



PAN MERSEY AREA PRESCRIBING COMMITTEE

PRESCRIBING POLICY STATEMENT

FIRST APC BOARD DATE: 05 NOV 2014

LAST APC BOARD DATE: 27 MAR 2019

**PENDING CCG APPROVAL**



**Pan Mersey**

Area Prescribing Committee

## LACTASE ENZYME drops 50,000 units/g (Colief®)

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**The Pan-Mersey Area Prescribing Committee recommends that Lactase Enzyme Drops 50,000 units/g (Colief®) are not prescribed on the NHS. Patients are advised to purchase Colief® if they wish.**

In individual patients where lactose intolerance is a longer-term condition and it has been confirmed by testing, Colief® may be considered for prescribing on the NHS (prescription endorsed “ACBS”). Such prescribing should be reviewed at regular intervals for continued clinical need.

Lactase is an enzyme that is intended to break down lactose in milk (both breast milk and formula feed).

The Advisory Committee on Borderline Substances (ACBS) advice is that Lactase Enzyme Drops (Colief®) may only be prescribed on the NHS if 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 tests, in which case the prescription should be endorsed ‘ACBS’<sup>(1)</sup>.

However testing for lactose intolerance before prescribing lactase enzyme drops is relatively impractical. Most hospitals do not offer testing, and the only viable test requires a fresh stool sample that requires sending to a hospital that does offer the test. It takes several days to report the result, and therefore there are practical limitations to testing, since in most babies the intolerance is short-term. Other tests are invasive and/or require the baby to visit hospital.

The evidence supporting use of lactase enzyme drops is of low quality with inconsistent benefit shown, supported by a systematic review that showed no benefit<sup>(2)</sup>.

Colief® is not a licensed medicine.

See [Pan Mersey Prescribing Guidelines for Specialist Infant Formula Feeds](#) for further information on lactose intolerance.

**Note:** Patients who are not eligible for treatment under this policy may be considered on an individual basis where their GP or consultant believes exceptional circumstances exist that warrant deviation from the rule of this policy. If appropriate an exceptional funding request will be required following the usual locally defined process.

Version: 3.0

Review date: Mar 2021

(or earlier if there is significant new evidence relating to this recommendation)

## LACTASE ENZYME drops 50,000 units/g (Colief®)

<p><b>EFFECTIVENESS</b></p> <p>Lactase enzyme helps break down lactose found in milk, breast milk and infant formulas.</p> <p>The evidence supporting use of lactase enzyme drops is of low quality with inconsistent benefit shown, supported by a systematic review that showed no benefit<sup>(2)</sup>. One double-blind crossover study in breastfed infants found no significant difference in total daily crying time between lactase and placebo<sup>(3)</sup>. Another crossover study that gave bottle-fed infants cow's milk formula or pooled breast milk that had been pre-treated (and then frozen) with lactase or placebo found no significant difference between lactase and placebo in the number of days when colic was present<sup>(4)</sup>. One randomized double-blind crossover study of bottle-fed infants found that lactase (added to the feed 24 hours before it was given) reduced daily crying time by about 1 hour compared with placebo<sup>(5)</sup>. A further randomized double-blind crossover study did not show a significant difference in crying time between babies given lactase or placebo<sup>(6)</sup>. However, a significant difference was found when the 14 babies whose mothers were non-compliant were excluded from the analysis.</p>	<p><b>SAFETY</b></p> <p>If a change in stool pattern occurs i.e. looser and more frequent, the number of drops used per feed should be reduced<sup>(7)</sup>.</p>
<p><b>COST</b></p> <p>Lactase enzyme 50,000 units/g (Colief®) 7ml: NHS price £8.40<sup>(1)</sup> (approx. £12 to purchase). Currently in the Pan-Mersey area, the cost of prescribing Colief® is approximately £37,000 per year, reduced from £50,000 per year previously.</p>	<p><b>PATIENT FACTORS</b></p> <p>Colief Infant Drops should be used at every feed until the baby is approx. 3 – 4 months old, by which time the symptoms of colic should have disappeared<sup>(7)</sup>.</p>

### PRESCRIBING INFORMATION

Prescribing is not recommended.

### IMPLEMENTATION NOTES

Prescribers should advise that lactase enzyme drops may be purchased.

### REFERENCES

1. British National Formulary, accessed 06/12/2018
2. [NICE Clinical Knowledge Summary: Infantile colic](#), June 2017 (accessed 06/12/2018)
3. Miller, J.J., McVeagh, P., Fleet, G.H. et al. (1990) Effect of yeast lactase enzyme on "colic" in infants fed human milk. *Journal of Pediatrics* 117(2 Pt 1), 261-263.
4. Stahlberg, M.R. and Savilahti, E. (1986) Infantile colic and feeding. *Archives of Disease in Childhood* 61(12), 1232-1233.
5. Kearney, P.J., Malone, A.J., Hayes, T. et al. (1998) A trial of lactase in the management of infant colic. *Journal of Human Nutrition & Dietetics* 11(4), 281-285.
6. Kanabar, D., Randhawa, M. and Clayton, P. (2001) Improvement of symptoms in infant colic following reduction of lactose load with lactase. *Journal of Human Nutrition & Dietetics* 14(5), 359-363.
7. Colief® [Patient Information](#), 2019.