CEO-TWO- laxative suppository
Beutlich Pharmaceuticals, LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

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 ºC (68-77 ºF). Do not exceed 30 ºC (86 ºF).
- 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

Prinicipal Display Panel - 54 count

NDC 0283-0808-54

CEO-TWO

Laxative Suppositories

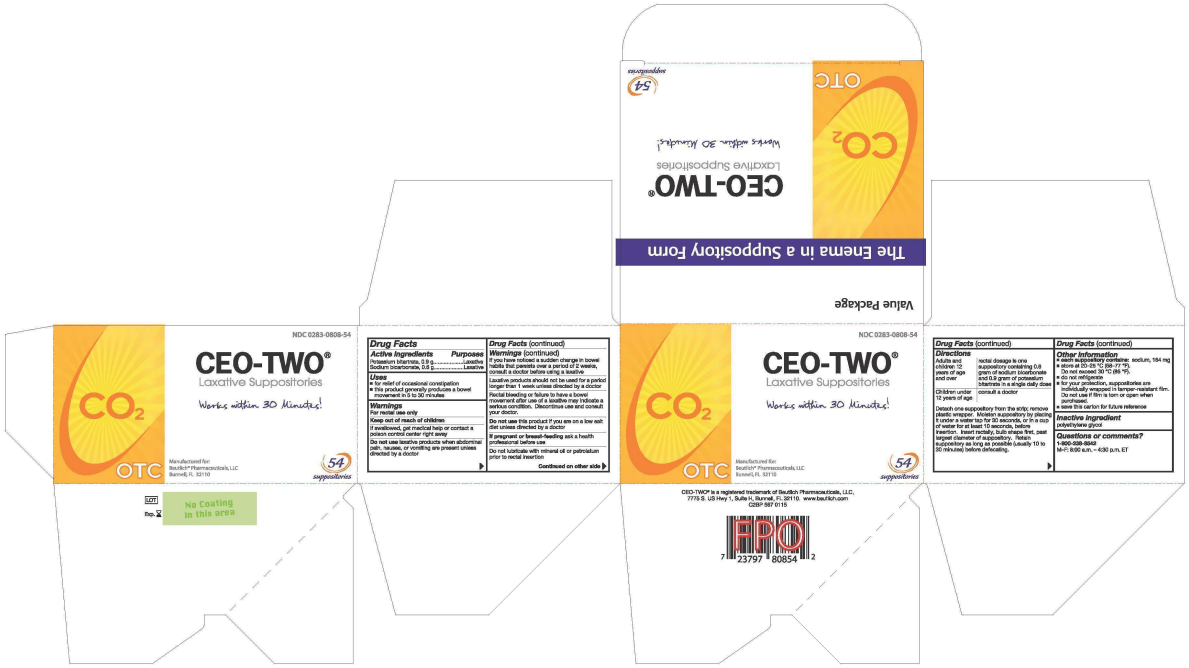
Works within 30 Minutes!

Manufactured for:

Beutlich Pharmaceuticals, LLC

Bunnell, FL 32110

54 suppositories



CEO-TWO

laxative suppository

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0283-0808
Route of Administration	RECTAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
POTASSIUM BITARTRATE (UNII: NPT6P8P3UU) (CARBON DIOXIDE - UNII:142M471B3J)	CARBON DIOXIDE	927 mg in 3.7 g
SODIUM BICARBONATE (UNII: 8MDF5V39QO) (SODIUM CATION - UNII:LYR4M0NH37)	SODIUM BICARBONATE	618 mg in 3.7 g

Inactive Ingredients	
Ingredient Name	**Strength**
POLYETHYLENE GLYCOL 1450 (UNII: OJ4Z5Z32L4)	2155 mg in 3.7 g

Product Characteristics			
Color	white	**Score**	
Shape	BULLET	**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0283-0808-12	12 in 1 BOX		
1	NDC:0283-0808-36	6 in 1 BOX		
1	NDC:0283-0808-11	2 in 1 BOX		
1	NDC:0283-0808-00	3.7 g in 1 DOSE PACK		
2	NDC:0283-0808-54	54 in 1 BOX		
2	NDC:0283-0808-36	6 in 1 BOX		
2	NDC:0283-0808-11	2 in 1 BOX		
2	NDC:0283-0808-00	3.7 g in 1 DOSE PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	08/15/2008	

Labeler - Beutlich Pharmaceuticals, LLC (005209325)

Registrant - Beutlich Pharmaceuticals, LLC (005209325)

Establishment

Name	Address	ID/FEI	Business Operations
DSC Laboratories		097807374	manufacture(0283-0808)

Establishment

Name	Address	ID/FEI	Business Operations
Beutlich Pharmaceuticals, LLC		005209325	repack(0283-0808)

Revised: 3/2015 Beutlich Pharmaceuticals, LLC