

*No. 1 choice
of hospitals
& mothers*

Calmita: Research-based hospital feeding solution
**Designed to support
neonatal oral feeding development**

“By allowing infants to apply a natural feeding behaviour, Calmita not only supports, protects and therefore increases breastfeeding in the hospital, but also helps to reduce length of stay.” Prof. Karen Simmer



Calmita Starter

Calmita

Allows similar mechanical action and tongue movement as at the breast.



Calmita Advanced

Breastfeeding is natural



Intrauterine life with placental support is completely different from that outside the womb and requires significant adaptations of both the mother and the infant. Breastfeeding assists in the transition from intrauterine to extrauterine life by maintaining the infant's connection to its mother. The close body contact during breastfeeding regulates infant respiration, acid-base balance and temperature, helps conserve energy reserves¹ and soothes the infants^{2,3}.

Suckling of the mammary gland to obtain milk for nourishment and immune protection is a behaviour unique to mammals. Suckling promotes numerous responses in both the mother and infant and these are thought to have evolved to ensure survival of the infant in harsh environmental conditions⁴. As such, human milk is species-specific and has been carefully tailored over time to meet the nutritional requirements of the human infant⁵.

Human milk, therefore, is the natural food for infants. It is unequalled and is universally recognised as the optimal feeding choice for every infant. As a global public health recommendation of the World Health Organisation, infants should be exclusively breastfed for the first six months of life. This recommendation aims to ensure infants benefit from human milk nutritionally, immunologically and developmentally⁶, in addition to the physical and psychological benefits direct breastfeeding provides to the health of the mother⁷.

For preterm infants, adaptation to extrauterine life occurs far too early, creating a unique and complex set of challenges. Preterm infants are not simply "small" full-term infants. Preterm birth introduces tiny infants into an extrauterine world for which their tissues and organs are not yet developed to completion. These infants have substantially diminished stores of micro- and macronutrients that are ordinarily deposited during the last trimester *in utero* in preparation for the outside world. Nevertheless, they still need to make the same adaptation to life outside the uterus that full-term infants do, but they do so with significant challenges.

The natural act of breastfeeding is a complex physiological process.

The benefits of this process run along two lines:

- I What is fed to the infant – human milk
- I How the infant is fed – the mechanics of breastfeeding

Human milk

In the case of preterm infants, human milk is especially important for the development of the gastrointestinal tract, for neurological development and for conferring immunological protection. Compared to milk of term mothers, preterm milk has higher levels of energy, lipids, protein, nitrogen, fatty acids, some vitamins, and minerals. In addition, the levels of immune factors, including cells, immunoglobulins, and anti-inflammatory elements in preterm milk are higher than in term milk⁸. The potent benefits of human milk are such that all preterm infants should receive it⁹.

However, preterm human milk still does not meet the micro- and macronutrient requirements of extremely premature infants due to their high nutrient demands, and the restrictions in the volumes these infants can safely ingest. Premature infants would normally be undergoing a period of rapid foetal growth and nutrient accumulation. They need to grow at a faster rate than full-term infants since they missed the intrauterine growth spurt of the last trimester.

Thus, the food for these infants needs to be higher in caloric value, but in smaller, more concentrated, volumes. Many facilities now strive to ensure that own mother's milk, fresh or frozen, should be the primary diet for these infants. For the infant born weighing less than 1.5 kg the American Academy of Pediatrics⁹ recommends that human milk should be fortified with protein, minerals, and vitamins to ensure optimal nutrient intake¹⁰, while deriving benefits from human milk^{11,12}.

The mechanics of breastfeeding

Research using ultrasound imaging has shown that 'lactiferous sinuses' cannot be observed in the lactating breast¹³. The low number and size of the ducts and the rapid branching under the areola, together with the absence of sinuses, suggest that ducts transport breast milk, rather than store it¹³.

Further ultrasound imaging research has demonstrated that, during breast-feeding, the tip of the nipple does not reach the junction of the hard and soft palate and that milk flow from the nipple into the infant's oral cavity coincides with both the lowering of the infant's tongue and with peak vacuum. Therefore, vacuum is likely to play a major role in milk removal from the breast¹⁴.

During a suck cycle¹⁴ (Figure 1), the vacuum begins at the baseline, that is the minimum vacuum required to maintain attachment without milk flow. As the tongue lowers, vacuum increases and milk begins to flow. Vacuum reaches a maximum when the tongue is at the lowest point. The tongue then rises and comes to rest again at the baseline – and the milk stops flowing.

Vacuum-controlled flow allows safe and coordinated milk removal, commanded by the infant. The process of breastfeeding may also impact upon the normal orofacial development of the infant. It is suggested that this is because the mechanical action of breastfeeding leads to a well-shaped jaw^{15,16}, proper development of the swallowing action of the tongue, alignment of the teeth, and the shaping of the hard palate^{16–20}. Breastfeeding has also been associated with lower risk of otitis media, improved oral motor development and improved speech quality compared to feeding with conventional teats^{21–25}.

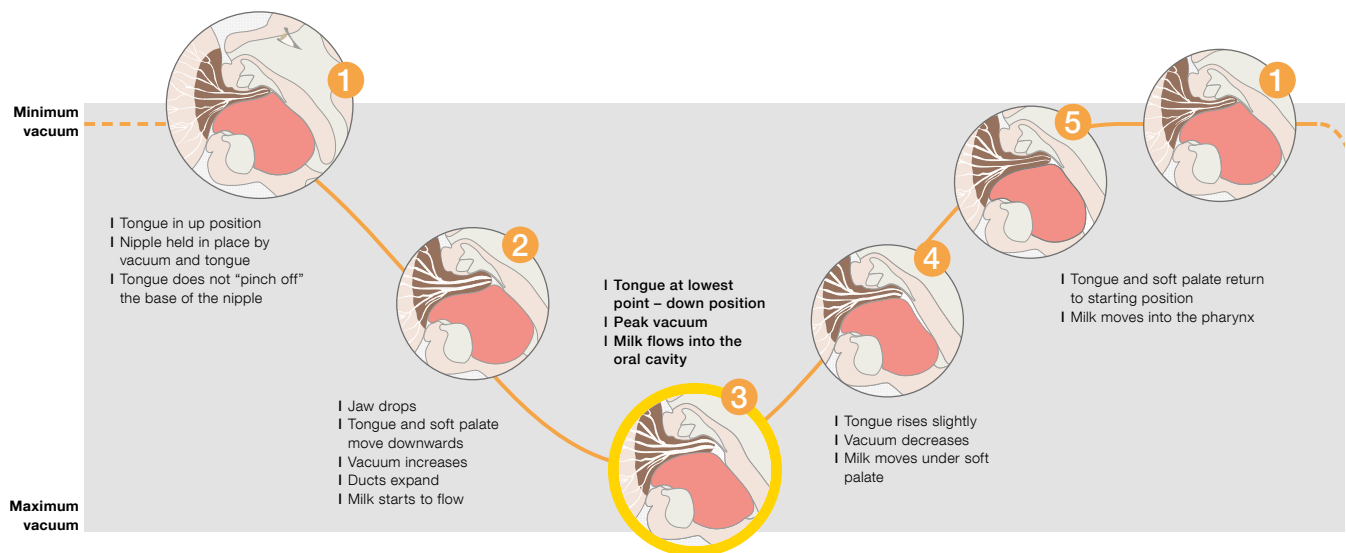
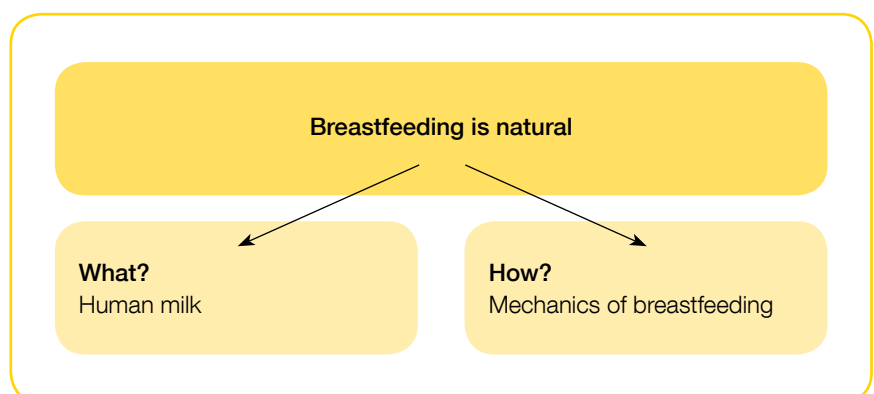


Figure 1 – The suck cycle ¹⁴



In the preterm scenario, the challenge to the gold standard of breastfeeding is not only the infant who is born earlier than expected; the mother and her anatomy also need to adapt to this earlier milestone. Mothers need extra support to initiate and maintain their milk supply. For those health situations in which infants cannot be fed at the breast, the choice of the best alternative to answer the question **what** to feed the infant – expressed milk from the infant's own mother, human milk from a milk bank, or formula – depends on individual circumstances. In any case, the answer to the question **how** to feed the infant should be feeding the newborn in such a way that the infant is in control of the milk flow, similarly as at the breast; thus avoiding the need to learn an unnatural feeding technique.

Challenges for breastfeeding



Both term and preterm populations can experience infant-related breastfeeding challenges. These are commonly associated with infants being too small, having a weak physical condition and/or other difficulties applying their natural feeding technique.

Breastfeeding in the neonatal intensive care unit (NICU) is uniquely challenging. Due to immaturity plus medical complications, it is often difficult for preterm infants to go directly to their mother's breast after birth and feed naturally. Safe and successful oral feeding requires not only appropriate sucking, swallowing, and breathing, but also the coordination of these three functions in order to prevent adverse episodes of apnoea, bradycardia, oxygen desaturation, and/or aspiration²⁶. Late preterm infants demonstrating cues for oral feeding are often able to coordinate sucking, swallowing, and breathing, and establish breastfeeding. In less mature infants, oral feeding may be difficult because of neurological immaturity or respiratory compromise²⁷.

Hypotonia (low muscle tone) is a significant factor affecting the extremely low-birth-weight infant's ability to feed orally because it decreases endurance and intraoral vacuum needed to control milk flow, leading to increased "work of sucking"²⁸. Hypotonia may prevent infants from achieving an effective latch because they may be unable to open their mouths wide enough or to maintain the latch during the sucking pause (baseline vacuum)²⁹.

The challenges for breastfeeding do not only come from the infant's side. It is widely acknowledged that mothers of preterm infants, especially extremely low-birth-weight infants, experience both physiological and emotional challenges that adversely affect breastfeeding rates for this population³⁰⁻³².

Due to maternal-infant separation, inadequate stimulation for milk ejection can take place³³. Separation thus interferes with the establishment of breastfeeding and increases the likelihood of complications such as insufficient milk supply³⁴.

Moreover, once a mother does achieve a milk supply, the milk might require fortification to meet the energy demands of the infant¹⁰. Therefore, for the feeding process the milk needs to be expressed from the breast, fortified, and then fed to the infant. This adds an extra layer of complexity when discussing mother-infant separation. There are also occasions in which, for medical reasons, mothers of term infants have difficulties breastfeeding. It is important that the principal goal when not feeding at the breast is the creation of an experience similar to breastfeeding, so that the infant can benefit from applying and developing a natural feeding behaviour.

Feeding the preterm infant



Currently several methods can be used to ensure nutrition for premature infants. These depend on infant gestational age, birth weight, condition and health care institution. Depending on the hospital facility, the feeding regime may vary; it can start with parenteral nutrition, moving to tube feeding and advancing to suck feeds, with the goal of using a natural feeding technique in order to reach full breastfeeding.

Most premature infants born before 32 weeks of gestation are unable to coordinate sucking, swallowing, and breathing effectively in the beginning. These infants may be fed enterally, that is, through a tube that is inserted into the stomach either through the nose (nasogastric feeding) or the mouth (orogastric feeding).

Preterm infants studied while they were in a transition from being enterally-fed to being fully bottle-fed, exhibited approximately three times as many episodes of desaturation with oral feeding compared to enteral feeding³⁵. One of the frequent observations noted in neonatal nurseries is the difficulty premature infants have in keeping up with the milk flow when introduced to oral feeding. It has therefore been suggested that a restricted pattern of milk flow be used when oral feeding is initiated in premature infants, especially for those born before 30 weeks of gestation^{36,37}.

For infants fed orally, there is a greater physiological stability during breastfeeding compared to bottle feeding with a conventional teat. Breastfeeding requires the infant's natural feeding behaviour, therefore presenting fewer physiological challenges to growing preterm infants^{38,39}. For example, oxygen saturation is higher during breastfeeding than during conventional bottle feeding⁴⁰⁻⁴². The swallow-induced breath-holding reduces minute ventilation; more rapid milk flow results in more frequent swallowing and more significant ventilatory interruption^{43,44}. A fast milk flow can lead to aspiration and choking, particularly in premature infants³⁷. Stress and low oxygen saturation can negatively affect infant development.

The modification of traditional feeding protocols in the healthy premature infant may reduce the number of days to transit from enteral feeding to oral feeding, maintain growth and reduce the length of hospitalisation⁴⁵. For instance, preterm infants receiving a non-nutritive sucking intervention have been found to have a significant decrease in transition time from tube to bottle feeds, a decrease in length of stay and a better "bottle feeding" performance⁴⁶.

To feed orally, an infant must be able to sustain awake behaviour, coordinate sucking, swallowing and breathing, and maintain cardiorespiratory stability for the time required to ingest a caloric volume adequate for growth⁴⁷. Although a healthy term infant has these abilities, a neurologically premature infant (less than 32–34 weeks post-menstrual age) often does not. Therefore, even though breastfeeding is clearly best for infants, it may not always be possible. In such cases, a differentiated teat – the function of which is close to the mechanics of breastfeeding – would be very useful, particularly for preterm infants with bronchopulmonary dysplasia, who exhibit significant desaturation during and immediately after bottle feeding⁴⁸.

Given the high *per diem* costs of NICUs, it is apparent that the most effective means of reducing costs is to shorten length of stay⁴⁹. Since discharge home is largely dependent on the ability to achieve full oral feeding⁴⁹, a reduction in length of stay could be achieved with earlier full suck feeds. Clearly, research should attempt to find the most efficient method to assist in the transition to natural oral feeding, so that mother and infant can achieve earlier the goal for all infants: the complete breastfeeding experience.

Meeting the challenges

The need for a hospital feeding solution to help premature and weak infants to attain the goal of ever being breastfed is evident. There is a necessity for a feeding device that combines the most successful strategies for these infants to improve oral feeding skills: self-paced feeding³⁷ and vacuum build-up training⁴⁶. A feeding device based on the infant's natural behaviour to remove milk, particularly the up/down tongue movement and the application of vacuum including the possibility to maintain a baseline vacuum to suck, swallow and breathe, would meet these needs.

Improving oral feeding skills will not only accelerate attainment of full suck feeds, thus shortening hospitalisation. It will also reduce the risk of nosocomial infection, lower the financial burden on families and society, allow earlier family unification, and facilitate the development of more appropriate mother-infant interaction and bonding⁵⁰. Potentially, it may also decrease long-term feeding difficulties/disorders²⁶. In order to fully explore these areas, while developing and testing the Calmita feeding solution, Medela partnered with King Edward Memorial Hospital and The University of Western Australia, in Perth, Australia.

Neonatologist Professor Karen Simmer conducted a randomised controlled trial with an intention-to-treat strategy that recruited 100 preterm infants (figure 2). These infants, whose mothers intended to breastfeed, were aged between 25 and 34 weeks post-menstrual age (median 31 weeks). Consent and enrolment was completed for 97 infants, who were randomised into two groups; intervention (n=51) or control (n=46).

Importantly, the design of the study was pragmatic in nature so that the only difference between the two study groups was the feeding device used. Moreover, no changes to hospital policy or practice were made. As such, the first suck feed offered was always the breast. When a suck feed other than the breast was required, the intervention group used the Calmita research device (developed by Medela) whilst the control group received standard hospital care (a common, conventional preterm teat). Additionally, infants from either group could be transferred from the primary research site to a secondary institution before being discharged home, as per usual hospital practice.

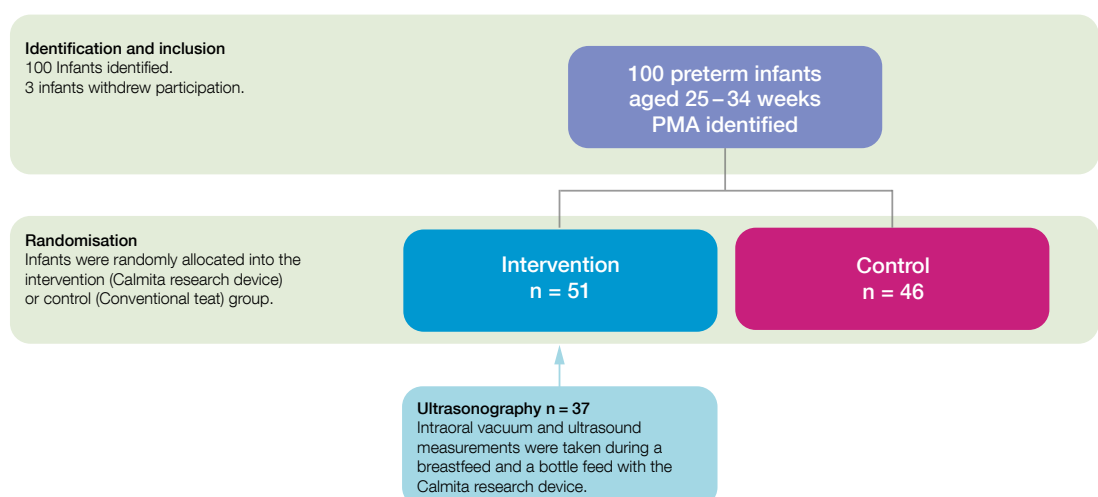


Figure 2 – Study protocol

Outcomes of the randomised controlled trial

The research device led to a decrease in length of hospital stay

Infants in the intervention group had a decreased total length of hospital stay of 2.5 days compared to the control group ($p < 0.05$). Therefore, infants had a corrected gestational age at discharge home on average 2.5 days younger than those infants in the control group ($p < 0.05$) (figure 3)⁵¹.

Attaining full suck feeds is one of the key hospital discharge criteria. Infants feeding with the research device reached full suck feeds (removal of the tube) 2.8 days younger than infants in the control group, although this was not significant ($p = 0.22$). This clinically relevant finding may be linked to the significant reduction in length of stay (figure 3)⁵¹.

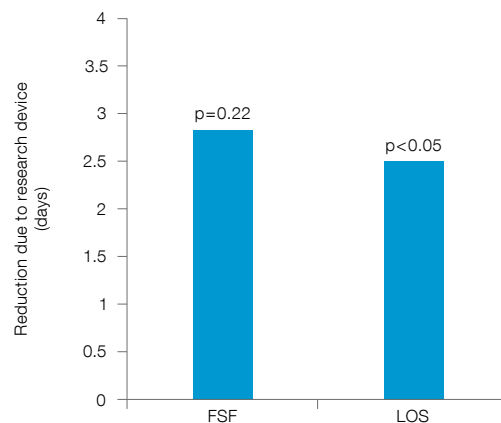


Figure 3 – Reduction (in days) associated with the research device. Full suck feeds (FSF) represents reduction in the age at which full suck feeds were reached; Length of stay (LOS) represents reduction in total length of stay in the hospital and age at discharge home⁵¹.

The research device positively affected breastfeeding in the hospital

At discharge from the primary research site, infants in the intervention group were significantly more likely to be doing any breastfeeding ($p < 0.05$) and at discharge home a similar, but not significant, increase in breastfeeding was seen ($p = 0.10$). Moreover, infants in the intervention group were receiving significantly ($p < 0.05$) fewer formula feeds at both time points (figure 4)⁵¹.

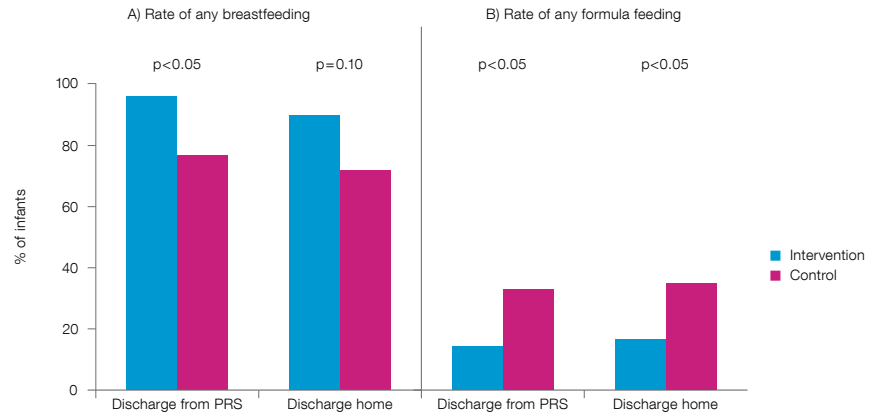


Figure 4 – A) Rate of any breastfeeding in the intervention and control groups at discharge from the primary research site (PRS) (96% vs. 78%, $p < 0.05$) and at discharge home (90% vs. 76%, $p = 0.10$). B) Rate of any formula feeds in the intervention and control groups at discharge from PRS (14% vs. 33%, $p < 0.05$) and at discharge home (16% vs. 35%, $p < 0.05$).

Infants discharged from the PRS went directly home (Intervention $n = 15$, Control $n = 21$) or to a secondary institution prior to home (Intervention $n = 36$, Control $n = 25$). The proportion of infants going home directly from the PRS or on to a secondary institution was statistically similar for both groups. Discharge to home represents all infants regardless of whether they were discharged home from the PRS or a secondary institution⁵¹.

The reason for the better breastfeeding outcomes may be linked to the mechanical action and tongue movement used by the infants in the intervention group when feeding from the research device⁵².

Figure 5 shows that the pattern of tongue movement used during feeding was similar to when breastfeeding. The fact that the infants do not have to learn a different, unnatural feeding technique might be positively affecting breastfeeding in the hospital.

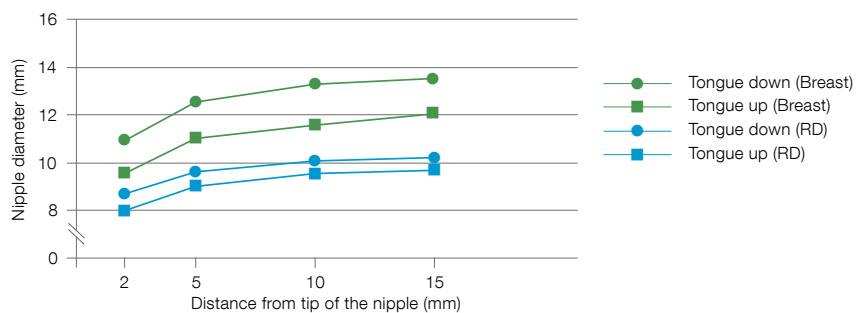


Figure 5 – Similar feeding behaviour (breast vs. research device): The up/down tongue movement observed during breastfeeding was also observed when feeding with the Calmita research device (RD). The graph shows the diameter of the nipple and the research device at points along the nipple/research device starting 2 mm back from the tip (0 mm) when the tongue is in the up and down positions⁵².

The evidence for Calmita



Calmita is a research-based hospital feeding solution that allows newborns to train and apply their individual and natural sucking behaviour⁵². The integrated vacuum-controlled valve allows the infant to decide when to drink and when to pause. Milk flows when the infant reaches a certain vacuum. The infant creates its own sucking rhythm, thereby efficiently removing just the right amount of milk at an individually suitable pace.

The use of Calmita has been shown to significantly reduce length of stay by helping the infant to meet hospital discharge criteria earlier⁵¹. Reaching full suck feeds is a key discharge criterion in many NICUs. Calmita's design, which allows similar mechanical action and tongue movement as at the breast, apparently enables infants using Calmita to reach full suck feeds younger. If the transition from enteral to full oral feeding is accelerated, the number of days with a feeding tube in place is reduced, thus lowering the risk of iatrogenic infection.

The technology behind Calmita lets infants apply their natural feeding behaviour, since Calmita allows a comparable mechanical action and up/down tongue movement as at the breast⁵². Infants using Calmita do not have to learn an unnatural feeding technique and in this manner, Calmita supports and protects breastfeeding. Indeed, there is an increase in breastfeeding in the hospital for infants using Calmita⁵¹.



Calmita Starter with 35ml Colostrum Container

Calmita is available in two versions in which the threshold levels of the vacuum-controlled valve are different. These levels reflect the infant's oral feeding development and offer the possibility of training the feeding behaviour of the infant in such a way that an incremental build-up of skills can be achieved. Depending on the capacity of the infant to generate an intraoral vacuum, the suitable Calmita version should be used.

Calmita Starter (white) has a low threshold level of the vacuum-controlled valve and is suitable for preterm infants in transition from enteral to oral feeding. Once these infants can create the necessary intraoral vacuum, they can move on to Calmita Advanced (yellow), which has a moderate threshold level of the vacuum-controlled valve. Late preterm and term infants unable to feed at the breast in the hospital might begin using Calmita Advanced directly.



Calmita Advanced with 80ml disposable bottle

The dimensions of Calmita (equal for both types) facilitate latching on for small premature infants. The nipple length of Calmita has been defined taking into account the dimensions of the foetal hard palate at 32 weeks⁵³. The shape of Calmita and the radius of its base ought to allow different latch on positions to meet the infant's orofacial development. Infants should attain their individual latch with the tip of the nipple positioned a few millimetres away from the hard and soft palate junction, thus allowing the creation of an anterior seal – as during breastfeeding¹⁴.

Calmita is a novel research-based hospital feeding solution that can be used to facilitate oral feeding of hospitalised infants, whenever direct breastfeeding is not possible. Calmita enables infants to apply their natural feeding behaviour, as at the breast, and thus supports and protects breastfeeding.

Calmita benefits

- **Earlier discharge home** ⁵¹

Using Calmita significantly reduces length of stay by helping the infant to meet hospital discharge criteria earlier. In many NICUs successful full suck feeding is considered as one of the key discharge criteria.

- **Natural feeding behaviour** ⁵²

Calmita's vacuum-controlled valve allows a natural feeding behaviour as the infants themselves control the milk flow. Therefore, the infant is able to pause and breathe while no milk flows.

- **Increased breastfeeding in the hospital** ⁵¹

Calmita increases the chance that the infant can ever be breastfed. By allowing similar mechanical action and tongue movement as at the breast, it supports and protects breastfeeding.

More information about Calmita is available on www.medela.com/calmita

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