Recommendations for the Prescribing of Lubiprostone

Summary

Lubiprostone is recommended as a treatment option for treating chronic idiopathic constipation, that is for adults in whom treatment with at least 2 laxatives from different classes, at the highest tolerated recommended doses for at least 6 months, has failed to provide adequate relief and for whom invasive treatment is being considered.

It is recommended for initiation by primary or secondary care in accordance with the treatment pathway outlined below.

NICE issued TA 138 in July 2014 with the following recommendations for the use of lubiprostone:

1.1 Lubiprostone is recommended as an option for treating chronic idiopathic constipation, that is, for adults in whom treatment with at least 2 laxatives from different classes, at the highest tolerated recommended doses for at least 6 months, has failed to provide adequate relief and for whom invasive treatment for constipation is being considered.

1.2 If treatment with lubiprostone is not effective after 2 weeks, the person should be re-examined and the benefit of continuing treatment reconsidered.

1.3 Lubiprostone should only be prescribed by a clinician with experience of treating chronic idiopathic constipation, who has carefully reviewed the person's previous courses of laxative treatments specified in 1.1

Comparative Treatments

The only comparative treatment is prucalopride which has the same NICE recommendation as above, except that it is only licensed for use in women. The recommended trial of treatment is 4 weeks as opposed to 2 weeks for lubiprostone.

- Lubiprostone has a different mechanism of action to prucalopride, as it activates chloride channels in gastrointestinal epithelial cells, relieving symptoms of chronic constipation by improving intestinal secretion.

- Prucalopride is a selective serotonin 5HT 4 receptor agonist with prokinetic properties.

<table>
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<tr>
<th>Drug</th>
<th>Dose</th>
<th>Cost for 28 dys</th>
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<tbody>
<tr>
<td>Lubiprostone</td>
<td>24mcg bd</td>
<td>£53.48</td>
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<td></td>
<td>24mcg od (mod - severe hepatic impairment)</td>
<td>£29.68</td>
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<tr>
<td>Prucalopride</td>
<td>1mg daily (over 65 yrs starting dose)</td>
<td>£38.69</td>
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<tr>
<td></td>
<td>2mg daily</td>
<td>£59.52</td>
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</tbody>
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Integrated Care Pathway for Chronic Idiopathic Constipation
Not to be used in <18 years of age or in pregnancy

Take patient history and physical examination
Alarm Features
- Weight Loss
- Blood in stool
- Anaemia
- Sudden change in bowel habit after the age of 50 years old
- Significant abdominal pain
- Family history of colon cancer or IBD

No Alarm features present
Consider lifestyle management
- Increase exercise
- Increase dietary fibre intake
- Increase fluid intake

Also if patient is on constipating drugs, try stopping drugs if possible

Patient not responding to lifestyle management
Initiate laxative treatment
Has the patient tried at least 2 laxatives from different classes, at the highest tolerated recommended doses for at least 6 months

Those patients not responding to Laxative treatment

Alarm features present
Consider referral to secondary care

Patient not responding to Prucalopride
Consider switch to Prucalopride (5-HT4 activator)
Licensed in adult women over the age of 18 years for the symptomatic treatment of Chronic Constipation in whom laxatives fail to provide adequate relief.
- One 2mg tablet once daily (1mg if >65 years old or has severe hepatic or renal impairment)
- Treatment for 28 days (evaluate benefit at 4 weeks). Continue with ongoing treatment if a suitable response is seen (>3 SBMs per week)

Female Patient
Patient not responding to Lubiprostone after 2 weeks
Initiate Lubiprostone (Amitiza) – Chloride channel – 2 (CLC-2) activator
Licensed for the treatment of Chronic Idiopathic Constipation and associated symptoms in adults (men and women) over the age of 18 years old when response to diet or other non-pharmacological measures (e.g. educational measures, physical activity) are inappropriate.
- One 24mcg capsule with food. If tolerated but adequate response not seen, the dose can be increased to the full dosing of one 24mcg capsule twice daily with food
- A course of treatment is 4 weeks. If no response is seen, refer to secondary care

Male Patient

Ref: Tack, Neurogastroenterol Motil (2011) 23, 697–710
Ref: Prucalopride (Resolor) SPC, NICE Technology Appraisal TA211
Ref: Lubiprostone (Amitiza) SPC

The information is issued for guidance and advice only. Always read the full summary of Product Characteristics for any drug or class of drug mentioned.

Approved by: East Kent Prescribing Group (Representing Ashford CCG, Canterbury and Coastal CCG, South Kent Coast CCG and Thanet CCG)
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