## MICROLAX ENEMA- microlax enema enema MEDIA NETWORKS SYDNEY PTY LIMITED

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

\_\_\_\_\_

Dosage Form Enema Route of Administration Rectal Visual Identification A colourless, opalescent and viscous preparation.

No Warnings included on Record

glycerol purified water sorbic acid

Permitted Indications No Permitted Indications included on Record Indication Requirements No Indication Requirements included on Record

keep out of reach of children

Single Medicine Product Specific Indications Rectal constipation, faecal incontinence; preparation for X-ray examination and rectoscopy

Active Ingredients

sodium citrate dihydrate 90 mg/mL

sodium lauryl sulfoacetate 9 mg/mL

sorbitol 625 mg/mL



Microlax Enema 5mlx12

## **MICROLAX ENEMA**

microlax enema enema

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84177-0020	
Route of Administration	RECTAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
SORBITOL (UNII: 506T60A25R) (SORBITOL - UNII:506T60A25R)	SORBITOL	625 mg in 1 g		

Inactive Ingredients			
Ingredient Name	Strength		
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	90 mg in 1 g		
SODIUM LAURYL SULFOACETATE (UNII: D0Y70F2B9J)	9 mg in 1 g		
GLYCEROL FORMAL (UNII: 3L7GR2604E)			
WATER (UNII: 059QF0KO0R)			
SORBIC ACID (UNII: X045WJ989B)			

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84177- 0020-1	1 g in 1 BOX; Type 0: Not a Combination Product	03/01/2024	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
unapproved drug other		03/01/2024		

## Labeler - MEDIA NETWORKS SYDNEY PTY LIMITED (748621327)

## Registrant - MEDIA NETWORKS SYDNEY PTY LIMITED (748621327)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
MEDIA NETWORKS SYDNEY PTY LIMITED		748621327	manufacture(84177-0020)	

Revised: 3/2024 MEDIA NETWORKS SYDNEY PTY LIMITED