Colesevelam

Colesevelam *(Cholestagel®)* (*TLS Amber with shared care*) 'Off label'

Shared Care Guidelines: For the treatment of bile salt malabsorption where colestyramine has been ineffective (off-label use of Colesevelam)

AREAS OF RESPONSIBILITY FOR THE SHARING OF CARE

This shared care agreement outlines suggested ways in which the responsibilities for managing the prescribing of Colesevelam for the treatment of diarrhoea associated with bile salt malabsorption, can be shared between the specialist and general practitioner (GP). GPs are **invited** to participate. If the GP is not confident to undertake these roles, then he or she is under no obligation to do so. In such an event, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist. If a specialist asks the GP to prescribe this drug, the GP should reply to this request as soon as practicable.

Sharing of care assumes communication between the specialist, GP and patient. The intention to share care is usually explained to the patient by the doctor initiating treatment. It is important that patients are consulted about treatment and are in agreement with it. Patients with the condition are under regular specialist follow-up, which provides an opportunity to discuss drug therapy.

The doctor who prescribes the medication legally assumes clinical responsibility for the drug and the consequences of its use.

RESPONSIBILITIES and ROLES

Specialist (consultant gastroenterologist) responsibilities

1 Assess the patient as clinically appropriate for treatment with colesevelam and provide any necessary monitoring during the first month of treatment.

2 Complete baseline tests where appropriate, including serum triglyceride levels. (The safety of colesevelam has not been established in patients with serum triglyceride levels >3.4mmol/L so caution is advised)

3 Initiate treatment and provide at least 28 days' supply.

4 Discuss the benefits and side effects of treatment with the patient.

5 Review concurrent medications, potential for interactions and practicality of dosing colesevelam to allow 4 hours before/after other medications.

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6 Ask the GP whether he or she is willing to participate in shared care, and agree with the GP as to who will discuss the shared care arrangement with the patient.

7 Supply GP with summary within 14 days of a hospital out-patient review or in-patient stay.

8 Provide monitoring details

9 Review the patient's condition and monitor response to treatment regularly where indicated.

10 Give advice to the GP on when to stop treatment.

11 Report adverse events to the MHRA

12 Ensure that clear backup arrangements exist for GPs to obtain advice and support.

General Practitioner responsibilities

1 Reply to the request for shared care as soon as practicable.
2 Prescribe the medicine at the dose recommended.
3 Refer promptly to the specialist when any loss of clinical efficacy is suspected (e.g. worsening of disease-related symptoms) or intolerance to therapy occurs.
4 Review any newly prescribed medications for interactions and practicality of dosing to allow 4 hours before/after other medications.
5 Report to and seek advice from the specialist on any aspect of patient care that is of concern to the GP and may affect treatment.
6 Stop treatment on the advice of the specialist.
7 Report adverse events to the specialist and MHRA.

Patient's role

1 Report to the specialist or GP if he or she does not have a clear understanding of the treatment.
2 Share any concerns in relation to treatment with medicine.
3 Report any adverse effects to the specialist or GP whilst taking the medicine.

BACK-UP ADVICE AND SUPPORT

Contact details	Telephone No.	Extn:	Fax:	Email address:
Specialist: Dr A Tanner Dr A Jamil Dr S Vyas Dr C Blanshard	01722 336262 O1722 336262 01722 336262 01722 336262	2034 2034 2034		Andrewtanner@nhs.net Aqeel.Jamil@nhs.net sam.vyas1@nhs.net Christine.blanshard@nhs.net
Medicines Information ((at Southampton Hospital)	023 8120 6908/9			

SUPPORTING INFORMATION

Summary of condition and indications

Colesevelam is indicated for:

- The treatment of diarrhoea related to bile acid malabsorption in patients who have failed treatment with colestyramine or other first line therapy
- Note that this is an off-label use of Colesevelam

Treatment Aims (Therapeutic plan)

Colesevelam is a bile acid sequestrant that forms a polymeric gel in the gastrointestinal tract which binds bile in the small bowel preventing the secretory actions of bile acids in the colon. The available evidence summarised by NICE (ESUOM22, 2013) summarises that there may be a role for colesevelam in reducing diarrhoea associated with bile acid malabsorption, although evidence from high quality RCTs is limited.

Treatment Schedule (including dosage and administration)

Colesevelam is available as 625mg tablets, the usual dose is 1.25 – 3.75g daily in two divided doses. The dose is often titrated according to response.
Treatment should be stopped after one month if there is a lack of response; if a patient has responded within one month colesevelam may be continued on an ongoing basis

Contra-indications and precautions for use

1. History of allergy or anaphylaxis to colesevelam or any of the excipients
2. History of bowel or biliary obstruction
3. Serum triglyceride level >3.4mmol/L
4. The safety and efficacy of Cholestagel in patients with dysphagia, swallowing disorders, severe gastrointestinal motility disorders, inflammatory bowel disease, liver failure or major gastrointestinal tract surgery have not been established. Consequently, caution should be exercised when Cholestagel is used in patients with these disorders.
5. Risk of constipation should be especially be considered in patients with coronary artery disease or angina pectoris

Side-effects

Refer to the SPC for a full list of adverse effects.

Very common: Flatulence, constipation

Common: Headache, vomiting, diarrhaoea, dyspepsia, abdominal pain, nausea, abdominal distension, abnormal stools, increased serum triglycerides
Uncommon: Dysphagia, myalgia, serum transaminases increased
Very rare: Pancreatitis
Not known: Intestinal obstruction – incidence likely to be increased in patients with a history of bowel obstruction or removal and colesevelam is contraindicated in these patients (see Contraindications above)
Colesevelam was launched in March 2004 and no longer has black triangle (▼) status. Serious suspected reactions (even if well recognised or causal link uncertain) should be reported to the MHRA

Monitoring

Parameter	Frequency of monitoring	Action (adjustment and referral back to hospital)
Fasting Lipids (including triglycerides)	Annually	Refer to specialist if >3.4mmol/L

Colesevelam may also lead to impaired absorption of fat soluble vitamins (A, D, E and K). This was not clinically significant in studies of up to 1 year so routine monitoring is not indicated. If a patient is susceptible to fat soluble vitamin deficiency referral to or discussion with specialist may be appropriate.

Drug Interactions

See BNF Appendix 1 for list of interactions

Clinically significant interactions include:
Ciclosporin, anticoagulants, oral contraceptives, metformin (modified release pre>

Patients should be reminded to take colesevelam at least 4 hours before or after any concomitant medication to reduce the risk of that medication not being absorbed

Cost

At current prices 180 colesevelam 625mg tablets costs £115.32. Monthly cost is dependent on the dose prescribed.

References

SPC for Cholestagel, Sanofi, last updated 13/06/2017 http://www.medicines.org.uk/emc/medicine/20298

BNF Online accessed July 2017 via medicinescomplete.com

NICE Evidence Summary 22 Bile acid malabsorption: colesevelam. October 2013
https://www.nice.org.uk/advice/esuom22/chapter/Key-points-from-the-evidence

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