

Lactase (Colief®), simeticone (Dentinox Colic Drops® and Infacol®) and gripe water in the management of infantile colic

This briefing provides the rationale for restricting or stopping the supply of infantile colic products on NHS prescriptions, and advising parents of their limited roles in managing infantile colic. Further bulletins, including the DROP-List (Drugs to Review for Optimised Prescribing),¹ are available on the PrescQIPP website.

Background

Infantile colic is defined for clinical purposes as repeated episodes of excessive and inconsolable crying in an infant that otherwise appears to be healthy and thriving.² The underlying cause of infantile colic is unknown, but a range of potential mechanisms and suggested treatments have been proposed.^{2,3} Proposed treatments include Colief®, a dietary supplement (not a licensed medicine) containing the enzyme lactase, which is added to breast milk or infant formula to reduce its lactose content,⁴ and simeticone, an antifoaming agent aimed at relieving wind.^{5,6} Gripe water has traditionally been used for colic,⁷ although it is not licensed for this indication.^{8,9}

Additional resources available:



Bulletin



Data pack



Patient letter, audit

<http://www.prescqipp.info/resources/viewcategory/337-infantile-colic-drop-list>

Recommendations

- The most useful intervention for infantile colic is support for parents and reassurance that infantile colic will resolve. Only consider other remedies if parents feel unable to cope despite advice and reassurance.²
- Other remedies for infantile colic could include a trial of lactase (Colief®) or simeticone (Dentinox Colic Drops® and Infacol®). Treatment should be stopped if there is no response after one week.²
- Colief® is classified as a Borderline Substance.¹⁰
- Parents of infants that do not meet the ACBS approved indication* should be advised to buy Colief® over the counter if they want to try it. They should be made aware that the evidence supporting Colief® is limited.^{11,12}
- Simeticone (Infacol® or Dentinox Colic Drops®) is readily available from pharmacies and other retail outlets.
- Parents wishing to try it should be advised to purchase it over the counter. They should be made aware that there is currently no convincing evidence that simeticone treatment helps^{13,14} but that some parents like to try it and assess their baby individually for signs of benefit.
- Gripe water should not be prescribed for infantile colic as it is not licensed for this condition.^{8,9}

*For the relief of symptoms associated with lactose intolerance in infants, provided that lactose intolerance is confirmed by the presence of reducing substances and/or excessive acid in stools, a low concentration of the corresponding disaccharide enzyme on intestinal biopsy or by breath hydrogen test or lactose intolerance test.¹⁰

Costs and savings available

Nationally over £1 million was spent on lactase (Colief®), simeticone (Dentinox Colic Drops® and Infacol®) and gripe water over the course of a year (Feb - Apr 2015).

Prescribing 80% less of these products would save almost £811,000 in England over 12 months. This equates to savings of £1,421 per 100,000 patients.

Evidence

There is some limited evidence from two small studies that adding lactase to breast milk or infant formula to lower the lactose content may be of benefit if the lactase is given time to incubate in the milk before the feed is given.^{11,12} However, studies that have shown any positive effect of lactase on colic symptoms have pre-treated the milk of formula-fed infants with lactase in a way that can not be recommended currently; the Department of Health recommend that formula feeds should be freshly made up as needed, and only be made in advance and stored if there is no choice.¹⁵ Out of three randomised controlled trials of simeticone for the treatment of colic, only one small study of 26 infants showed any possible benefit,^{2,13} and a systematic review rated the methodological quality of this study as insufficient.¹⁴ When the data was pooled no significant difference between simeticone and placebo was seen.¹⁴ A more recent systematic review similarly concluded that the evidence did not support simeticone treatment for infantile colic.¹⁶

The use of gripe water is not supported by clinical trial evidence,¹⁷ and it is not licensed for the treatment of colic.^{8,9} It has a significant sodium content¹⁸ so cannot be viewed as a placebo.

References

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