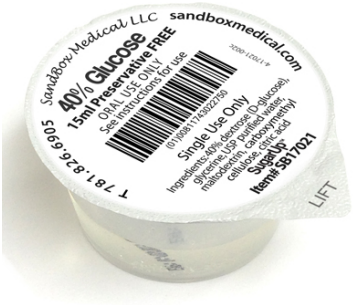
SandBox Medical

SugarUp™ 40% Glucose Gel FAQs

ORAL ADMINISTRATION, SINGLE PATIENT USE



15ml Cup
Preservative-Free

Individually Bagged

2.25ml* Prefilled Oral-Only Syringes
With Preservatives

** Each syringe contains approximately 2.25ml of gel.*

1. **What is the formulation of SugarUp™?**
   CUPS: Each cup contains 15ml of gel.
   Gel formulation: 40% dextrose (D-glucose), glycerine, USP purified water, maltodextrin, carboxymethyl cellulose, and citric acid (buffer). 12 month shelf life. Latex free, DEHP free, BPA free.

   PREFILLED ORAL-ONLY SYRINGES: Each 3ml oral-only syringe contains approximately 2.25ml of gel.
   Gel formulation: 40% dextrose (D-glucose), glycerine, USP purified water, maltodextrin, carboxymethyl cellulose, methylparaben & potassium sorbate (preservatives), citric acid & NACL (sodium chloride) (buffers). 24 month shelf life. Latex free, DEHP free, BPA free.
   Gel made and packaged in the USA. Syringe made in China.
   Note: Preservatives are the same as used in SweetUms™ 24% Sucrose solution.

2. **Does SugarUp™ have an NDC code? Is SugarUp™ registered with any drug databases**?
   No, SugarUp does not have an NDC code. NDC codes are reserved for drugs and SugarUp is considered a food by the FDA.

   SugarUp is searchable within the First Data Bank (FDB) drug database using the UPC codes assigned by FDB. You can also search for **SugarUp** or **Sandbox Medical**.

   The SugarUp UPC codes assigned by FDB are:
   11743-0022-81 SUGARUP 40% GLUCOSE GEL Box of 144 Cups
   11743-0022-85 SUGARUP 40% GLUCOSE ORAL SYRNGE, Box of 250 Oral Syringes

3. **Is SugarUp™ barcoded and marked with lot number and expiration date?**
   Yes, the barcode, lot number and expiration date are on the cup.
   The syringe bag is barcoded. The label on each syringe contains the lot number and expiration date, which are visible through a window in the outer bag.

4. **How is the 40% Glucose level determined and what is the margin of error for the level?**
   The 40% glucose level is established by the percentage weight of glucose (40%) in the overall formulation. A Brix meter is used to measure the percentage of sugar in each lot. The acceptable range is plus/minus 2%.

5. **How is SugarUp™ different from other glucose gel products?**
   Commercially available 40% glucose gels are limited to tubes and packets, all of which contain preservatives, artificial colors, and flavors. Many also contain xanthan gum, which can cause necrotizing enterocolitis.

   SugarUp contains no artificial flavor/colors and does not contain xanthan gum. SugarUp also is less expensive than other brands.

   SugarUp 15ml cups are preservative-free.

   SugarUp prefilled oral-only syringes contain baby-appropriate preservatives to prevent mold and bacteria growth. Preservatives are necessary due to our syringe filling procedures.

6. **Why do SugarUp prefilled oral-only syringes contain preservatives?**
   Baby appropriate preservatives insure the prefilled oral-only syringes are bacteria-free and appropriate for oral use. Preservatives are necessary due to our syringe filling procedures.

   The hot fill sterilizing process used for the SugarUp cups cannot be used in syringe filling process. The preservatives in SugarUp prefilled oral-only syringes are methylparaben & potassium sorbate, and are the same preservatives used in SweetUms 24% sucrose.
   These preservatives pass USP <51> Preservative Effectiveness Testing indicating SugarUp is free of bacteria and passes bacteria challenges.

   SugarUp in oral syringes contains the same preservative in our SweetUms™ 24% sucrose solution. SweetUms with preservatives is used by 50% of our customers, including many of the largest children's hospitals in the country.

7. **How is SugarUp™ controlled for potency and purity?**
   The percentage of glucose is determined by weight – 40% of the overall final solution. We also use a Brix meter to test the final sugar content for each lot, with a tolerance range of plus/minus 2%. For more information on the purity issue see the following question on our manufacturing processes.

8. **Where is SugarUp™ manufactured?**
   SugarUp™ is manufactured at an FDA registered and inspected food facility in the USA. Our manufacturing partner has achieved Level Three certification by the internationally recognized Safe Quality Food (SQF) program for food manufacturers. Level Three certification (the highest obtainable level) indicates the company has implemented a comprehensive safety and quality management system for food manufacturing

9. **What manufacturing processes are used to make SugarUp™?**
   SugarUp Manufacturing Process: CUPS
   Our manufacturing partner uses two FDA approved manufacturing processes to insure Commercial Sterility: hot fill/inversion and controlling for Water Activity (Aw).
   Essentially, hot fill/inversion is the process by which a hot liquid is injected into a container and then the container is inverted, allowing the heat to sterilize the container and container cap. After filling with the heated gel, the container is hermetically sealed. The heated liquid must be between 71c and 72 Celsius (160 to 162 degrees Fahrenheit) to ensure sterilization and requires the use of containers that do not change form at high temperatures, such as glass and certain types of plastic like our 40% glucose cups. The heat treatment lasts at least 20 seconds, which is long enough to ensure sterilization. This process produces a "Commercially Sterile Product" by killing all microorganisms capable of growing in it.

   In addition to hot fill/inversion, the Water Activity (Aw) is also controlled during manufacturing of SugarUp™. Low Aw results in a Commercial Sterile food product. Most foods have a water activity above 0.95 which provides sufficient moisture to support the growth of bacteria, yeasts and mold. The amount of available moisture can be reduced to a point which will inhibit the growth of organisms. If the water activity level of a food is controlled to 0.85 or less in the finished product, a state of Commercial Sterility is achieved. The water activity level of SugarUp™ is tested for each lot to less than 0.85 and is typically in the 0.4 to 0.5 range.

   More information on water activity and food safety can be found at:
   https://www.fda.gov/ICECI/Inspections/InspectionGuides/InspectionTechnicalGuides/ucm072916.htm

   More information on hot fill/inversion processes can be found on the FDA website under TITLE 21—Part 113, Chapter 1, FOOD AND DRUG ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES, SUBCHAPTER B--FOOD FOR HUMAN CONSUMPTION: Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers.
   https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=113

   SugarUp Manufacturing Process: ORAL-ONLY SYRINGES
   SugarUp for oral-only syringes is prepared in a food grade manufacturing environment and filled in a clean-room environment per FDA Food Processing Standards. The gel is manufactured at the same facility that produces SugarUp in cups.

10. What is Commercial Sterility?

The FDA defines Commercial Sterility as:

(1) "Commercial sterility" of thermally processed food means the condition achieved--

(i) By the application of heat which renders the food free of--

(*a*) Microorganisms capable of reproducing in the food under normal nonrefrigerated conditions of storage and distribution; and

(*b*) Viable microorganisms (including spores) of public health significance; or

(ii) By the control of water activity and the application of heat, which renders the food free of microorganisms capable of reproducing in the food under normal nonrefrigerated conditions of storage and distribution.

11. What testing has been done on SugarUp™?

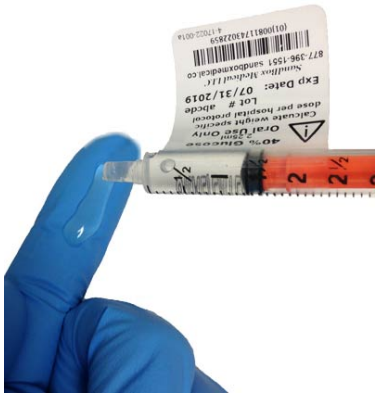
During development we tested the SugarUp™ gel for viscosity, stability, and potency. Each lot is tested for percentage of sugar, testing to rule out possible microbiologic contamination and the Water Activity (Aw) of the final product. The gel formulation for SugarUp oral syringes has been tested in accordance with USP <51> for preservative effectiveness.

12. How do we avoid bubbles when drawing SugarUp™ in a syringe?

Drawing a gel into an oral-only syringe is a challenge but gets easier with practice and experience. Here are some suggestions:

- Use a 3 or 5ml syringe.
- Draw the gel up SLOWLY – this avoids creating voids around the tip of the syringe. Voids allow air to get into the syringe.
- If there are large bubbles in the syringe – SLOWLY squirt the gel back into the cup and repeat the process.
- Small bubbles may be suspended in the gel but should not measurably impact the dose.

13. How is SugarUp™ administered?



Follow your hospital protocol to determine weight specific dose and administration protocols.

Suggested protocol based on clinical literature:

Dispense one-half dose from oral syringe onto gloved finger, in a stream - not a glob. The gel is thick enough to stay on the finger.

Massage into the buccal mucosa of one cheek.

Administer remaining half-dose inside alternate cheek.

Note: do not squirt gel directly into the baby's mouth. Always rub into the buccal mucosa where the blood flow insures absorption into the blood stream.

14. How many grams of glucose in SugarUp™?

The density of a glucose solution is approximately 1.02 grams, which is equal to approximately 1ml. Therefore, in a 15ml Cup containing 40% glucose, there would be approximately 6 grams of glucose; in a 2.25ml oral-only syringe, there would be approximately 0.9 grams of glucose.

15. Why are SugarUp™ cups packaged as 15ml of gel if only a few mls are required to treat a baby?

We found that using a lower volume made it harder to draw up in a syringe, more susceptible to sucking up air and causing air bubbles.

Why are SugarUp™ oral-only syringes prefilled as 2.25ml?

2.25ml is adequate for 95% of babies as one treatment. Calculate dose per weight. Follow your hospital protocol. The 2.25 volume in a 3ml syringe also makes sure the plunger is stable during shipping.

16. What is the shelf life of SugarUp™?

CUPS: SugarUp™ is aseptically packaged with a 12 month shelf life in unopened containers. We also have been using the same aseptic process with the same manufacturing partner for our preservative-free cups of SweetUms 24% sucrose (used for pain management in infants) for years, with no evidence of bacterial growth.

PREFILLED ORAL-ONLY SYRINGES: 24 months shelf life in unopened individual polybags.

17. Can I use the glucose gel remaining after an application?

Follow your hospital protocol.

CUPS: Because SugarUp™ glucose gel is preservative-free, it is single-patient, single-use only. Once opened, SugarUp™ is to be used, the cup and any remaining glucose gel should be discarded.

PREFILLED ORAL ONLY SYRINGES: The oral-only syringe is a single patient, single use item.

18. Are the cups and prefilled oral-only syringes containing the glucose gel recyclable?

The cup (with lid removed) and the syringes may be recycled with other #5 plastics (polypropylene).

19. How is the dose of glucose gel determined?

By the weight of the neonate. The current clinical literature indicates 0.5ml/kg of body weight per dose. Refer to your hospital protocol.

20. Do the cups and syringes contain BPA?

No, they are free of Latex, DEHP, and BPA.

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