LINACLOTIDE – Prescribing Support (December 2015)

- Linaclotide is licensed for the symptomatic treatment of moderate to severe irritable bowel syndrome with constipation (IBS-C) in adults.
- Treatment should be initiated only by a hospital consultant.
- The most frequently occurring adverse effect is diarrhoea.
- No specific monitoring is recommended as part of this therapy.

Licensed Indication
Linaclotide is licensed for the symptomatic treatment of moderate to severe irritable bowel syndrome with constipation (IBS-C) in adults.

Dosage
Linaclotide 290mg ONE capsule once a day.
Take 30 minutes before a meal.

Starting Criteria
Treatment should be initiated only by a hospital consultant* when the patient has:

- A confirmed diagnosis by hospital specialist of IBS-C.
- Failed at least 2 previous laxatives from different classes (maximum tolerated doses) over a period of at least 6 months.
- Constipation for more than 12 months

Efficacy will be reviewed at 4 weeks after initiation by the hospital specialist. If there is a beneficial effect it is anticipated treatment will be continued in primary care.

* A specialist registrar may also request continued prescribing by a GP but it should clearly state in their communication, e.g. letter, that this has been discussed with a hospital consultant.

Stopping Criteria
It is recommended that treatment is reviewed initially at 3 months and thereafter annually by the GP for efficacy and tolerability.

Treatment should continue for at least 12 months or longer if the patient has:

- on-going spontaneous bowel motions (greater than at the time linaclotide was initiated)
- reduction in abdominal pain

Treatment should be stopped if the patient has:

- less than TWO spontaneous bowel movements per week AND/OR no improvement in abdominal pain
- tolerability issues due to adverse effects, e.g. diarrhoea.

Contraindications
Hypersensitivity to linaclotide or to any of the excipients listed in the Summary of Product Characteristics. Patients with known or suspected mechanical gastrointestinal obstruction.

Drug Interactions
No drug-drug interaction studies have been performed. However, in vitro studies have shown that linaclotide does not affect the cytochrome P450 enzyme system.

Concomitant treatment with proton pump inhibitors, laxatives or NSAIDs may increase the risk of diarrhoea.

In cases of severe or prolonged diarrhoea, absorption of other oral medicinal products may be affected. The efficacy of oral contraceptives may be reduced and the use of an additional contraceptive method is recommended to prevent possible failure of oral contraception (see oral contraceptive prescribing information).

Caution should also be exercised when prescribing medicinal products absorbed in the intestinal tract with a narrow therapeutic index such as levothyroxine as their efficacy may be reduced.
Adverse effects
The most frequently reported adverse effect associated with linaclotide is diarrhoea, mainly mild to moderate in intensity, occurring in less than 20% of patients.

In rare and more severe cases, this may – as a consequence – lead to the occurrence of dehydration, hypokalaemia, blood bicarbonate decrease, dizziness, and orthostatic hypotension.

Patients should be made aware of the possible occurrence of diarrhoea during treatment. They should inform their GP if severe or prolonged diarrhoea occurs.

Should prolonged (e.g. more than 1 week) or severe diarrhoea occur linaclotide may be temporarily discontinued until the episode is resolved. Additional caution should be exercised in patients who are prone to a disturbance of water or electrolyte balance (e.g. elderly, patients with CV diseases, diabetes, hypertension), and electrolyte control should be considered.

Other common adverse reactions (>1%) were abdominal pain, abdominal distension and flatulence.

Monitoring
No specific monitoring is required but see information regarding diarrhoea in the ‘adverse effects’ section.

References
- Stockley’s Drug Interactions (online) Accessed 27.11.15 via https://www.medicinescomplete.com