

New Purple Vials!

Hawaii Medical  
**TootSweet™** 24% Sucrose Solution FAQs  
Frequently Asked Questions

**Q What is TootSweet used for?**

According to clinical studies, 24% sucrose solution is considered safe and effective for reducing procedural pain from single painful events (such as heel lance, line placement and circumcision) and to help calm and soothe babies in distress or during painful procedures.<sup>1, 2, 3</sup>

**Q What's different about TootSweet compared to other brands?**

TootSweet is the first 24% sucrose solution:

- To include baby appropriate preservatives that eliminate the possibility of bacterial growth, mold and growth of organisms which may be harmful to infants
- To meet USP preservative effectiveness tests so TootSweet is guaranteed mold and bacteria free
- Packaged in convenient Twist-Tip vials (0.5ml, 1ml or 2ml), unbagged or bagged; single dose, single patient use
- Packaged wide-based cups to avoid tipping and overflow (12ml in a 1oz cup); single dose, single patient use
- Packaged in transparent containers for easy visual inspection
- Packaged in stable container materials – keep formulation consistent, eliminate evaporation and prevent increased sucrose concentration
- To have a two year shelf life – reduces costs, inventory hassles, and waste

**Q What is TootSweet made of?**

TootSweet contains 24% Sucrose (published as the safe and effective strength)<sup>1</sup> purified water, two buffers – citric acid and dibasic sodium phosphate, two baby appropriate preservatives – methylparaben and potassium sorbate. These same preservatives are in OraSweet™, caffeine citrate and gentamicin, and are commonly administered to infants in the NICU.<sup>1, 4, 5</sup>

**Q Why include preservatives?**

Tests show that bacteria growth in nonpreserved 24% sucrose solution begins soon after opening. Independent studies found nonpreserved 24% sucrose solution became highly contaminated (53 large colonies and small colonies too numerous to count) with bacteria and mold in a matter of hours after contact with a pacifier used by an infant. (Copy of report available on request.) If re-administered from an open cup, the unpreserved sucrose solution can expose fragile preemies to bacteria. TootSweet greatly reduces the risk of sucrose borne bacteria and gives hospitals the convenience of a two year shelf life. Our Medical Advisory Board, as well as many clinicians, believe the benefits of preservatives far outweigh the risk of bacteria that can be borne in unpreserved sucrose.

**Q Why include two preservatives?**

TootSweet contains two preservatives (.095% total, by volume) to insure a safe, bacteria free product for your babies. Methylparaben and potassium sorbate are used as preservatives in TootSweet to minimize the risk of bacterial growth during manufacturing, in open product by the bed side and to provide a two year shelf life. Our formulation of preservatives has been used for years in OraSweet.



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## TooSweet™ 24% Sucrose Solution FAQs

### Q Is there documented use of sucrose with these preservatives in the NICU?

Yes. Literature published March 2002 references use of OraSweet (at Our Lady of Lourdes Medical Center, Camden, NJ, among other institutions) diluted 1:1 with bottled water to make a 27% sucrose solution to ameliorate pain in infants who are undergoing painful procedures.<sup>1</sup> It contains methylparaben and potassium sorbate (the preservatives in TooSweet). We've improved on OraSweet by eliminating the need to dilute and dispense, and by eliminating unnecessary ingredients like glycerine, sorbitol and flavorings. OraSweet has been used in drug formulations for babies for over ten years.

### Q What USP testing has TooSweet passed?

TooSweet is the first 24% sucrose to meet USP criteria for Antimicrobial Preservative Effectiveness and is guaranteed mold and bacteria free. TooSweet has been tested in accordance with USP Preservative Effectiveness Test (27 NF 22 2004) by ISO certified Toxicon Testing Laboratory. The test results (on file) meet current USP criteria for Antimicrobial Preservative Effectiveness.

### Q Is TooSweet classed as a medical product or food?

Sucrose is considered a food. There is no license or legal class required in the U.S.

### Q Does TooSweet have an NDC number (National Drug Code)?

Because TooSweet is considered a food product, not a drug, it does not require an NDC number. You and your pharmacy may be familiar with Ora-Sweet, used in medicine formulation for babies. Ora-Sweet is also considered a food and therefore is not registered as a drug with the FDA. Both products are made in FDA inspected and approved facilities.

### Q What sizes does TooSweet come in?

TooSweet is the first 24% sucrose to offer these packaging choices:

- 12ml in a 1oz cup – wide based cup for easy pacifier dipping. No mess. No overflow and no accidental tipping over!
- Convenient Twist-Tip vials – 0.5ml, 1ml or 2ml.

### Q Why offer a Twist-Tip vial?

Clinicians told us they wanted a convenient way to administer sucrose for heel sticks and other procedures. The Twist-Tip vial is perfect when clinicians want a small amount of sucrose, when they are pressed for time and in transport, when a cup would be unstable and messy. The TooSweet Twist-Tip vial means clinicians are more likely to administer sucrose for pain management.

### Q Why are TooSweet vials purple?

The vials are purple but nothing else has changed. Purple is becoming a standard color to indicate oral use – eliminates confusion with other oral vials (albuterol, etc) and easier to see in the bed.

### Q What is so important about TooSweet's stable container materials?

TooSweet is the first 24% sucrose solution packaged in transparent, stable polypropylene packaging materials which do not allow evaporation. As a result, TooSweet sucrose solution does not change in concentration while it is in your inventory. It lasts for two years on the inventory shelf, without refrigeration. So, babies won't accidentally receive an incorrect, higher concentration of sucrose. We chose polypropylene because the commonly used polystyrene (used in creamer style cups) allows evaporation and changes in concentration while in inventory. In addition, we specifically designed the cup to prevent spilling and enable easy pacifier dipping.



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## TooSweet™ 24% Sucrose Solution FAQs

### Q When is TooSweet administered?

- TooSweet should be administered according to your hospital's guidelines
- Clinical studies report nurses administer to babies two minutes before a painful procedure begins, during the procedure if necessary, and to calm babies in distress<sup>1, 2, 3</sup>
- Some hospitals require a physician order for sucrose
- Sucrose solution is considered a food substance, USDA (not FDA) regulated, it's not considered a drug

### Q How is TooSweet in a cup administered?

By dipping a pacifier into a small cup of sucrose solution, drawing up in an oral syringe.

### Q How long can I safely use an open container of TooSweet?

- Discard single dose cup after one procedure
- Single dose, single patient use

### Q How do I administer TooSweet from the Twist-Tip vial?

Twist off the tip and apply a few drops of TooSweet to the infant's tongue a few minutes before a painful procedure. Single dose, single patient use. Be sure to follow your hospital protocol for sucrose administration for infant pain management.

### Q How much TooSweet is administered in a Twist-Tip vial drop?

Each drop is approximately 40ul (microliters).

### Q Once opened, can I lay the Twist-Tip vial down without losing all the TooSweet?

Yes, you can lay the Twist-Tip vial on its side without dripping for easy re-application to the same baby during the same procedure.

### Q How does the Twist-Tip vial cost compare to the 12ml cup?

The Twist-Tip vial is a few pennies less than the cup.

The Twist-Tip vials mean less waste of sucrose solution, eliminates the cost of oral syringes used to draw up sucrose, and saves time spent on cleaning up spilled sucrose solution.

### Q What's the shelf life for the Twist-Tip vials?

Two years – same as the TooSweet cup.

### Q What makes TooSweet more economical and convenient for my hospital?

- Stable, broad-based cups are less prone to tipping (single dose, 12ml in 1oz cup)
- Twist-Tip vials (single dose, 0.5ml, 1ml or 2ml vials) eliminate waste and cost of oral syringes
- Two year shelf life so manufacturing costs are lower – which means lower product cost
- Inventory can be kept in stock – reducing the need for frequent, time-consuming reorders
- Eliminates time-consuming mixing in hospital pharmacy or at bedside
- No risk of inconsistent formulation
- No waste of outdated inventory with short shelf life



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**Q If you give a baby too much sucrose (2ml instead of 1ml) would there be a problem?**

Sucrose’s clinical efficacy is a result of mucosal absorption, not ingestion. There have been no reports of the use of sucrose for pain causing an elevation of glucose levels in a baby. Literature suggests the recommended dosage is 1-2ml. In Canada, protocols call for 0.5ml. Please follow your hospital protocol in place.

**Q Are there any studies or research materials related to babies overdosing on sucrose?**

There are no reports of elevated glucose levels in babies after sucrose has been administered for pain. We recommend clinicians adhere to their facility’s protocol.

**Q For what age babies is sucrose effective?**

There is little literature regarding the use of sucrose in infants older than a few weeks. We currently supply TootSweet to a number of pediatricians’ offices. They report good results when TootSweet is used during immunizations, etc.

**Q What packaging options and quantities are available when ordering TootSweet?**

ITEM #	DESCRIPTION	QUANTITY
<b>24% Sucrose Solution</b>		
1040021	1oz cups with 12ml	Box of 40
1040022	1oz cups with 12ml	Case of 240 (6 Boxes)
1040029-100	Twist-Tip Vials – 0.5ml each	Box of 100
10400212-100	Twist-Tip Vials – 0.5ml <b>indiv. bagged</b>	Box of 100
1040027-100	Twist-Tip vials – 1ml each	Box of 100
10400213-100	Twist-Tip vials – 1ml <b>indiv. bagged</b>	Box of 100
1040028-100	Twist-Tip vials – 2ml each	Box of 100
10400214-100	Twist-Tip vials – 2ml <b>indiv. bagged</b>	Box of 100

**Product Specifications:**

1oz cup containing 12ml; Twist-Tip vials containing 0.5ml, 1ml or 2ml.

24% sucrose in purified water; 0.022% methylparaben and 0.073% potassium sorbate as preservatives; citric acid and dibasic sodium phosphate as buffers.

**Footnotes:**

1. Grazel R, Neonatal Pain Management with Oral Sucrose. The Online Journal of Knowledge Synthesis For Nursing (OJKSN) Clinical Column, Document Number 7C, March 6, 2003. 2. Stevens B, Yamada J, Ohlsson A, Sucrose for analgesia in newborn infants undergoing painful procedures. The Cochrane Library, Issue 3, 2004. Chichester, UK: John Wiley & Sons, Ltd. 3. Barr RG, Quek VSH, Cousineau D, Oberlander TF, Brian JA, Young SN, Effects of Intra-Oral Sucrose on Crying, Mouthing and Hand-Mouth Contact in Newborn and Six-Week-Old Infants; Developmental Medicine and Child Neurology, 1994, 36, 608-618 4. RxMed: Pharmaceutical Information; Garamycin Parenteral; 12-13-2003 5. Barnes AR, Hebron BS, Smith J.; Stability of caffeine oral formulations for neonatal use. J Clin Pharm Ther.1994 Dec; 19 (6):391-6

Other references of interest: Blass EM, Smith BA, Differential Effects of Sucrose Fructose, Glucose and Lactose on Crying in 1-to 3-Day-Old Human Infants: Qualitative and Quantitative Considerations. Developmental Psychology. 1992, Vol. 28, No. 5, 804-810 Smith BA, Fillion TJ, Blass EM, Orally Mediated Sources of Calming in 1-to 3- Day-Old Human Infants. Developmental Psychology. 1990, Vol. 26, No. 5, 731-737.



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