

**CEO-TWO- laxative suppository**  
**Beutlich Pharmaceuticals, LLC**

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**CEO TWO**

**Active ingredients**

Potassium bitartrate, 0.9 g

Sodium bicarbonate, 0.6 g

**Purposes**

Laxative

**Uses**

- for relief of occasional constipation
- this product generally produces a bowel movement in 5 to 30 minutes

**Warnings**

**For rectal use only**

**Keep out of reach of children**

If swallowed, get medical help or contact a poison control center right away

**Do not use** laxative products when abdominal pain, nausea, or vomiting are present unless directed by a doctor

**Do not use** this product if you are on a low salt diet unless directed by a doctor

Do not lubricate with mineral oil or petrolatum prior to rectal insertion

If you have noticed a sudden change in bowel habits that persists over a period of 2 weeks, consult a doctor before using a laxative

Laxative products should not be used for a period longer than 1 week unless directed by a doctor

Rectal bleeding or failure to have a bowel movement after use of a laxative may indicate a serious condition. Discontinue use and consult your doctor.

**If pregnant or breast-feeding**

ask a health professional before use

## **Directions**

Adults and children 12 years of age and over: rectal dosage is one suppository containing 0.6 gram of sodium bicarbonate and 0.9 gram of potassium bitartrate in a single daily dose

Children under 12 years of age: consult a doctor

Detach one suppository from the strip; remove plastic wrapper. Moisten suppository by placing it under a water tap for 30 seconds, or in a cup of water for at least 10 seconds, before insertion. Insert rectally, bulb shape first, past largest diameter of suppository. Retain suppository as long as possible (usually 10 to 30 minutes) before defecating.

- **each suppository contains:** sodium, 164 mg

## **Other information**

- store at 20-25 °C (68-77 °F). Do not exceed 30 °C (86 °F).
- do not refrigerate
- for your protection, suppositories are individually wrapped in tamper-resistant film. Do not use if film is torn or open when purchased.
- save this carton for future reference

## **Inactive ingredient**

polyethylene glycol

## **Questions or comments?**

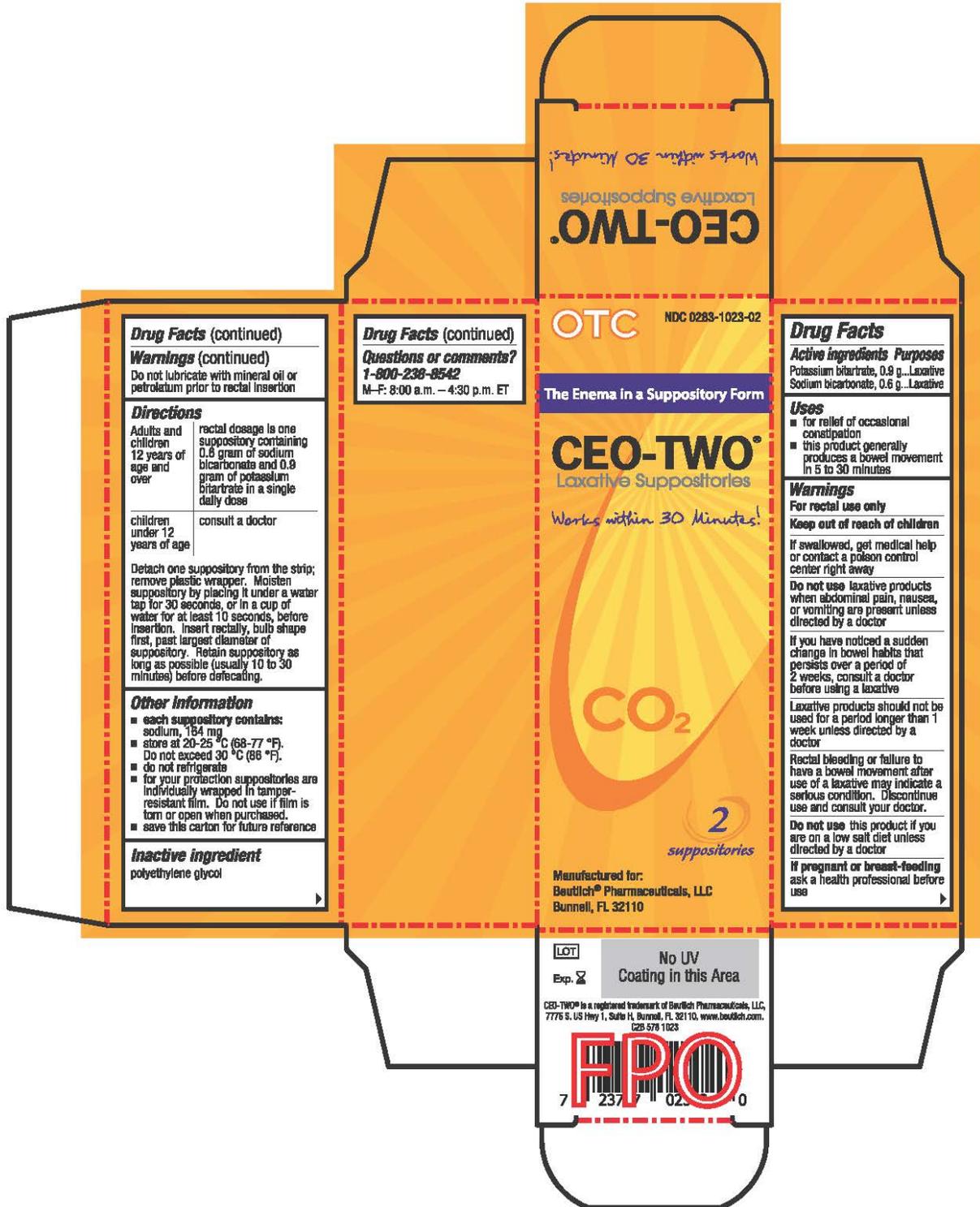
**1-800-238-8542**

M-F: 8:00 a.m. - 4:30 p.m. ET

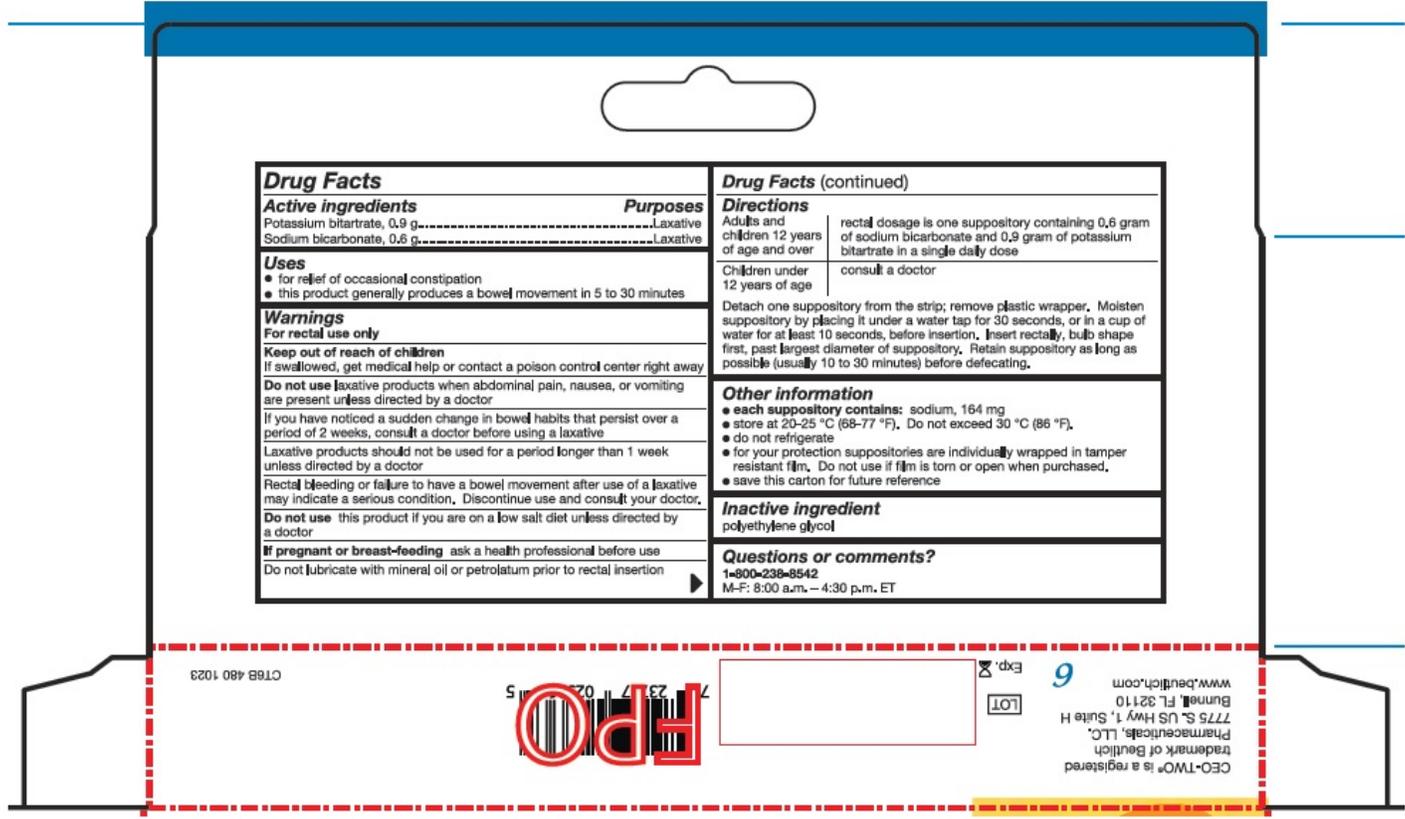
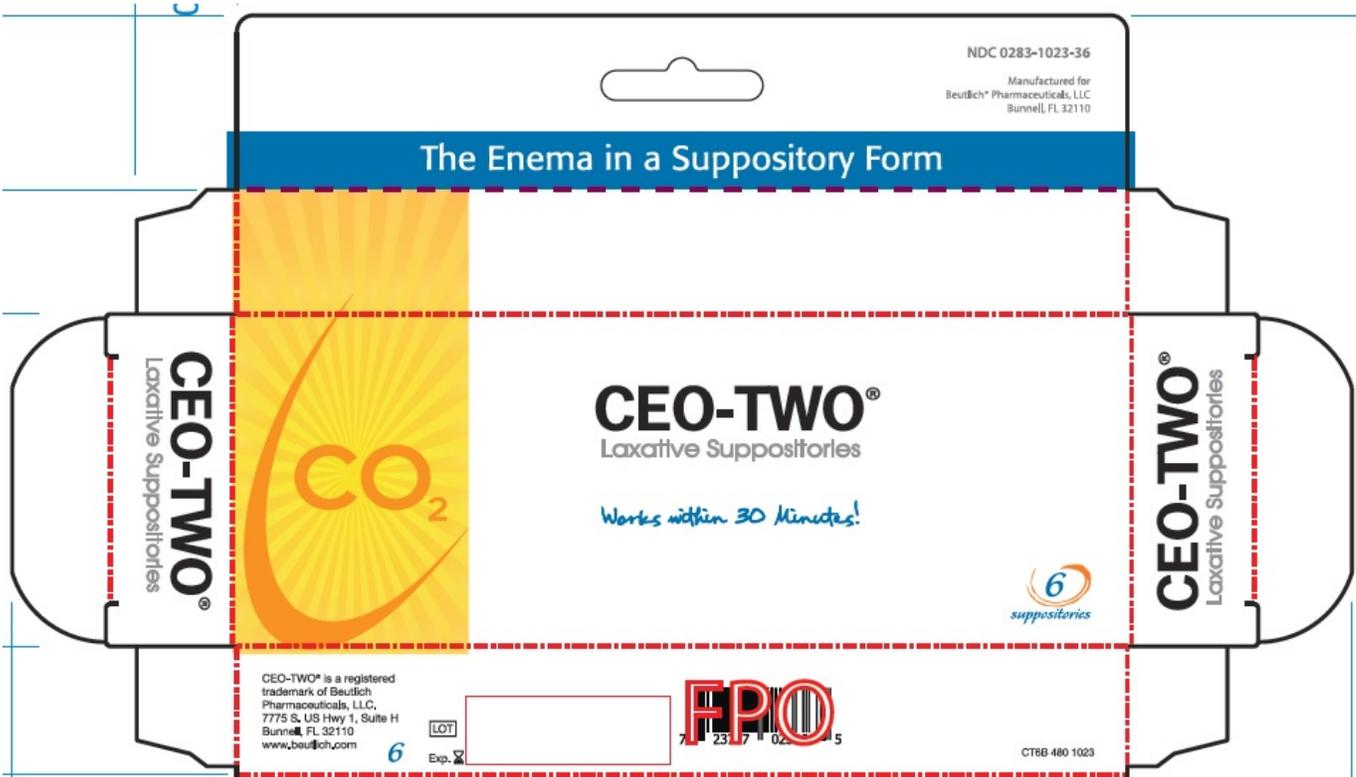
## **Principal Display Panel - 54 count**

CEO-TWO Laxative Suppositories

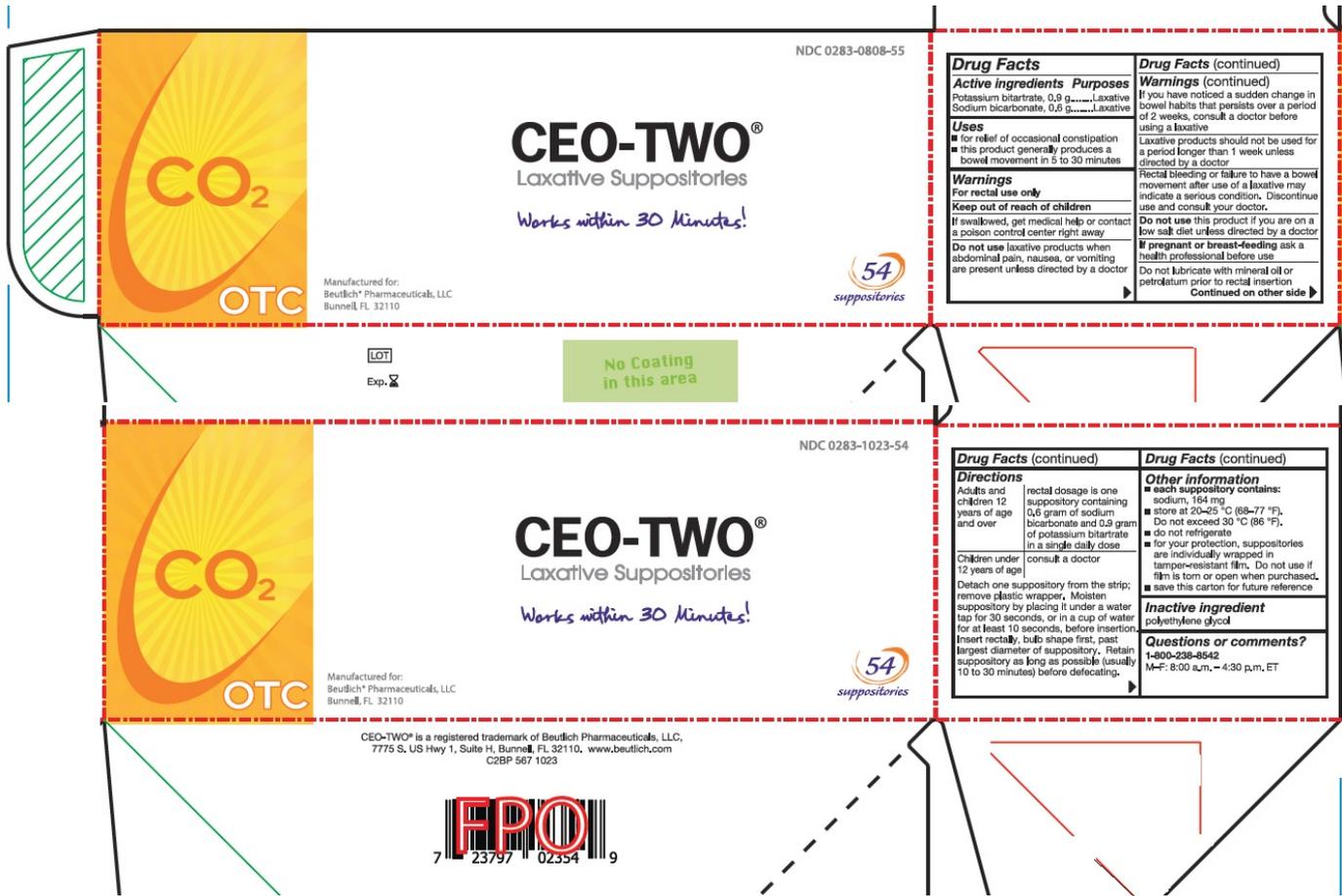
Box of 2:



Box of 6:



Box of 54:



<b>Drug Facts</b>		<b>Drug Facts (continued)</b>	
<b>Active ingredients</b>	<b>Purposes</b>	<b>Warnings (continued)</b>	
Potassium bitartrate, 0.9 g.....Laxative Sodium bicarbonate, 0.6 g.....Laxative	■ for relief of occasional constipation ■ this product generally produces a bowel movement in 5 to 30 minutes	If you have noticed a sudden change in bowel habits that persists over a period of 2 weeks, consult a doctor before using a laxative Laxative products should not be used for a period longer than 1 week unless directed by a doctor	
<b>Uses</b>		<b>Warnings</b>	
■ for relief of occasional constipation ■ this product generally produces a bowel movement in 5 to 30 minutes		Rectal bleeding or failure to have a bowel movement after use of a laxative may indicate a serious condition. Discontinue use and consult your doctor.	
<b>Warnings</b>		<b>Do not use this product if you are on a low salt diet unless directed by a doctor</b>	
For rectal use only		<b>If pregnant or breast-feeding ask a health professional before use.</b>	
<b>Keep out of reach of children</b>		<b>Do not use this product if you are on a low salt diet unless directed by a doctor</b>	
If swallowed, get medical help or contact a poison control center right away		<b>Do not use this product if you are on a low salt diet unless directed by a doctor</b>	
<b>Do not use laxative products when abdominal pain, nausea, or vomiting are present unless directed by a doctor</b>		<b>Do not lubricate with mineral oil or petroleum prior to rectal insertion</b>	
		<b>Continued on other side</b>	

<b>Drug Facts (continued)</b>		<b>Drug Facts (continued)</b>	
<b>Directions</b>		<b>Other information</b>	
Adults and children 12 years of age and over	rectal dosage is one suppository containing 0.6 gram of sodium bicarbonate and 0.9 gram of potassium bitartrate in a single daily dose	■ each suppository contains: sodium, 164 mg ■ store at 20-25 °C (68-77 °F). Do not exceed 30 °C (86 °F). ■ do not refrigerate ■ for your protection, suppositories are individually wrapped in tamper-resistant film. Do not use if film is torn or open when purchased. ■ save this carton for future reference	
Children under 12 years of age	consult a doctor	<b>Inactive ingredient</b> polyethylene glycol	
Detach one suppository from the strip; remove plastic wrapper. Moisten suppository by placing it under a water tap for 30 seconds, or in a cup of water for at least 10 seconds, before insertion. Insert rectally, bulb shape first, past largest diameter of suppository. Retain suppository as long as possible (usually 10 to 30 minutes) before defecating.		<b>Questions or comments?</b> 1-800-238-8542 M-F: 8:00 a.m. - 4:30 p.m. ET	

# CEO-TWO

laxative suppository

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0283-1023
<b>Route of Administration</b>	RECTAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>POTASSIUM BITARTRATE</b> (UNII: NPT6P8P3UU) (CARBON DIOXIDE - UNII:142M471B3J)	CARBON DIOXIDE	0.9 g in 5.7 g
<b>SODIUM BICARBONATE</b> (UNII: 8MDF5V39QO) (BICARBONATE ION - UNII:HN1Z RA3Q20)	SODIUM BICARBONATE	0.6 g in 5.7 g

## Inactive Ingredients

Ingredient Name	Strength
<b>POLYETHYLENE GLYCOL 1450</b> (UNII: OJ4Z5Z32L4)	4.2 g in 5.7 g

## Product Characteristics

<b>Color</b>	white	<b>Score</b>	
<b>Shape</b>	BULLET	<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0283-1023-02	2 in 1 BOX	10/15/2023	
1	NDC:0283-1023-00	5.7 g in 1 DOSE PACK; Type 0: Not a Combination Product		
2	NDC:0283-1023-36	6 in 1 BOX	10/15/2023	
2	NDC:0283-1023-00	5.7 g in 1 DOSE PACK; Type 0: Not a Combination Product		
3	NDC:0283-1023-54	54 in 1 BOX	10/15/2023	
3	NDC:0283-1023-00	5.7 g in 1 DOSE PACK; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M007	10/15/2023	

**Labeler** - Beutlich Pharmaceuticals, LLC (005209325)

**Registrant** - Beutlich Pharmaceuticals, LLC (005209325)

## Establishment

Name	Address	ID/FEI	Business Operations
Beutlich Pharmaceuticals, LLC		005209325	label(0283-1023) , pack(0283-1023)

## Establishment

Name	Address	ID/FEI	Business Operations
Speciality Pharma Manufacturing		013957125	manufacture(0283-1023)

Revised: 10/2023

Beutlich Pharmaceuticals, LLC