

SugarUp™ 40% Glucose Gel FAQs ORAL ADMINISTRATION, SINGLE PATIENT USE



**Individually
Bagged**



**2.25ml* Prefilled Oral-Only Syringes
With Preservatives**

* Each syringe contains approximately 2.25ml of gel.

1. What are the SugarUp™ product specifications?

Each 3ml oral-only syringe contains approximately 2.25ml of gel.

Gel formulation: 40% dextrose (D-glucose), USP purified water, glycerine, maltodextrin, carboxymethyl cellulose, methylparaben & potassium sorbate (preservatives), citric acid & NACL (sodium chloride) (buffers).

24 month shelf life in unopened polybags.

Does not contain xanthan gum, artificial colors or flavors.

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:

11743-0022-85 SUGARUP 40% GLUCOSE ORAL SYRNGE, Box of 250 Oral Syringes

3. Is SugarUp™ barcoded and marked with lot number and expiration date?

The polybag containing the syringe and the label on the syringe itself both have a barcode.

In addition, the label on each syringe contains the lot number and expiration date, which are visible through a window in the outer polybag.

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 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 ensure the prefilled oral-only syringes are bacteria-free and appropriate for oral use. Preservatives are necessary due to our syringe filling procedures.

The preservatives in SugarUp prefilled oral-only syringes are methylparaben & potassium sorbate. 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 as 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 is the SugarUp™ Manufacturing Process?

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.

10. 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. The gel formulation for SugarUp oral syringes has been tested in accordance with USP <51> for preservative effectiveness.

11. 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.

12. 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 2.25ml oral-only syringe of 40% glucose, there would be approximately 0.9 grams of glucose.

13. 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.

14. What is the shelf life of SugarUp™?

24 month shelf life in unopened individual polybags.

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

Follow your hospital protocol.

The oral-only syringe is a single patient, single use item.

16. Are the prefilled oral-only syringes containing the glucose gel recyclable?

The syringes may be recycled with other #5 plastics (polypropylene).

17. 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.

18. What type of syringe is used for SugarUp™?

The SugarUp syringe has an oral only tip that is larger than an IV syringe tip. The SugarUp oral only syringe will not fit into an IV luer. If there is a need, we could offer SugarUp in an Enfit syringe. Please contact us if you would like to see an Enfit SugarUp syringe.

19. Do the syringes contain BPA?

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

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