustments are not necessary in renal patients, although reduced metabolism and excretion can increase susceptibility to side effects and necessitate careful initiation and dose titration. As a result of this, a very limited role for nefopam in combination with paracetamol is acknowledged within ULH guidance on *Pain Management in Chronic Kidney Disease*. Repeated or chronic administration should be avoided in end stage renal disease and in patients on dialysis.

Despite the fact that nefopam is a relatively minor product, escalating prices have made it a significant cost issue in primary care. The following table illustrates the quarterly cost of nefopam in each of the Lincolnshire CCGs in April to June 2015 compared to the same quarter in 2016 and reveals a six-fold increase in cost over the period. Alarmingly, the annual cost of nefopam 30mg tablets across Lincolnshire primary care is now approaching £700,000.

CCG	Actual Cost: April to June 2015	Actual Cost: April to June 2016
Lincolnshire East CCG	£9,508	£61,074
Lincolnshire West CCG	£14,162	£85,767
South Lincolnshire CCG	£1,333	£10,581
South West Lincolnshire CCG	£2,983	£16,279
Lincolnshire	£27,986	£173,701

A cost comparison reveals the huge difference in cost between the alternative options:

Drug	Dose	Cost (28 days)
Ibuprofen 400mg tablets	400mg three times daily	£3.89
Naproxen 250mg tablets	250mg three times daily	£2.70
Tramadol 50mg capsules	Two every six hours	£6.50
Co-codamol 30/500 tablets (Zapain)	Two every six hours	£6.79
Dihydrocodeine 30mg tablets	Two every six hours	£9.36
Codeine 30mg tablets	Two every six hours	£8.96
<b>Nefopam 30mg tablets</b>	<b>One three times daily</b>	<b>£59.82</b>
	<b>Two three times daily</b>	<b>£119.64</b>

**PACEF Recommendation:**

Following review, nefopam 30mg tablets are re-designated from GREEN to RED-RED and are no longer approved for use through the *Lincolnshire Joint Formulary*. All existing patients should be reviewed and moved to an alternative therapy wherever possible. New initiations should be restricted to exceptional circumstances only, for example when paracetamol, NSAIDs and opioids are considered insufficiently effective or inappropriate. A very limited role for nefopam in combination with paracetamol is acknowledged within ULH guidance on *Pain Management in Chronic Kidney Disease Patients* and the product remains AMBER without shared are within this context.

**RAPID DRUG ASSESSMENT: BUDESONIDE 200 MICROGRAM /FORMOTEROL 6 MICROGRAM PER ACTUATION METERED DOSE INHALER (SYMBICORT PMDI)**

***Symbicort pMDI* is a new lower cost metered dose inhaler alternative to *Symbicort Turbohaler 200/6*. The product has been approved for inclusion in the *Lincolnshire Joint Formulary*, but product switching is not advocated.**

AstraZeneca have recently launched a metered dose inhaler formulation of the budesonide 200microgram/formoterol 6microgram combination under the brand name of *Symbicort pMDI*. The product is licensed in adults for the symptomatic treatment of COPD with a post-bronchodilator forced expiratory volume in 1 second (FEV1), <70% predicted and an exacerbation history despite regular bronchodilator therapy. It has been introduced to provide an alternative MDI equivalent to the dry powder device, *Symbicort 200/6 Turbohaler*. The MDI offers a specially designed cap to reduce the risk of accidental activation and potential waste; an easy view dose counter on the top of the canister is also designed to support patient compliance. The device is compatible with the *Aerochamber*, but not the *Haleraid*.

Supporting evidence for the pMDI comes from three clinical studies, all published between 2008 and 2012. The studies demonstrate effectiveness in the treatment of moderate to severe COPD and good tolerability; there is no published evidence supporting the use of the product in the treatment of asthma. The active comparators used in the trials were: formoterol dry powder device and budesonide pMDI (vs placebo); there is no direct comparative evidence against any strength of *Symbicort Turbohaler*.

A cost comparison with equivalent products reveals *Symbicort pMDI* as the lowest cost option:

<b>Drug</b>	<b>Indications</b>	<b>Daily dose</b>	<b>Cost</b>
Budesonide/formoterol 200microgram/ 6microgram per actuation metered dose inhaler ( <i>Symbicort pMDI</i> ) (AstraZeneca)	Symptomatic treatment of COPD with a post-bronchodilator FEV1 <70% predicted and a history of exacerbations despite regular bronchodilator therapy.	2 puffs twice daily	£28.00 (120 puffs)

<p>Budesonide/formoterol 200microgram/ 6microgram per Inhalation breath-actuated dry powder inhaler (<i>Symbicort 200/6 Turbohaler</i>) (AstraZeneca)</p>	<p>Regular treatment of asthma where long acting beta2 agonist and inhaled corticosteroid is appropriate.</p> <p>Symptomatic treatment of COPD with a post-bronchodilator FEV1 &lt;70% predicted and a history of exacerbations despite regular bronchodilator therapy.</p>	<p>1-2 inhalations twice daily</p>	<p>£38.00 (120)</p>
<p>Budesonide/formoterol 200microgram/ 6microgram per Inhalation breath-actuated dry powder inhaler (<i>DuoResp Spiromax 160/4.5</i>) (Teva)</p>	<p>Regular treatment of asthma where long acting beta2 agonist and inhaled corticosteroid is appropriate.</p> <p>Symptomatic treatment of COPD with a post-bronchodilator FEV1 &lt;70% predicted and a history of exacerbations despite regular bronchodilator therapy.</p>	<p>2 inhalations twice daily</p>	<p>£29.97(120)</p>

**PACEF Recommendation**

In view of the fact that other products in the *Symbicort* range are available on the *Lincolnshire Joint Formulary* and that the *Symbicort pMDI* is lower cost than alternatives, PACEF felt that it would unreasonable not to approve this product for inclusion in the *Formulary*; designation: GREEN. However, there are reservations: (1) Only one strength of the product is available with no apparent plans to widen the range; (2) The product is only licensed for the treatment of COPD with no apparent plans to widen the license to include asthma; (3) There is no comparative data versus *Symbicort Turbohaler*. As a result of this, PACEF will not be advocating review and possible switch of appropriate *Symbicort Turbohaler* patients to *Symbicort pMDI*. Many practices have already implemented the switch from *Symbicort Turbohaler* to *DuoResp Spiromax* or are in the process of doing so; this remains the preferred PACEF strategy in terms of improving cost-effectiveness of treatment for these patients.

**RAPID COST COMPARISON: TIOTROPIUM BROMIDE MONOHYDRATE 2.5MICROGRAM PER ACTUATION (SPIRIVA RESPIMAT) PRICE REDUCTION**

Despite the recent price reduction of tiotropium bromide monohydrate 2.5 microgram per puff (*Spiriva Respimat*), prescribers are not advised to switch patients from the *Spiriva Handihaler* to the *Respimat* device due to: (1) patient and clinician preference for the *Spiriva Handihaler* due to its ease of use; and (2) patent expiry of tiotropium in

**March 2016 and the imminent launch of a lower cost generic alternative to the *Handihaler* later in the year.**

Boehringer Ingelheim have announced a significant price reduction for the tiotropium bromide monohydrate 2.5 microgram per puff *Spiriva Respimat* device which has rendered it significantly less costly than its sibling product tiotropium bromide 18 microgram per dose *Spiriva Handihaler* (see cost comparison)

<b>Drug</b>	<b>Indications</b>	<b>Daily dose</b>	<b>Cost</b>
Tiotropium bromide monohydrate 2.5 microgram per puff <i>Spiriva Respimat</i> (Boehringer Ingelheim)	For the maintenance treatment of COPD.  Add-on maintenance treatment for asthma in patients receiving inhaled corticosteroids ( $\geq$ 800 microgram budesonide/day or equivalent) and long-acting beta <sub>2</sub> agonists with $\geq$ 1 severe exacerbation in previous year.	Two puffs once daily	£23.00 (60 puff cartridge plus <i>Respimat</i> device)
Tiotropium bromide 18 microgram per capsule <i>Spiriva Handihaler</i> (Boehringer Ingelheim)	For the maintenance treatment of COPD.	Inhale contents of one capsule once daily	£34.87 (30 caps plus <i>Handihaler</i> )
Tiotropium bromide 18 microgram per capsule <i>Spiriva Handihaler</i> (Boehringer Ingelheim)	For the maintenance treatment of COPD.	Inhale contents of one capsule once daily	£33.50 (refill)

Reference:  
MIMS, September 2016.

Such a significant price reduction has the potential to deliver efficiency savings of over £10.50 per patient per month if patients are switched from the *Handihaler* to the *Respimat* device with a total potential annual saving of £857,850 across the four Lincolnshire CCGs.

However, the recent patent expiry on tiotropium hard capsules has opened the UK market place to new generic tiotropium products with the expectation that the first of these will arrive by Christmas 2016. In addition, advice from local respiratory specialists is that the *Respimat* device can be difficult to use as it requires a relatively high level of dexterity, strength and coordination both to prime the device and to administer a dose. In general, local preference is for the *Handihaler* device and this is borne out by significantly higher prescribing volume of *Handihaler* (86% of items) compared to *Respimat* (14%).

**PACEF Recommendation:**

**Both tiotropium bromide 18 microgram per capsule *Spiriva Handihaler* and tiotropium bromide monohydrate 2.5 microgram per puff *Spiriva Respimat* are approved for use through the *Lincolnshire Joint Formulary*; designation: GREEN. PACEF recognise the recent price reduction of *Spiriva Respimat*, but are not inclined to encourage product switching from *Spiriva Handihaler* at this stage due to: (1) patient and clinician preference for the *Spiriva Handihaler* due to its ease of use; and (2) patent expiry of tiotropium in March 2016 and the imminent launch of a lower cost generic alternative to the *Handihaler* later in the year. As a result of this, prescribers are advised not to move patients from *Spiriva Handihaler* to an alternative device at this stage.**

### **RAPID COST COMPARISON: FOSFOMYCIN 3G GRANULES (MONURIL)**

**A new lower cost fosfomycin 3g granule preparation (Monuril) is now available through the *Lincolnshire Joint Formulary*; designation AMBER prescribed on the advice of a microbiologist only. It should always be prescribed by brand to ensure that the lower cost product is dispensed.**

Fosfomycin 3g granules for oral solution are available through the *Lincolnshire Joint Formulary* for the treatment of uncomplicated lower urinary tract infections caused by multiple antibacterial resistant organisms when other antibacterials cannot be used; designation AMBER on the advice of a microbiologist only. *Monuril* is a new lower cost branded version of the product previously only available from Concordia International (previously known as Amdipharm Mercury Company (AmCo) Limited) (see cost comparison).

<b>Product</b>	<b>Indication</b>	<b>Dose</b>	<b>Cost (£)</b>
Fosfomycin trometamol 3g granules for oral solution (Monuril) (Profile Pharma Ltd)	For the treatment of acute lower uncomplicated urinary tract infections, caused by pathogens sensitive to fosfomycin in adult and adolescent females.  For prophylaxis in diagnostic and surgical transurethral procedures.	1x 3g sachet once	£4.86
Fosfomycin trometamol 3g granules for oral solution (Concordia International)	For the treatment of acute lower uncomplicated urinary tract infections, caused by pathogens sensitive to fosfomycin in adult and adolescent females.  For periprocedural prophylaxis in diagnostic and surgical transurethral procedures.	1 x 3g sachet once	£75.45

#### **PACEF Recommendation:**

**Fosfomycin trometamol 3g granules for oral solution (*Monuril*) are significantly lower in cost than the alternative fosfomycin 3g product and should be prescribed preferentially. *Monuril* is approved for use through the *Lincolnshire Joint Formulary*; designation AMBER prescribed on the advice of a microbiologist only. It should always be prescribed by brand to avoid inadvertent dispensing of the high-cost alternative product. Fosfomycin trometamol 3g granules for oral solution from Concordia International are prohibitively expensive and should no longer be prescribed; designation RED-RED and removed from the *Lincolnshire Joint Formulary*.**

### **RAPID DRUG ASSESSMENT: LOTE Prednol ETABONATE 0.5% EYE DROPS (LOTEMAX)**

Loteprednol etabonate 0.5% eye drops (*Lotemax*) is an ocular steroid preparation licensed for the treatment of postoperative inflammation following ocular surgery. All of the other ocular steroids on *Formulary* hold a more general marketing authorisation for non-infected inflammatory ocular conditions. Loteprednol is licensed for a maximum duration of 14 days treatment; use beyond 14 days and for longer-term conditions such as uveitis is unlicensed.

Loteprednol 0.5% eye drops were requested by ULH ophthalmologists for use in a small

number of patients each year with inflammatory conditions of the eye or post-ocular surgery who have raised intra-ocular pressure. A review of the trial evidence confirms that loteprednol is significantly better than placebo in the management of ocular inflammation. There is also limited evidence comparing loteprednol with other corticosteroid eye drops suggesting that it is associated with less of an increase in intraocular pressure.

A cost comparison reveals that loteprednol 0.5% eye drops (*Lotemax*) is significantly higher in cost than alternative ocular steroids:

Product	Indications	Pack size	Cost
Loteprednol 0.5% eye drops ( <i>Lotemax</i> ) (Bausch & Lomb)	For the treatment of postoperative inflammation following ocular surgery.	5ml	£5.50
Prednisolone 1% eye drops ( <i>Pred Forte</i> ) (Allergan)	For the short-term treatment of non-infected inflammatory eye conditions.	5ml 10ml	£1.82 £3.66
Dexamethasone 0.1% eye drops ( <i>Maxidex</i> ) (Alicon)	For inflammation of the anterior segment.	5ml 10ml	£1.42 £2.80
Betamethasone 0.1% drops ( <i>Betnesol</i> )	For non-infected inflammatory conditions.	10ml	£2.32
Fluorometholone 0.1% eye drops ( <i>FML</i> ) (Allergan)	For non-infected inflammatory ocular conditions.	5ml 10ml	£1.71 £2.95

**PACEF Recommendation:**

**Loteprednol 0.5% eye drops (*Lotemax*) are designated RED for the treatment of postoperative inflammation following ocular surgery. As the maximum treatment duration for this condition is 14 days, all of the post-operative treatment will be provided by ULH. Treatment for uveitis is longer term; it will be initiated by ULH ophthalmology with the expectation that the GP will prescribe any further supply necessary; designation AMBER following ophthalmologist initiation.**

**RAPID DRUG ASSESSMENT: BUDESONIDE 9MG MULTIMATRIX TABLETS (*CORTIMENT*)**

Budesonide 9mg sustained release gastro-resistant tablet (*Cortiment*) is the only oral budesonide product licensed specifically for treatment of ulcerative colitis (see table below). The multimatrix (MMX) formulation is taken orally but exerts its action topically on the colon. The tablets have a gastro-resistant coating that dissolves in lower intestinal fluids with a pH of more than 7 where the multimatrix system releases budesonide at a controlled rate throughout the colon minimizing systemic absorption of steroid.

In common with other budesonide preparations, *Cortiment* is 10 times more expensive than oral prednisolone, which remains the preferred first line treatment.

A 2015 Cochrane review of oral budesonide for the induction of remission in ulcerative colitis concluded that there is moderate quality evidence to support the use of budesonide MMX at a 9mg dose for induction of remission in active ulcerative colitis, particularly in patients with left-sided colitis. It appears to be safe, and does not lead to significant impairment of adrenocorticoid function compared to placebo.

The table below confirms that *Cortiment* is the only budesonide formulation that is licensed for ulcerative colitis and that the product is not significantly different in cost to alternative budesonide preparations for Crohn's disease:

Product	Indications	Cost	Cost of an 8 week course
Budesonide 9mg sustained release gastro-resistant tablets ( <i>Cortiment</i> ) (Ferring)	For the induction of remission in mild to moderate active ulcerative colitis where mesalazine is not sufficient.	£75.00 (30)	£140
Budesonide 3mg gastro-resistant sustained release capsules ( <i>Entocort CR</i> ) (Tillotts)	For mild to moderate Crohn's disease affecting the ileum or ascending colon.	£99.00 (100)	£166.32
Budesonide 3mg gastro-resistant capsules ( <i>Budenofalk</i> ) (Dr Falk)	For mild to moderate Crohn's disease affecting the ileum or ascending colon. For collagenous colitis. For autoimmune hepatitis.	£75.05 (100)	£126.08

There is potential for confusion between these three products at both the prescribing and dispensing stage. Patients should be carefully counselled and provided with appropriate advice to ensure that they are aware of the dosing schedule of their medication. This is particularly important for patients previously prescribed a budesonide product for which the number of capsules/tablets taken was different.

*Cortiment* is contraindicated in patients with a soya or peanut allergy; *Budenofalk* and *Entocort CR* do not contain peanut oil and are not contraindicated within this context.

**PACEF Recommendation:**

**Budesonide 9mg sustained release gastro-resistant MMX tablet (*Cortiment*) is approved for use for the induction of remission in mild to moderate active ulcerative colitis where mesalazine is not sufficient. It should be prescribed second line as an alternative to prednisolone. It is prescribed in eight week courses that will be supplied in their entirety by ULH. It is designated RED and approved for inclusion in the *Lincolnshire Joint Formulary*.**

**NICE TECHNOLOGY APPRAISAL TA404: DEGARELIX FOR TREATING ADVANCED HORMONE-DEPENDENT PROSTATE CANCER (AUGUST 2016)**

**Key Recommendations**

- Degarelix is recommended as an option for treating advanced hormone dependent prostate cancer in people with spinal metastases, only if the commissioner can achieve at least the same discounted drug cost as that available to the NHS in June 2016.

Degarelix (*Firmagon*) 80mg and 120mg injection are licensed for the treatment of adult male patients with advanced hormone-dependent prostate cancer.

**PACEF Recommendation**

**Degarelix (*Firmagon*) 80mg and 120mg injection is already designated AMBER and available through the *Lincolnshire Joint Formulary* for this indication.**

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