# LAXATIVE PILLS MAXIMUM STRENGTH- sennosides tablet Freds Inc

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.

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#### **DRUG FACTS**

### **Active ingredient (in each tablet)**

Sennosides USP, 25 mg

#### **Purpose**

Stimulant laxative

#### Uses

• relief of occasional constipation (irregularity). This product generally produces bowel movement within 6 to 12 hours.

## Warnings

#### Do not use

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

#### Ask a doctor before use if

• you notice a sudden change in bowel habits that persists over a period of 2 weeks

### Stop use and ask a doctor if

- you have rectal bleeding
- you fail to have a bowel movement after use. These may be signs of a serious condition.

#### If pregnant or breast-feeding,

ask a health care professional before use.

#### Keep out of reach of children

In case of overdose, get medical help or contact a Poison Control Center right away.

## **Directions**

adults and children 12 years of age and older	take 2 tablets once or twice daily with a glass of water
children 6 to under 12 years of age	take 1 tablet once or twice daily with a glass of water
children under 6 years of age	consult a doctor

#### Other information

- each tablet contains: calcium 40 mg/tablet
- each tablet contains: magnesium 10 mg/ tablet

- each tablet contains: **sodium 3 mg/ tablet** VERY LOW SODIUM
- store at 15° 30° C (59°-86° F)
- keep in a dry place
- do not expose to excessive heat

## **Inactive ingredients**

acacia, anhydrous lactose\*, calcium sulfate anhydrous, carnauba wax, colloidal silicon dioxide, corn starch, croscarmellose sodium, dibasic calcium phosphate dihydrate, FD&C Blue #1 Aluminum Lake, iron oxide, iron oxide Black, iron oxide Yellow, isopropyl alcohol\*, kaolin, Lake Brilliant Blue FCF\*, magnesium stearate, malto dextrin\*, microcrystalline cellulose, Opacode Black S-1-17823\*, Opagloss 6000P\*, polyethylene glycol, povidone, pregelatinized starch, shellac, sodium lauryl sulfate, stearic acid, sugar, talc, tartaric acid\*, titanium dioxide.

\*contains one or more of these ingredients

## **Questions or Comments?**

Call toll free 1-877-753-3935 Monday-Friday 9AM-5PM EST

## **Principal Display Panel**

Compare to active ingredient in maximum strength EX-LAX® †

Maximum Strength

Laxative Pills

Sennosides USP, 25 mg

natural senna ingredient

for gentle, dependable overnight relief

#### TAMPER EVIDENT- USE ONLY IF BLISTERS ARE INTACT

#### KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

 $\dagger$  This product is not manufactured or distributed by Novartis Consumer Health, Inc., owner of the registered trademark Ex-Lax®

#### **Product Label**



## LAXATIVE PILLS MAXIMUM STRENGTH

sennosides tablet

Product Information				
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:55315-140	
Route of Administration	ORAL	DEA Schedule		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
SENNOSIDES (SENNOSIDES)	SENNOSIDES	25 mg	

Inactive Ingredients	
Ingredient Name	Strength
ACACIA	
CALCIUM SULFATE ANHYDRO US	
CARNAUBA WAX	
SILICON DIO XIDE	
STARCH, CORN	
CROSCARMELLOSE SODIUM	
CALCIUM PHO SPHATE, DIBASIC, DIHYDRATE	
FD&C BLUE NO. 1	
FERRIC OXIDE RED	
FERROSOFERRIC O XIDE	
FERRIC OXIDE YELLOW	
KAOLIN	
MAGNESIUM STEARATE	
CELLULOSE, MICRO CRYSTALLINE	
POLYETHYLENE GLYCOLS	
POVIDONES	
STARCH, CORN	
SHELLAC	
SODIUM LAURYL SULFATE	
STEARIC ACID	
SUCROSE	
TALC	
TITANIUM DIO XIDE	
ANHYDROUS LACTOSE	
ISOPROPYL ALCOHOL	
MALTO DEXTRIN	
TARTARIC ACID	

Product Characteristics				
Color	BLUE	Score	no score	
Shape	ROUND	Size	10 mm	
Flavor		Imprint Code	TCL083;S25	
Contains				

]	Packaging				
#	tem Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:55315-140-03	2 in 1 CARTON			
1		12 in 1 BLISTER PACK			

## **Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part334	07/08/2010	

## **Labeler -** Freds Inc (005866116)

**Registrant** - P and L Development of New York Corporation (800014821)

Revised: 1/2013 Freds Inc