

HARRIS TEETER- mineral oil
Harris Teeter

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.

Harris Teeter 831.000-AA

active ingredients

mineral oil 99.9%

Purpose

Lubricant laxative

Use

for relief of occasional constipation (irregularity). Generally produces bowel movement in 6 to 8 hours

Do not use

- if you have difficulty swallowing
- in children under 6 years of age
- if you are pregnant
- for a period longer than 1 week
- if you are bedridden or aged

Ask a doctor before use if you have

- abdominal pain, nausea, or vomiting
- noticed a sudden change in bowel habits that persists over a period of 2 weeks

Ask a doctor or pharmacist before use if you are

- presently taking a stool softener laxative
- taking any other drug. Take this product 2 or more hours before or after other drugs. Laxatives may affect how other drugs work.

When using this product

do not take with meals. Take only at bedtime.

Stop use and ask a doctor

if you have rectal bleeding or failure to have a bowel movement after use. These could be signs of a serious condition.

If breast feeding,

ask a health professional before use

Keep out of reach of children

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

Direction

- do not take with meals
- take only at bedtime
- may be taken as a single daily dose or in divided doses

adults and children 12 years of age and over - 1 to 3 Tablespoons (15 to 45 mL)
maximum 3 Tablespoons (45 mL) in 24 hours

children 6 to 12 year old of age - 1 to 3 teaspoons (15 mL) in 24 hours

children under 6 years of age - do not use, consult a doctor

Other information

keep tightly closed. Protect from sunlight

Inactive ingredients

mixed tocopherols (added as a stabilizer)

Questions?

Call 1-888-593-0593

principal display panel

Harris Teeter

MINERAL OIL

U.S.P.

LUBRICANT LAXATIVE

FOR RELIEF OF OCASIONAL CONSTIPATION

ODORLESS - TASTELESS - COLORLESS

SEALED WITH PRINTED FOIL UNDER CAP FOR YOUR PROTECTION

16 FL OZ (1 PT) 473 mL



HARRIS TEETER

mineral oil

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69256-831
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MINERAL OIL (UNII: T5L8T28FGP) (MINERAL OIL - UNII:T5L8T28FGP)	MINERAL OIL	999 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
TOCOPHEROL (UNII: R0ZB2556P8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69256-831-43	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/03/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	05/03/2017	

Labeler - Harris Teeter (048463103)

Registrant - Vi-Jon, LLC (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(69256-831)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(69256-831)

Revised: 5/2022

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