

INSTRUCTIONS FOR USE
SYNDROS® (sin dros)
(dronabinol)
oral solution, CII

Read these Instructions for Use before you start taking SYNDROS oral solution and each time you get a refill. There may be new information. This information does not take the place of talking to your doctor about your medical condition or your treatment.

Important information about measuring SYNDROS oral solution:

- Always use the oral syringe that comes with your SYNDROS oral solution to measure your prescribed dose. Ask your doctor or pharmacist to show you how to measure your prescribed dose.

Important information about giving SYNDROS oral solution through a feeding tube:

- Give SYNDROS oral solution through feeding tubes that are made with silicone and that are size 14 French or larger. **Do not** give SYNDROS oral solution through feeding tubes that are not made with silicone or that are smaller than size 14 French.
- **Do not** use feeding tubes made with polyurethane.
- SYNDROS oral solution can be given through a naso-gastric tube (NG tube), gastrostomy tube (G-tube), percutaneous endoscopic gastrostomy tube (PEG-tube), and gastrojejunostomy tube (GJ-tube).
- Each SYNDROS carton contains (See Figure A):

- 1 bottle of SYNDROS oral solution
- 1 oral syringe
- 1 adapter (You will need to insert the adapter into the bottle before using the bottle for the first time.)

The contents in the SYNDROS carton are wrapped in plastic. Do not use the contents if they are not wrapped in plastic when you receive them.

Call Benuvia Operations, LLC at 1-844-558-8289 or www.syndros.com if:

- you do not receive an oral syringe or adapter with your SYNDROS
- you lose the oral syringe that comes with SYNDROS
- the contents in the SYNDROS carton are not wrapped in plastic when you receive them.

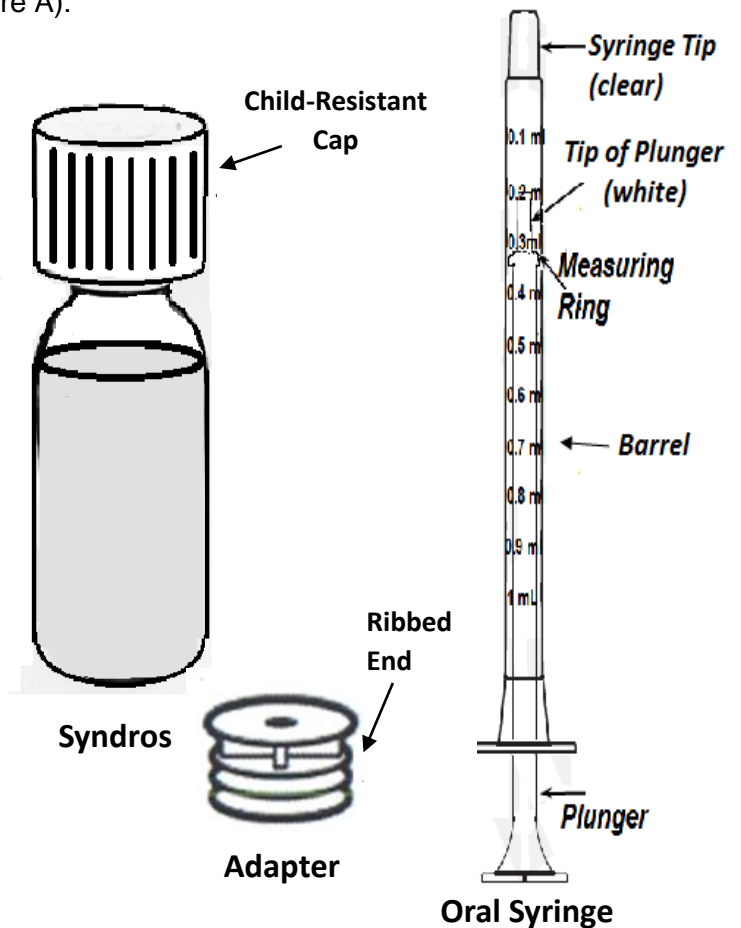


Figure A

How to prepare a bottle of SYNDROS oral solution before using for the first time:

Step 1: Remove the plastic wrap from the bottle and throw it away.

Step 2: Open the bottle by pushing down firmly on the child-resistant cap and turning it counter-clockwise (See Figure B). Do not throw away the child-resistant cap.

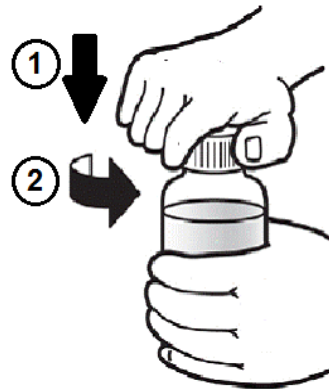


Figure B

Step 3: Remove the adapter from the plastic wrap. You may need to use a pair of scissors.

Step 4: Place the open bottle upright on a flat surface. Firmly push down on the adapter until the ribbed end of the adapter fits into the neck of the bottle as far as it will go and is firmly in place (See Figure C). The top edge of the adapter should be in full contact with the top rim of the bottle. **Do not remove the adapter from the bottle after it is inserted.**



Figure C

Step 5: Follow the instructions in “**How to prepare a dose of SYNDROS oral solution after the adapter is inserted.**”

How to prepare a dose of SYNDROS oral solution after the adapter is inserted:

Step 1: Open the bottle by pushing down firmly on the child-resistant cap and turning it counter-clockwise (See Figure D). Do not throw away the child-resistant cap.



Step 2: If you are using the oral syringe for the first time, remove the oral syringe from the plastic wrap. You may need to use a pair of scissors.

Step 3: Hold the oral syringe in one hand. With your other hand, fully push down (depress) the plunger (See Figure E).

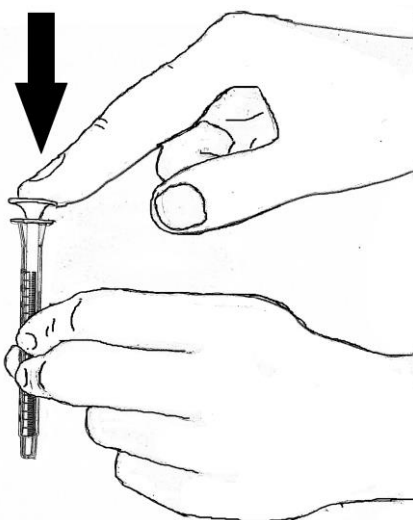


Figure E

Step 4: Keeping the bottle in an upright position, insert the syringe tip firmly into the adapter (See Figure F).

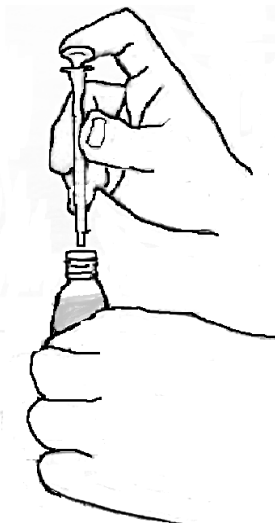


Figure F

Step 5: Carefully turn the bottle upside down with the syringe tip firmly inserted into the adapter (See Figure G).



Figure G

Step 6: Slowly pull back on the plunger until the measuring ring is at the line marking for the dose prescribed by your doctor. The measuring ring is the widest part of the plunger at the bottom of the tip of plunger. (See Figures H(a) and H(b)). Figure H(a) shows a dose of 0.4 mL as an example.

If you see air bubbles in the oral syringe, fully push in the plunger so that the oral solution flows back into the bottle. Then, withdraw your prescribed dose of oral solution.

If your prescribed dose is more than 1 mL, you will need to draw up two or more doses.

For example, if your dose is 1.2 mL, you will need to draw up a 1 mL dose followed by a 0.2 mL dose.

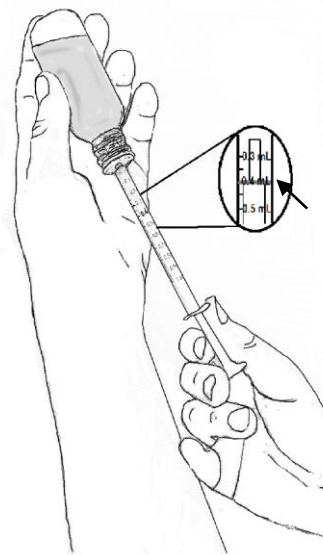


Figure H(a)

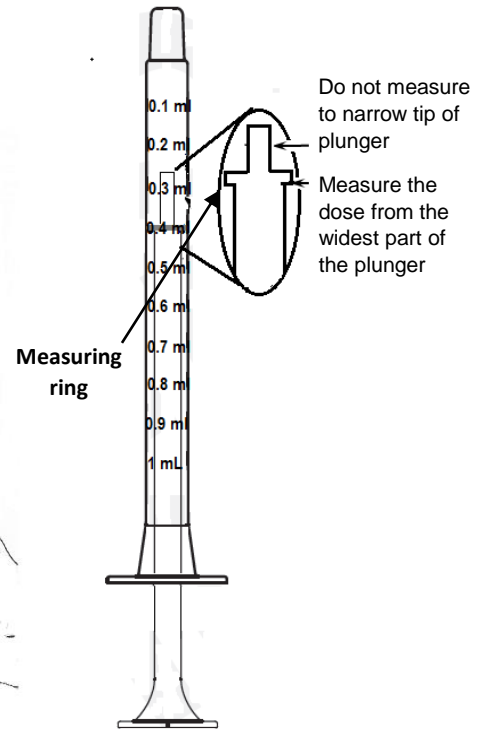


Figure H(b)

Step 7: Leave the oral syringe in the adapter and turn the bottle to an upright position. Place the bottle onto a flat surface. Remove the oral syringe from the bottle adapter by gently pulling straight up on the oral syringe (See Figure I).

Step 8: Check that the correct dose of SYNDROS oral solution was drawn up into the oral syringe.

If the dose is not correct, insert the syringe tip firmly into the bottle adapter. Fully push in

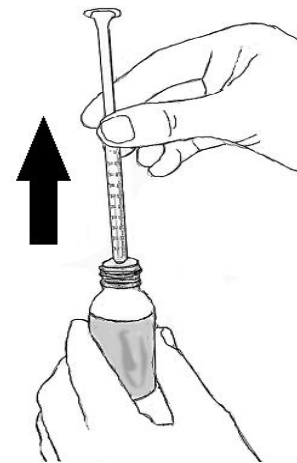


Figure I

the plunger so that the oral solution flows back into the bottle (See Figure J).

Repeat Steps 5-8.

If you are taking your dose of SYNDROS by mouth, follow the instructions in “**How to take a dose of SYNDROS oral solution by mouth.**”

If you are taking your dose of SYNDROS through a feeding tube, follow the instructions in “**How to take a dose of SYNDROS oral solution through a feeding tube.**”

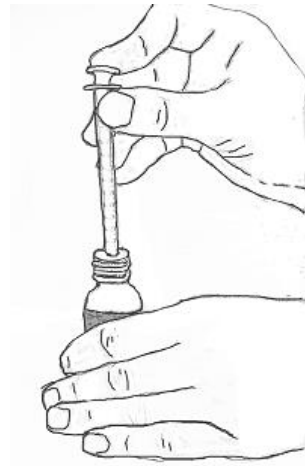


Figure J

How to take a dose of SYNDROS oral solution by mouth:

Step 1: Open your mouth. Place the oral syringe tip in the back of your mouth on top of your tongue. Tilt your head back slightly and close your lips around the barrel of the oral syringe. Slowly push down the plunger until the oral syringe is empty (See Figure K).

Swallow the oral solution.

If your prescribed dose is more than 1 mL, repeat Steps 4-8 in “**How to prepare a dose of SYNDROS oral solution after the adapter is inserted**” to draw up the remaining dose until the prescribed dose is given. For example, if your prescribed dose is 1.6 mL, take a 1 mL dose first, then an additional dose of 0.6 mL.

Take your SYNDROS oral solution right away after it is drawn up into the oral syringe.



Figure K

Step 2: Drink a full glass of water (6 to 8 ounces) right after you take your prescribed dose of SYNDROS oral solution (See Figure L).

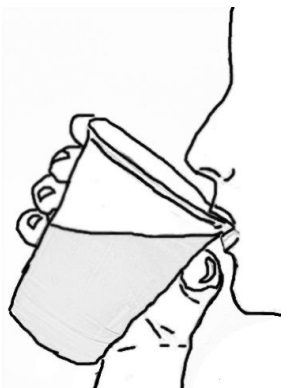


Figure L

Step 3: Leave the adapter in the bottle. Put the child-resistant cap back on the bottle (See Figure M).

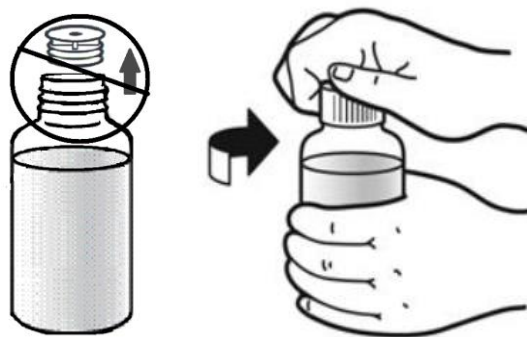


Figure M

Step 4: Remove the plunger from the oral syringe barrel. Rinse the oral syringe barrel and plunger with warm water after each use and let them air dry. When the oral syringe barrel and plunger are dry, put the plunger back into the oral syringe barrel for the next use. Keep SYNDROS oral solution and the oral syringe in the carton that it comes in. **Do not throw away the oral syringe.**

How to take a dose of SYNDROS oral solution through a feeding tube:

See “Important information about giving SYNDROS oral solution through a feeding tube.”

Step 1. Place the oral syringe into the feeding tube. Slowly push down the plunger until the oral syringe is empty (See Figure N).

If your prescribed dose is more than 1 mL, repeat Steps 4-8 in “How to prepare a dose of SYNDROS oral solution after the adapter is inserted” to draw up the remaining dose until the prescribed dose is given. For example, if your prescribed dose is 1.6 mL, take a 1 mL dose first, then an additional dose of 0.6 mL.

Take your SYNDROS oral solution right away after it is drawn up into the oral syringe.

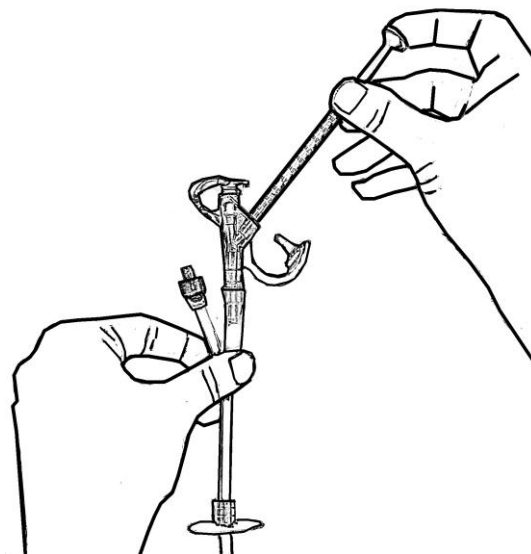


Figure N

Step 2. Using a catheter-tip syringe, flush the feeding tube with 1 ounce (30 mL) of water (See Figure O).

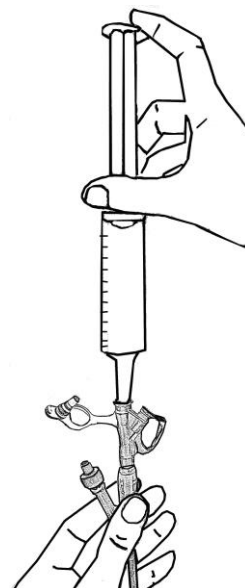


Figure O

Step 3: Leave the adapter in the bottle. Put the child-resistant cap back on the bottle (See Figure P).

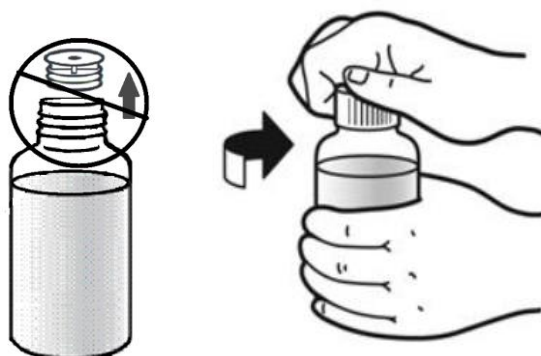


Figure P

Step 4: Remove the plunger from the oral syringe barrel. Rinse the oral syringe barrel and plunger with warm water after each use and let them air dry. When the oral syringe barrel and plunger are dry, put the plunger back into the oral syringe barrel for the next use. Keep SYNDROS oral solution and the oral syringe in the carton that it comes in.

Do not throw away the oral syringe.

How should I store SYNDROS?

- Store SYNDROS in the refrigerator between 36°F and 46°F (2°C and 8°C).
- After the bottle is opened, SYNDROS can be stored at room temperature, between 68°F and 77°F (20°C and 25°C), for up to 42 days.
- Do not use SYNDROS that has been stored in the refrigerator or at room temperature 42 days after opening the bottle. Write the date that you open the bottle of SYNDROS on the bottle and carton it comes in. See “**How should I dispose of unused SYNDROS?**”

Keep SYNDROS and all medicines out of the reach of children.

How should I dispose of unused SYNDROS?

- Dispose of unused SYNDROS as soon as you no longer need it or 42 days after opening the bottle.

Talk to your doctor or pharmacist if you have questions about how to use SYNDROS oral solution.

For more information, go to www.syndros.com or call 1-844-558-8289.

This Patient Information and Instructions for Use have been approved by the U.S. Food and Drug Administration.

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