## DOCUSOL PLUS- docusate sodium w/benzocaine liquid Enemeez LLC DBA Summit Pharmaceuticals

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.

-----

#### **DocuSol® Plus**

# **Drug Facts**

# Active Ingredients (per delivered dose)

Benzocaine 20 mg

Docusate Sodium USP 283 mg

# **Purpose**

(Benzocaine)..... Anesthetic

(Docusate Sodium).... Stool Softener Laxative

#### Uses

- For the relief of occasional constipation (irregularity).
- This product generally produces a bowel movement in 2 to 15 minutes.

# Warnings

For rectal use only. Individuals with sensitivity to Benzocaine should not use this product. Drug Interaction Precaution: Do not take this product if you are presently taking mineral oil, unless directed by a doctor.

#### Do not use

- Laxative products when abdominal pain, nausea or vomiting are present.
- Laxative products for a period longer than 1 week unless directed by a doctor.

# Stop use and ask a doctor if you have:

- Rectal bleeding.
- Noticed a sudden change in bowel habits that persists over a period of 2 weeks.
- Failed to have a bowel movement after use. This may indicate a serious condition.

Pregnant or Lactating Women, ask a health professional before use.

**Keep out of reach of children**. In case of accidental ingestion, get medical help or contact a Poison Control Center immediately.

#### **Directions**

Adults and children 12 years of age and older (with adult supervision) one to three units daily. Children under 12 years of age, consult a doctor prior to use.

- Twist off and remove tip.
- Lubricate tip prior to insertion: Place a few drops of the tube's liquid content on the shaft prior to insertion. Also apply liquid content or lubricant to the anus before inserting the mini-enema.
- Positioning: For best results, lay on the left side with knees bent. Alternate Positions: Administer while seated on the toilet. Or, kneel, then lower head and chest forward until side of face is resting on the surface.
- With steady pressure, gently insert the tube into the rectum with care to prevent damage to the rectal wall. Insert up to the shoulder of tube. Squeeze to empty the contents. Keep the tube squeezed until it is removed from the rectum. After the contents have been emptied, remove the disposable tube and discard. A small amount of liquid may remain in the unit after use.

#### Other Information

Store at room temperature 15° - 30° C (59° - 86° F)

## **Inactive Ingredients**

Glycerin USP and Polyethylene Glycol



# **DOCUSOL PLUS**

docusate sodium w/benzocaine liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:17433-9883
Route of Administration	RECTAL		

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	283 mg in 5 mL	
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	20 mg in 5 mL	

Inactive Ingredients	
Ingredient Name	Strength
POLYETHYLENE GLYCOL 300 (UNII: 5655G9Y8AQ)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging		
	Markating Start	Markating End

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17433- 9883-5	5 in 1 BOX	07/12/2013	10/31/2024
1	NDC:17433- 9883-1	5 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	07/12/2013	10/31/2024

# Labeler - Enemeez LLC DBA Summit Pharmaceuticals (010717819)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Enemeez LLC DBA Summit Pharmaceuticals		010717819	manufacture(17433-9883)	

Revised: 11/2022 Enemeez LLC DBA Summit Pharmaceuticals