

# Product Brief



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## Dispensing advice on infant formula in community pharmacy: Aptamil Gold + Colic & Constipation

### Role of pharmacist in providing support and advice on infant nutrition

Functional gastrointestinal disorders (FGIDs) present in a significant proportion of infants younger than 12 months and may have an impact on future health outcomes.<sup>1</sup> Up to 50% of infants present with symptoms of FGIDs in the first six months.<sup>2,3</sup> According to Rome IV criteria, FGIDs are defined as variable combinations of chronic or recurrent gastrointestinal signs or symptoms without obvious structural or biochemical alterations.<sup>2,4</sup> The worldwide prevalence of the three most common FGIDs in infants include infantile regurgitation (30%), colic (20%) and functional constipation (15%).<sup>1,2</sup> Although considered mostly benign conditions, FGIDs are a cause of concern and frustration for many families.<sup>2</sup>

Pharmacists are in a key position to provide parental reassurance and education as well as medical and nutritional advice to help alleviate parental stress.<sup>4,5</sup> Pharmacists are easily accessible and have frequent interactions with soon-to-be and new parents.<sup>5</sup> A small study surveying 47 pharmacies found almost 50% of pharmacists reported getting inquiries from breastfeeding mothers on a weekly or daily basis.<sup>5</sup> During the postpartum period, there are many potential points of intervention including the provision of medication advice and alleviating pain and discomforts, advice regarding breastfeeding concerns, medication use with breastfeeding, guidance regarding infant formula and providing advice regarding infant health care.<sup>5</sup>



### Practice Points

Consider recommending an infant formula that contains:

- Structured vegetable oil (41% beta-palmitate) to reduce the formation of calcium soaps, leading to softer stools, decreased crying duration and frequency, improved sleep and overall wellbeing.<sup>11, 13</sup>
- 100% partially hydrolysed whey protein for faster transit time and gastric emptying, and stool characteristics are more similar to that of breastfed infants.<sup>17, 18</sup>
- Prebiotic oligosaccharides GOS and FOS for gut microbiota closer to that of breastfed infants. Improving the gut microbiota and intestinal function produces softer stools and protects against atopic dermatitis in infants at risk of atopy.<sup>7, 10, 15, 16</sup>
- Low lactose (3.3g/100 mL) for decreased fermentation of undigested lactose, leading to less distension and pain.<sup>21</sup>
- Starch slightly thickened to decrease regurgitation.<sup>17, 19</sup>



### Practice Tip

Australian infant feeding guidelines recommend that women exclusively breastfeed infants until six months of age, at which time solid foods can be introduced while breastfeeding continues until the age of 12 months and beyond, if both mother and child desire to continue.<sup>6</sup> Although the initiation rate of breastfeeding in Australia is high at 96%, only 15% of infants continue to be exclusively breastfed at six months of age.<sup>9</sup> Infant nutrition formulas are recommended as an alternative to breast milk until 12 months.<sup>6</sup>

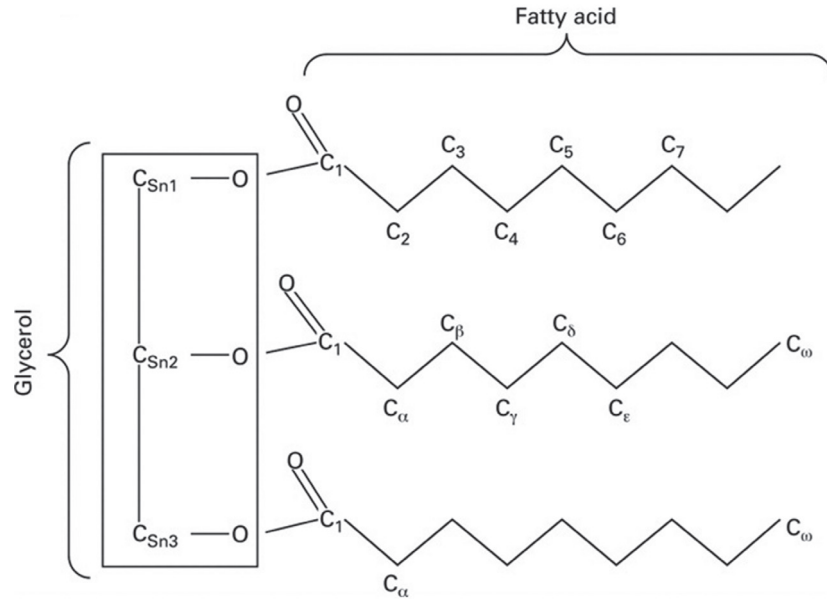
## Aptamil Gold+ Colic & Constipation

Aptamil Gold+ Colic & Constipation is an infant formula designed for the dietary management of FGIDs such as colic and constipation.<sup>7-10</sup> Aptamil Gold+ Colic & Constipation contains the following:

- Structured vegetable oil (41% beta-palmitate)
- 100% partially hydrolysed whey protein
- Prebiotic oligosaccharides: fructooligosaccharides (FOS) and galactooligosaccharides (GOS)
- Low lactose (3.3g/100 mL)
- Starch thickener

## Beta-palmitate

**Figure 1:** Triacylglycerol molecule showing the Sn positions and the numerical and alphabetical nomenclatures of fatty acids.



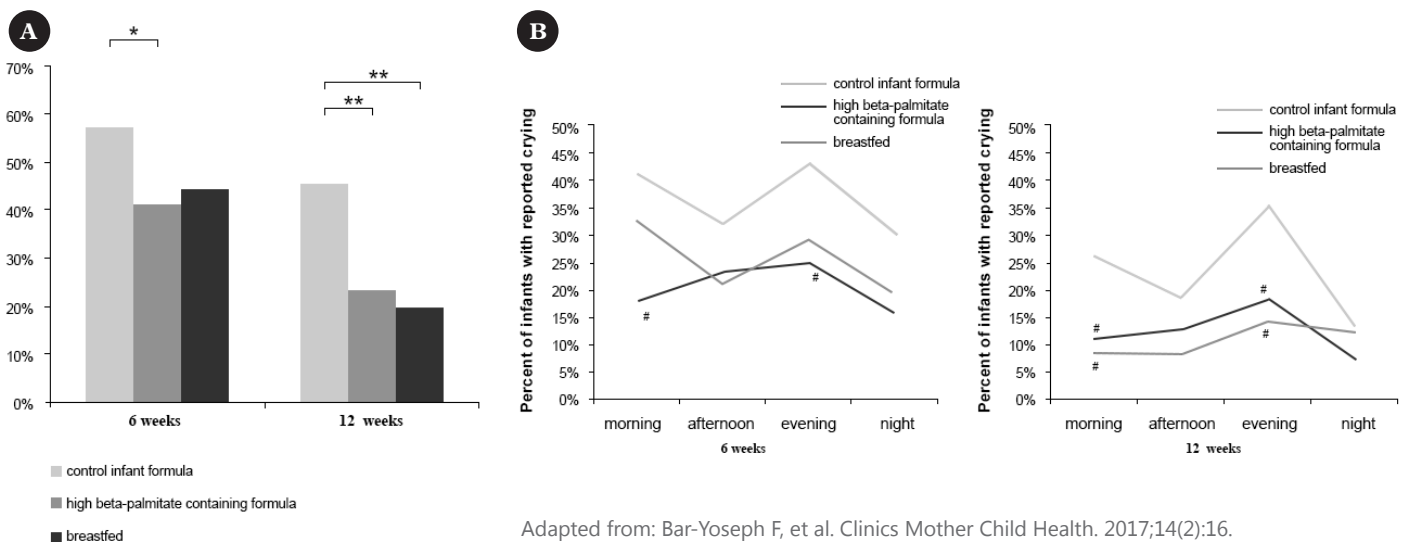
Manson WG, Weaver LT Fat digestion in the neonate Archives of Disease in Childhood - Fetal and Neonatal Edition 1997;76:F206-F211.

Palmitic acid is the major fatty acid in human breast milk, and accounts for 17-25% of the total fatty acids.<sup>11</sup> Over 70-75% of the palmitic acid is esterified at the sn-2 (beta) position of the triglyceride.<sup>11</sup> In contrast, palmitic acid in traditional infant nutrition formula consists mainly (>80%) of palmitic acid esterified to the sn-1 and sn-3 positions.<sup>11</sup> Palmitic acid in the sn-1 and sn-3 positions have poor absorption as they create complexes with dietary minerals such as calcium.<sup>11</sup> These complexes are known as fatty acid soaps and are insoluble, indigestible and contribute to stool hardness.<sup>11</sup> The formation of calcium soaps may contribute to differences in bowel habits and stool consistency between infants who are breastfed and fed with traditional formulas.<sup>11</sup>

The addition of high beta-palmitate reduces stool soaps, leads to softer stools and increased bifidobacteria.<sup>12</sup> Importantly, infant formulas with high beta-palmitate were shown to improve crying, sleep patterns and overall well-being of infants and consequently also the quality of life of their parents.<sup>13</sup> **Figure 2** demonstrates results of a 2017 study of high beta-palmitate (43%) infant formulas given to healthy term infants. Another study showed that high beta-palmitate formula reduced crying duration and frequency compared to breastfed infants.<sup>11</sup> Beta-palmitate may also increase early bone mineralisation and development, influence the composition of the intestinal microbiota and may have neurobiological effects such as modulation of early infant crying.<sup>14</sup>

**Figure 2:** Percentage of infants with crying reported during each period of the day (A) at six weeks and (B) at twelve weeks postnatal. Data are percentage of infants with reported crying for each six-hour period of the day (morning 06:00-11:59, afternoon 12:00-17:59, evening 18:00-23:59, night 00:00-05:59).

\*\*p<0.05, \*p<0.1, # significantly different from protocol, p<0.05.13



Adapted from: Bar-Yoseph F, et al. Clinics Mother Child Health. 2017;14(2):16.

## Pharmacist's take home message:

*Pharmacists often focus on medications to treat conditions and control symptoms. However, two of the primary tenets of quality use of medicines (QUM) are appropriate and judicious use of medicines. Applying both these tenets it is easy to see that "no drug" is also a viable prescription. Parents of infants are at times reticent to use medications, for obvious reasons.*

*Products that provide an alternative to drug therapy are always worth exploring. A formula containing the ingredients shown to reduce FGIDs without resorting to medications is a plus for parents and the pharmacy profession. This development allows pharmacists to offer an evidence-based solution to parents who are often at their wits end with a grumpy baby who will not settle.*

*Breast feeding is always the best option, however, there are a range of circumstances where this is not possible. In these cases, selecting the formula most appropriate for the infant is crucial, and using an evidence base to solve FGID issues that the infant may also have provides additional reassurance to parents. Pharmacists should speak with the parents and explain the options and benefits of their intervention (in this case, nutritional). They should also develop a plan that covers when to review this approach in the pharmacy and when to escalate to the GP if the recommended intervention is not working.*

*Aptamil Gold+ Colic & Constipation provides an additional option for pharmacists to try before introducing medications.*

## Prebiotics: GOS and FOS

Oligosaccharides are not digested in the small intestine and reach the colon unchanged, where they act as prebiotics.<sup>7</sup> A prebiotic mixture for infant formulas was developed from analysis of human milk oligosaccharides.<sup>15</sup> Supplementation of infant formula with a prebiotic mixture of 90% short-chain galactooligosaccharides (GOS) and 10% long-chain fructooligosaccharides (FOS) has a dose-dependent stimulating effect on the growth of Bifidobacteria and Lactobacilli in the intestine.<sup>16</sup> Intestinal microflora dominated by these beneficial microbes supports the gut barrier and has positive effects on intestinal function and on the development of the immune system.<sup>7,16</sup> Bifidobacteria are non-pathogenic and may protect against pathogenic intestinal microorganisms and may exert a beneficial effect on the development of atopic dermatitis among infants at high risk of atopy.<sup>10,15</sup> Moreover, since oligosaccharides are non-digestible, they may be considered to be a form a soluble fibre and contribute to softer stools.<sup>7</sup>

## Partially hydrolysed formula

Hydrolysed formulas use enzymatic processes to break the proteins into smaller fragments.<sup>17</sup> Infants fed partially hydrolysed formula have faster transit time and gastric emptying and twice as many stools compared to standard formulas.<sup>17</sup> Studies have shown that preterm infants on hydrolysed formulas have less gastro-oesophageal reflux and improved feeding tolerance.<sup>18</sup> A study on healthy term infants demonstrated that partially hydrolysed whey protein formula supports the growth of healthy term infants, comparable to breastfed infants during the first three months of life.<sup>18</sup> In addition, stool characteristics of infants fed partially hydrolysed formula were closer to those of breastfed infants than regular infant formula.<sup>18</sup>

## Starch

Starch, particularly rice starch, is a thickening agent that has been shown to effectively reduce spit-up frequency in otherwise healthy term infants.<sup>17,19</sup> A 2017 Cochrane review that included eight trials and 637 infants concluded that feed thickeners can be useful in term babies up to six months of age who are bottle feeding and have troublesome gastro oesophageal reflux.<sup>20</sup>

## Reduced lactose

Lactose intolerance as a result of relative lactase deficiency may be a contributing factor to infant colic.<sup>21</sup> The inability to break down lactose in food results in significant amounts of lactose entering the bowel where it ferments and leads to the production of lactic acid and hydrogen.<sup>21</sup> The fast production of hydrogen in the lower bowel distends the colon, sometimes causing pain.<sup>21</sup> It is thought that by reducing the lactose content of infant formulas, colic symptoms may be relieved.<sup>21</sup>

## Summary

The combination of partially hydrolysed formula, supplementation with the prebiotics GOS and FOS and low-lactose has been shown to significantly improve symptoms of the gastrointestinal tract.<sup>8,21</sup> A study\* of 267 formula-fed infants with infantile colic showed that this combination of partially hydrolysed whey, GOS and FOS supplementation and high beta-palmitate reduced crying time compared with standard formula and simethicone.<sup>22</sup> Another study of 903 formula fed infants showed this formulation reduced the frequency of colic, regurgitation and increased stools among infants with constipation.<sup>8</sup> The majority of infants followed by paediatricians for minor gastrointestinal complaints improved within two weeks of feeding with this formula combination.<sup>8</sup>

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