5/2/01 (1)

Petition FDA;

RE: Polyethylene Glycol Poisoning in my 3 yr old.

This is not an environmental impact State is not required

My daughter is 4 yrs old She was given Mira Lax (Polyethylene Glycol) by her Gastro Interologist She went into a state of panic or freaking. See attached: 28 symptoms. I would like some Immediate action taken to Investigate these findings before more children are exposed to this chemical. It has only been on the market for 1 year and states on

the insert DO NOT GIVE TO PEDIATRIC PATIENTS These Doctors are using it "off Labeled" and needs to be stopped through my investigation I have found other pediatric patients that had the same side affects see: Insert as young as 16 mon old. the company Braintree labs as well as the Doctors are certain it's not aborbed by the body and I am convinced the somehow it does and is causing serious damage. In the UK they don't use polyethylene

Glycol because it's so toxic and Dangerous. Please investigate further. Out of my daughter's 28 symptoms, some have not went away, tremors, Neurological symptoms
Abdominal pain
PAranoia
movement disorder
fear
Disturbance in Attention

It has been 7 months and her symptoms have not went away and her tremors are worse and need more medical attention.

Sincerely
Jeanie Ward

Jeanie Ward
586 Somerset Ln #5
Crystal Lake IL 60014
815 356-8945

5/17/01

9607 Certification Document

I Jeanie Ward, am stating that all material to the best of my Knowledge is correct I am aware of this

Jeanie Ward

RE:

Polyethylene Glycol Investigation

This chemical could have been absorbed threw "leaky Gut" We need to find out how this is happening & how we can help my daughter. She is still undergoing medical Attention.

Any Q's 815 356-8945

Jeanie Ward
586 Somerset Ln # 5
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5/17/01

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Jeanie Ward

RE:

Polyethylene Glycol Investigation

This chemical could have been absorbed threw "leaky Gut" We need to find out how this is happening & how we can help my daughter. She is still undergoing medical Attention.

Any Q's 815 356-8945

Jeanie Ward
586 Somerset Ln # 5
Crystal Lake IL 60014

FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report
Standard Report - All Preferred Terms in Cases

4

MedDRA Preferred Term Reaction	Count	%Rpts
Drug maladministration	4	57.1%
Nausea	2	28.6%
Abdominal pain NOS	1	14.3%
Abnormal behaviour NOS	1	14.3%
Antisocial behaviour	1	14.3%
Appetite decreased	1	14.3%
Bipolar I disorder	1	14.3%
Feeling cold	1	14.3%
Insomnia NEC	1	14.3%
Tremor NEC	1	14.3%
Throat tightness	1	14.3%
Staring	1	14.3%
Speech disorder NEC	1	14.3%
Paranoia	1	14.3%
Obsessive-compulsive disorder	1	14.3%
Night sweats	1	14.3%
Neurological symptoms NOS	1	14.3%
Movement disorder NOS	1	14.3%
Frequent bowel movements	1	14.3%
Fear, focus NEC	1	14.3%
Convulsions NOS	1	14.3%
Depressed mood	1	14.3%
Diarrhoea NOS	1	14.3%
Disturbance in attention NEC	1	14.3%

Total Reactions: 28

20 pages

DEPARTMENT OF HEALTH AND HUMAN SERVICES **Public Health Service**

Center for Drug Evaluation and Research
Office of Training and Communication
Freedom of Information Staff HFD-205
5600 Fishers Lane 12 B 05
Rockville, Maryland 20857

April 23, 2001

In Response Refer to File : F01-5826

Jeanie Ward
586 Somerset Lane, #5
Crystal Lake, IL 60014

Dear Ms. Ward:

This is in response to your request dated 4/2/01, in which you requested adverse reactions associated with the use of Miralax. Your request was received in the Center for Drug Evaluation and Research on 4/4/01.

Please find the enclosed data which summarizes reports of events to the above mentioned drug(s). This data contains only reports of adverse events which have been entered into the computerized filing system maintained by the Office of Post-Marketing and Drug Risk Assessment.

Charges of $55.00 (Search $0, Review $0, Reproduction $0, Computer time $55.00) will be included in a monthly invoice. **DO NOT SEND ANY PAYMENT UNTIL YOU RECEIVE AN INVOICE.**

If there are any problems with this response, please notify us in writing of your specific problem(s). Please reference the above file number.

This concludes the response from the Center for Drug Evaluation and Research.

Sincerely,

Hal Stepper

Hal Stepper
Paralegal Specialist
Office of Training and Communications
Freedom of Information Staff, HFD-205

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date: 01/28/98 **ISR Number:** 3021591-1 **Report Type:** Direct **Company Report #** **Age:** 50 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Nausea		Colyte	PS		ORAL	4L PO X 1	

Date: 01/28/98 **ISR Number:** 3021649-7 **Report Type:** Direct **Company Report #** **Age:** 68 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Vomiting Nos Weakness		Colyte	PS			4 L PO X1	

Date: 01/28/98 **ISR Number:** 3087029-3 **Report Type:** Direct **Company Report #** **Age:** 50 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Nausea		Colyte	PS		ORAL	4 L PO X 1	

Date: 04/03/98 **ISR Number:** 3061359-3 **Report Type:** Expedited (15-Day) **Company Report #** B0053861 **Age:** 37 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Hospitalization - Initial or Prolonged	Abdominal Pain Nos Blood Amylase Increased Blood Creatinine Increased Blood Urea Increased Intestinal Obstruction Nos Lipase Increased Lymphoma Nos Necrosis Pancreatitis Acute	Foreign	Valaciclovir Magnesium Pidolate Zovirax Macrogol 4000 Morphine Septra	PS SS SS SS SS SS		ORAL ORAL INTRAVENOUS DRIP ORAL ORAL ORAL	ORAL ORAL 600 MG/THREE TIMES PER DAY INTRAVENOUS SIX TIMES PER DAY ORAL 20 MG/TWICE PER DAY/ORAL 480 MG/PER DAY/ORAL	

Date: 05/07/98 **ISR Number:** 3074639-2 **Report Type:** Expedited (15-Day) **Company Report #** B0053861 **Age:** 37 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Hospitalization - Initial or Prolonged Other	Abdominal Pain Nos Blood Amylase Increased Blood Creatinine Increased Blood Urea Increased Lipase Increased Necrosis Occlusion Nos Pancreatitis Acute	Foreign	Valaciclovir Magnesium Pidolate Zovirax Sterile Powder Macrogol 4000 Morphine Sulphate Septra	PS SS SS SS SS SS		ORAL ORAL INTRAVENOUS DRIP ORAL ORAL ORAL	ORAL ORAL 600 MG/THREE TIMES PER DAY INTRAVENOUS SIX TIMES PER DAY/ORAL 20 MG/TWICE PER DAY/ORAL 480 MG /PER DAY/ORAL	

FDA - Adverse Event Reporting System (AERS)

Freedom Of Information (FOI) Report

Date: 08/23/00 **ISR Number:** 3556117-7 **Report Type:** Direct **Company Report #** **Age:** 16 YR **Gender:** Male **I/FU:** 1

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Abdominal Distension Blood Creatinine Increased Blood Urea Increased Hypotension Sluggishness Tachycardia Nos Wound Drainage Increased		Golytely	PS			150 CC/HR PER G-TUBE	

Date: 09/08/00 **ISR Number:** 3568189-4 **Report Type:** Direct **Company Report #** USP 53263 **Age:** 42 YR **Gender:** Female **I/FU:** 1

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Maladministration		Mirapex Miralax	PS SS	Pharmacia/Upjohn Braintree Lab			

Date: 10/19/00 **ISR Number:** 3598396-6 **Report Type:** Direct **Company Report #** **Age:** 3 YR **Gender:** Female **I/FU:** 1

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abdominal Pain Nos Abnormal Behaviour Nos Antisocial Behaviour Appetite Decreased Bipolar I Disorder Convulsions Nos Depressed Mood Disturbance In Attention Nec Fear, Focus Nec Feeling Cold Frequent Bowel Movements Insomnia Nec Movement Disorder Nos Neurological Symptoms Nos Night Sweats Obsessive-Compulsive Disorder Paranoia Speech Disorder Nec Staring Throat Tightness Tremor Nec		Miralax Mfd By Braintree Labs	PS	Braintree Labs		SEE ITEM B5	11 DAY

Nicole

Date: 10/20/00 **ISR Number:** 3598900-8 **Report Type:** Direct **Company Report #** **Age:** 71 YR **Gender:** Male **I/FU:** 1

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Life-Threatening	Haemoglobin Decreased Haemorrhage Nos Intestinal Perforation Nos Sepsis Nos		Golytely	PS			AS DIRECTED	

Date: 11/28/00 **ISR Number:** 3622981-6 **Report Type:** Periodic **Company Report #** 000022 **Age:** 41 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Hypersensitivity Nos	Consumer	Miralax	PS	Braintree Laboratories Inc	ORAL	17 GRAMS PO	

Date: 11/28/00 **ISR Number:** 3622985-3 **Report Type:** Periodic **Company Report #** 000017 **Age:** 26 MON **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Convulsions Nos	Consumer	Miralax	PS	Braintree Laboratories Inc	ORAL	8.5 GRAMS QD PO	1 WK

Date: 11/28/00 **ISR Number:** 3622987-7 **Report Type:** Periodic **Company Report #** 000015 **Age:** 63 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Chest Pain	Other	Miralax	PS	Braintree Laboratories Inc	ORAL	17 GRAMS QD PO	
			Mavik	SS		ORAL	2 MCG QD PO	
			Atenolol	SS		ORAL	50 MG QD PO	
			Ms Contin/Morphine Sulfate	SS		ORAL	30 MG BID PO	
			Dilaudid/Hydromorphone Hydrochloride	SS		ORAL	2 MG PRN PO	
			Pericolace	SS		ORAL	1 TAB BID PO	
			Flomax/Mormiflumate	SS		ORAL	0.4 MG QD PO	
			Amaryl/Glimepiride	SS		ORAL	2 MG QD PO	
			Asa/Acetylsalicylic Acid	C				
			Lopid/Gemfibrozil	C				
			Tagamet/Cimetidine	C				

Date: 11/28/00 **ISR Number:** 3631935-5 **Report Type:** Periodic **Company Report #** 000016 **Age:** 3 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Hypersensitivity Nos	Health Professional	Miralax	PS	Braintree Laboratories Inc	ORAL	17 GRAMS QD PO	

Date: 11/28/00 **ISR Number:** 3631937-9 **Report Type:** Periodic **Company Report #** 000018 **Age:** **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Vomiting Nos	Consumer	Miralax	PS	Braintree Laboratories Inc	ORAL	17 GRAMS QD PO	

Anuria Back Pain Blood Bilirubin Increased Blood Chloride Increased Blood Creatinine Increased Blood Ph Decreased Blood Urea Increased Dyspnoea Nos Gastric Cancer Nos Hypotension Liver Function Tests Nos Abnormal Metabolic Acidosis Nos	Report Source Foreign Health Professional	Product Minocin Injection (Minocycline) Carbenin (Panipenem/Betamipro n) Injection Human Intravenous Immunoglobulin (Polyethylene Glycol-Treated) Injection	Role PS SS SS	Manufacturer	Route INTRAVENOUS DRIP INTRAVENOUS DRIP INTRAVENOUS DRIP	Dose 200 MG DAILY IV 2 GRAMS DAILY IV 17.5 GRAM DAILY IV	Duration

Date: 08/23/99 **ISR Number:** 3332612-0 **Report Type:** Expedited (15-Day) **Company Report #** 002#1#1999-00294 **Age:** 16 MON **Gender:** Male **I/FU:** I

Outcome Hospitalization - Initial or Prolonged	PT Aspiration Drug Maladministration Respiratory Disorder Nos	Report Source Health Professional	Product Colyte-For-Oral-Solu tion (Sodium Bicarbonate, Potassium Chloride, Sodium Chloride, Sulfamethoxazole/Tri methoprim	Role PS C	Manufacturer	Route ORAL	Dose 4 UNIT, 1 IN 1 D/ORAL	Duration

Date: 08/31/99 **ISR Number:** 3338228-4 **Report Type:** Expedited (15-Day) **Company Report #** 201719 **Age:** 88 YR **Gender:** Female **I/FU:** F

Outcome Death Hospitalization - Initial or Prolonged	PT Abdominal Pain Nos Hallucination, Visual Ileus Miosis Urinary Retention Vomiting Nos	Report Source Foreign Other	Product Loxen (Nicardipine Hydrochloride) Rocephine (Ceftriaxone Sodium) Maalox (Aluminum Hydroxide/Magnesium Hydroxide) Forlax (Polyethylene Glycol) Clivarine (Reviparin Sodium) Morphine Sulfate	Role PS SS SS SS SS C	Manufacturer	Route ORAL INTRAMUSCULAR	Dose ORAL INTRAMUSCULAR	Duration 9 DAY

Date: 09/01/99 **ISR Number:** 3339417-5 **Report Type:** Expedited (15-Day) **Company Report #** 201719 **Age:** 88 YR **Gender:** Female **I/FU:** F

Outcome Death Hospitalization - Initial or Prolonged	PT Abdominal Pain Nos Hallucination Nos Ileus Miosis

			Macrogol (Forlax) Powder For Oral Solution	SS		ORAL	20 G DAY PO

Date: 01/25/01 **ISR Number:** 3654125-9 **Report Type:** Direct **Company Report #** USP #53641 **Age:** **Gender:** **I/FU:** 1

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Maladministration		Golytely	PS	Braintree		POWDER FOR RECONSTITUTIO N	
			Miralax (Polyethylene Glycol)	SS	Braintree		POWDER FOR RECONSTITUTIO N	

Date: 01/25/01 **ISR Number:** 3654131-4 **Report Type:** Direct **Company Report #** **Age:** 10 YR **Gender:** Female **I/FU:** 1

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Mouth Ulceration		Miralax	PS		ORAL	17 GRAMS ORAL	
			Bactrim	C				

Date: 02/23/01 **ISR Number:** 3669899-0 **Report Type:** Expedited (15-Day) **Company Report #** 010007 **Age:** 77 YR **Gender:** Male **I/FU:** 1

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Maladministration	Health Professional	Golytely	PS	Braintree Laboratories Inc		2 LITRES OG	

Date: 03/06/01 **ISR Number:** 3675237-X **Report Type:** Direct **Company Report #** **Age:** **Gender:** Male **I/FU:** 1

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Abdominal Tenderness		Miralax 17 G/Capful Braintree Labs	PS	Braintree Labs	ORAL	1 CAPFUL BID ORAL	
	Constipation		Vincristine 2mg/2ml Faulding	SS	Faulding	INTRAVENOUS BOLUS	1.4 Q7D TID INTRAVENOUS BOLUS	
			Prednisone 20mg	SS	Udl		20 MG	
			Fluconazole	C				
			Bactrim Ss	C				
			Filgrastim	C				
			Prednisone	C				
			Peri-Colace	C				
			Bisacodyl	C				
			Peridex Oral Rinse	C				
			Ranitidine	C				

Date: 10/23/00 **ISR Number:** 3599878-3 **Report Type:** Expedited (15-Day) **Company Report #** 002#1#2000-00228 (0) **Age:** 71 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Abdominal Pain Nos Acute Circulatory Failure Flatulence	Health Professional	Colyte Digoxin Levothyroxine-Sodium Isosorbide-Dinitrate Atenolol	PS C C C C	Schwarz Pharma Inc	ORAL	41, ONCE, ORAL	

Date: 11/06/00 **ISR Number:** 3607898-5 **Report Type:** Expedited (15-Day) **Company Report #** 002#1#2000-00228(1) **Age:** 71 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Abdominal Pain Nos Acute Circulatory Failure X-Ray Nos Gastrointestinal Tract Abnormal	Health Professional	Colyte Digoxin Levothytroxine-Sodium Isosorbide-Dinitrate Atenolol	PS C C C C	Schwarz Pharma Inc	ORAL	41, ONCE, ORAL	

Date: 11/14/00 **ISR Number:** 3610886-6 **Report Type:** Direct **Company Report #** **Age:** 3 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Abnormal Behaviour Nos Adjustment Disorder Nec Appetite Decreased Bipolar I Disorder Convulsions Nos Depressed Mood Enuresis Fear, Focus Nec Feeling Abnormal Frequent Bowel Movements Muscle Cramps Nervousness Neurological Disorder Nos Night Sweats Obsessive-Compulsive Disorder Paranoia Sleep Disorder Nos Throat Tightness Tremor Nec		Miralax	PS	Braintree Labs		SEE ITEM B5	11 DAY

Date: 11/28/00 **ISR Number:** 3622979-8 **Report Type:** Periodic **Company Report #** 000019 **Age:** 3 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Convulsions Nos Delusion Nos Paranoia Social Avoidant Behaviour Tremor Nec	Other	Miralax	PS	Braintree Laboratories Inc	ORAL	17 G QD PO	

Citalopram				PER DAY ORAL
(Citalopram)	SS		ORAL	PER DAY ORAL
Macrogol 3350				
(Macrogol 3350)	SS		ORAL	FOUR TIMES PER DAY ORAL
Trimebutine	C			
Di-Antalvic	C			
Carbomere	C			
Potassium Chloride	C			

Date: 03/07/00 **ISR Number:** 3470394-2 **Report Type:** Direct **Company Report #** **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Peritonitis		Golyte	PS			PO	

Date: 03/14/00 **ISR Number:** 3474503-0 **Report Type:** Direct **Company Report #** USP 52905 **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Maladministration		Miralax	PS	Braintree Labs			
			Mirapex					
			(Promipexole)	SS	Pharmacia & Upjohn			

Date: 04/14/00 **ISR Number:** 3487816-3 **Report Type:** Direct **Company Report #** USP 52991 **Age:** 79 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Drug Maladministration		Mirapex	PS	Pharmacia & Upjohn			
			Miralax					
			(Polyethylene Glyol)	SS	Braintree Labs			

Date: 04/21/00 **ISR Number:** 3490965-7 **Report Type:** Expedited (15-Day) **Company Report #** 1346832A **Age:** 39 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other Required Intervention to Prevent Permanent Impairment/Damage	Dysphagia Laryngospasm Pharyngitis Nos Sensation Of Foreign Body Nos Speech Disorder Nec Swallowing Painful Throat Tightness Vomiting Nos	Consumer	Tylenol Sore Throat Product	PS		ORAL	2 TABLESPOONS, PRN, PO	

Date: 05/25/00 **ISR Number:** 3566076-9 **Report Type:** Periodic **Company Report #** 000008 **Age:** 76 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Nausea	Other	Miralax	PS	Braintree Laboratories Inc	ORAL	17 GRAMS ONE/DAY, ORAL 6	MON

Date: 11/16/99 **ISR Number:** 3397967-X **Report Type:** Direct **Company Report #** **Age:** 81 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Rhinorrhoea	Health Professional	Golightly	PS			4 LITERS/CUP Q15 MIN PER NGT	

Date: 12/01/99 **ISR Number:** 3411732-6 **Report Type:** Direct **Company Report #** USP 52654 **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Maladministration	Health Professional	Miralax	PS	Braintree Labs			
			Mirapex (Pramipexole Dihydrochloride)	SS	Pharmacia & Unjohn			

Date: 01/18/00 **ISR Number:** 3446137-5 **Report Type:** Expedited (15-Day) **Company Report #** HQ0042430DEC1999 **Age:** 58 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Other	Burns Second Degree Erythema Multiforme Localised Exfoliation Pain Nos	Health Professional	Temesta Tablet (Lorazepam)	PS				
			Deroxat (Paroxetine Hydrochloride)	SS				
			Klean-Prep (Macrogol, Potassium Chloride, Sodium Bicarbonate, Sodium Chloride, Sodium	SS				
			Lioresal (Baclofen)	SS				
			Normacol (Frangula Extract, Sterulia)	SS			SEE IMAGE	

Date: 02/22/00 **ISR Number:** 3462012-4 **Report Type:** Expedited (15-Day) **Company Report #** 2000CG00101 **Age:** 64 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Leukocytoclastic Vasculitis Nodular Vasculitis Purpura Nos	Foreign Health Professional Other	Diprivan	PS				
			Rapifen	SS				
			Hypnovel	SS				
			Ephedrine	SS				
			Visceralgine	SS				
			Ulcar	SS				
			Klean-Prep	SS				
			Atorvastatin	C				
			Fonzylane	C				
			Kardegic	C				

Date: 02/28/00 **ISR Number:** 3464392-2 **Report Type:** Expedited (15-Day) **Company Report #** B0076632A **Age:** 92 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Hyponatraemia Inappropriate Adh Secretion Oedema Lower Limb	Foreign	Zantac Tablet -Effervescent (Ranitidine Hydrochloride)	PS		ORAL	150 MG ORAL	
			Domperidone (Domperidone)	SS		ORAL	THREE TIMES	

Urinary Retention Vomiting Nos	**Report Source**	**Product**	**Role**	**Manufacturer**	**Route**	**Dose**	**Duration**
	Foreign Other	Loxen (Nicardipine Hydrochloride)	PS		ORAL	ORAL	9 DAY
		Rocephine (Ceftriaxone Sodium)	SS		INTRAMUSCULAR	INTRAMUSCULAR	
		Maalox (Aluminum Hydroxide/ Magnesium Hydroxide)	SS				
		Forlax (Polyethylene Glycol)	SS				
		Clivarine (Reviparin Sodium)	SS				
		Morphine Sulfate	C				

Date: 09/02/99 **ISR Number:** 3339800-8 **Report Type:** Expedited (15-Day) **Company Report #** B0069440A **Age:** 95 YR **Gender:** Male **I/FU:** I

Outcome	**PT**	**Report Source**	**Product**	**Role**	**Manufacturer**	**Route**	**Dose**	**Duration**
Hospitalization - Initial or Prolonged	Cholangitis Nos Coombs Direct Test Positive Haemolytic Anaemia Nos	Foreign	Macrogol (Formulation Unknown)	PS				
			Potassium Chloride (Formulation Unknown)	SS				
			Gelopectose (Formulation Unknown)	SS				
			Zyloprim Tablet	SS				
			Omeprazole (Formulation Unknown)	SS		ORAL	20 MG DAILY ORAL	
			Isosorbide Dinitrate (Formulation Unknown)	SS		ORAL	ORAL	
			Colchimax (Formulation Unknown)	SS		ORAL	ORAL	
			Quinapril (Formulation Unknown)	SS		ORAL	ORAL	
			Frusemide (Formulation Unknown)	SS		ORAL	ORAL	
			Nitroglycerin (Formulation Unknown)	SS			PATH	
			~~Alfuzosin Tablet~~	~~SS~~		~~ORAL~~	~~1 TABLET PER~~ DAY ORAL	
			Nicoumalone Tablet	SS		ORAL	1 TABLET PER DAY ORAL	

FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report

Date: 11/29/00 **ISR Number:** 3618929-0 **Report Type:** Expedited (15-Day) **Company Report #** 2000-10-1189 **Age:** 49 YR **Gender:** Male **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged Disability	Cardiomegaly Nos Dyspnoea Nos Electrocardiogram Abnormal Nos Hypoxia Interstitial Lung Disease Oedema Nos Pulmonary Oedema Nos Respiratory Failure (Exc Neonatal) Weakness	Study Health Professional	Rebetol Peg-Intron (Peginteron Alfa 2b) Glucotrol Prinivil Prevacid Celebrex Actos K-Dur Glucophage Xalatan	PS SS C C C C C C C C	Schering Plough Research Institute	ORAL SUBCUTANEOUS	800 MG QD 207-145 MCG	

Date: 12/01/00 **ISR Number:** 3620980-1 **Report Type:** Expedited (15-Day) **Company Report #** 001034 **Age:** **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Corneal Disorder Nos	Foreign Health Professional Other	Hypotears Effexor Xr 150mg	PS C		OPHTHALMIC		1 DAY

Date: 12/01/00 **ISR Number:** 3628282-4 **Report Type:** Periodic **Company Report #** 02-#1#2000-00101(0) **Age:** 40 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Anaphylactoid Reaction	Health Professional	Colyte	PS	Schwarz Pharma Inc	ORAL	ORAL	

Date: 12/07/00 **ISR Number:** 3625146-7 **Report Type:** Expedited (15-Day) **Company Report #** 00OCG00794 **Age:** 62 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Angioneurotic Oedema Drug Interaction Nos	Foreign Health Professional Other	Zestoretic Polyethylene Glycol Atenolol Ibuprophene Lipur	PS SS C C C	Astrazeneca Pharmaceuticals Lp	ORAL	20 MG DAILY PO ; 12.5 MG DAILY PO;	

Date: 12/20/00 **ISR Number:** 3635048-8 **Report Type:** Expedited (15-Day) **Company Report #** 00Z1279FR **Age:** 89 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Hospitalization - Initial or Prolonged	Anaemia Nos Antibody Nost Abnormal Condition Aggravated Fall Haematuria Present Haemoptysis Rectal Bleeding Thrombocytopenia	Foreign Health Professional Other	Lasix Zopiclone Ferrous Sulfate (Tardyferon) Amlodipine Besilate (Amlor)	PS SS SS SS	Aventis Pharmaceuticals Inc	ORAL ORAL ORAL ORAL	40 MG DAY PO 7.5 MG DAY PO QD PO SEE IMAGE	2 WK 2 WK 28 DAY

Date: 09/08/99 **ISR Number:** 3343153-9 **Report Type:** Expedited (15-Day) **Company Report #** 214164 **Age:** 48 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Petechiae Vascular Purpura	Foreign Other	Valium (Diazepam) 1%	PS		ORAL	4 DROP DAILY ORAL	
			Lutheran (Chlormadinone Acetate) 5 Mg	SS		ORAL	5 MG DAILY ORAL	
			Depakine (Valproate Sodium)	SS		ORAL	ORAL	
			Lioresal (Baclofen) 10 Mg	SS		ORAL	30 MG 3 PER DAY ORAL	
			Forlax (Polyethylene Glycol) 10gram	SS		ORAL	30 GRAM DAILY ORAL	

Date: 09/09/99 **ISR Number:** 3347059-0 **Report Type:** Periodic **Company Report #** 990007 **Age:** 89 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Other	Diarrhoea Nos Nausea	Consumer	Miralax	PS		ORAL	17 GRAM DAILY PO	

Date: 09/27/99 **ISR Number:** 3358169-6 **Report Type:** Direct **Company Report #** **Age:** 81 YR **Gender:** Male **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Cardiac Failure Congestive Condition Aggravated	Health Professional	Golytely	PS			ONCE	

Date: 11/15/99 **ISR Number:** 3399336-5 **Report Type:** Expedited (15-Day) **Company Report #** 10167070 **Age:** 74 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Tongue Oedema	Foreign Health Professional Other	Vasten Tabs 20mg (Pravastatin Sodium)	PS		ORAL	10 MILLIGRAM, 1 DAY ORAL	
			Diamicron(Gliclazide)	SS				
			Zestril(Lisinopril)	SS			4000	
			Lasilix(Furosemide)	SS				
			Diffu-K(Potassium Supplements)	SS				
			Macrogol	SS				
			Tanakan(Ginkgo Biloba)	C				
			Jonctum(Oxaceprol)	C				
			Ginkor(Ginkgo Biloba+Heptaminol+)	C				

Urinary Retention Vomiting Nos	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Foreign Other	Rocephine	PS		INTRAVENOUS DRIP	1 GRAM 1 X PER DAY INTRAVENOUS	
		Loxen	SS		ORAL	ORAL	
		Maalox	SS		ORAL	3 DOSE FORM 3 X PER DAY ORAL	
		Forlax	SS		ORAL	2 DOSE FORM 1 X PER DAY ORAL	
		Clivarine	SS		SUBCUTANEOUS	SUBCUTANEOUS	
		Skenan	SS		ORAL	60 MG 2 X PER DAY ORAL	

Date: 01/22/99 **ISR Number:** 3184608-X **Report Type:** Expedited (15-Day) **Company Report #** 990001 **Age:** 60 YR **Gender:** Female **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Required Intervention to Prevent Permanent Impairment/Damage	Intestinal Perforation Nos	Health Professional	Golytely	PS		ORAL	500 CC PO	

Date: 03/16/99 **ISR Number:** 3220543-6 **Report Type:** Direct **Company Report #** **Age:** **Gender:** **I/FU:** I

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
	Drug Maladministration		Colyte	PS		ORAL		

Date: 04/30/99 **ISR Number:** 3251233-1 **Report Type:** Expedited (15-Day) **Company Report #** 201719 **Age:** 88 YR **Gender:** Female **I/FU:** F

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death Hospitalization - Initial or Prolonged	Abdominal Pain Nos Hallucination Nos Ileus Miosis Urinary Retention Vomiting Nos	Foreign Other	Loxen (Nicardipine Hydrochloride)	PS		ORAL		9 DAY
			Rocephine (Ceftriaxone Sodium)	SS		INTRAMUSCULAR		
			Maalox (Aluminum Hydroxide/Magnesium Hydroxide)	SS				
			Forlax (Polyethylene Glycol)	SS				
			Clivarine (Reviparin Sodium)	SS				
			Morphine Sulfate (Morphine Sulfate)	C				

Date: 05/05/99 **ISR Number:** 3254371-2 **Report Type:** Expedited (15-Day) **Company Report #** 8-99116-085A **Age:** 51 YR **Gender:** Male **I/FU:** I

Outcome	PT
Death	Acute Circulatory Failure Anaphylactic Shock

FDA - Adverse Event Reporting System (AERS)
Freedom Of Information (FOI) Report

Date: 07/02/98 **ISR Number:** 3108606-7 **Report Type:** Direct **Company Report #** **Age:** 49 YR **Gender:** Female **I/FU:** 1

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Abdominal Pain Upper		Golytely	PS				
	Anaphylactoid Reaction							
	Cardiac Failure Congestive							
	Coronary Artery Disease Nos							
	Diarrhoea Nos							
	Diverticulum Nos							
	Dysphonia							
	Dyspnoea Nos							
	Nausea							
	Sore Throat Nos							
	Tongue Oedema							
	Vomiting Nos							

Date: 08/03/98 **ISR Number:** 3111591-5 **Report Type:** Direct **Company Report #** **Age:** **Gender:** **I/FU:** 1

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Death	Cerebral Oedema		Golytely	PS	Braintree Laboratories Inc		2400CC PER NG TUBE OVER 12 HOURS	
Life-Threatening	Hyponatraemia							
Other	Metabolic Acidosis Nos							
	Peripheral Neuropathy Nec							
			Fentanyl	C				
			Ondansetron	C				

Date: 08/11/98 **ISR Number:** 3115488-6 **Report Type:** Expedited (15-Day) **Company Report #** 002#4#1998-00152000 **Age:** **Gender:** **I/FU:** 1

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Life-Threatening	Drug Maladministration	Health Professional	Colyte	PS		NASAL	NASAL	
Hospitalization - Initial or Prolonged	Lung Function Decreased							

Date: 11/11/98 **ISR Number:** 3155050-2 **Report Type:** Direct **Company Report #** **Age:** 71 YR **Gender:** Male **I/FU:** 1

Outcome	PT	Report Source	Product	Role	Manufacturer	Route	Dose	Duration
Hospitalization - Initial or Prolonged	Chest Pain		Golytely	PS			ONCE	
	Pyrexia		Colace	C				
	Retching		Asa	C				
	Rigors		Dorzolamide Ophthalmic	C				
	Tremor Nec							
	Vomiting Nos							

Date: 12/31/98 **ISR Number:** 3177008-X **Report Type:** Expedited (15-Day) **Company Report #** 111159 **Age:** 88 YR **Gender:** Female **I/FU:** 1

Outcome	PT
Death	Abdominal Pain Nos
Hospitalization - Initial or Prolonged	Hallucination Nos
	Intestinal Obstruction Nos
	Miosis

For VOLUNTARY reporting by health professionals of adverse events and product problems

Form Approved: OMB No. 0910-0291 Expires: 12/31/96
See OMB statement on reverse

FDA use only
Triage unit sequence #

A. Patient information

1. Patient Identifier: N.O. (In confidence)
2. Age at time of event: 3 y.o. / Date of birth:
3. Sex: ☒ female ☐ male
4. Weight: 35 lbs / ____ kgs

B. Adverse event or product problem

1. ☒ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)
☐ death ____ (mo/day/yr)
☐ life-threatening
☒ hospitalization
☐ disability
☐ congenital anomaly
☐ required intervention to prevent permanent impairment/damage
☐ other: ____

3. Date of event (mo/day/yr): 09/20/2000
4. Date of this report (mo/day/yr): 10/12/2000

5. Describe event or problem
The reporter's daughter suffers from chronic constipation, but the reporter states it seems as if she is just afraid to have a bowel movement and holds onto her stool voluntarily. The prescribed dose was 1 tablespoon by mouth daily. The reporter started her daughter on 1/2 tbsp for the first 2 days, then continued with 1 tbsp until she was instructed to increase the dose to 1-1/2 tbsp (somewhere around the weekend of 9/29) when she started holding on to her stool again. Sunday, 10/1 was her last dose. The drug was prescribed by a doctor who saw the child only once. The doctor primarily was an academician. He did not believe the early events were related. A nurse practitioner advised the reporter to continue the drug. Her daughter experienced multiple events. She lost her apetite. She complained that her throat felt like it was closing up and that she had cotton in her throat. She was very shaky, to the point it was thought she was having seizures. This was not necessarily after the dose. She also had goosebumps from head to toe with the shakiness. She started exhibiting behavioral changes. She seemed to become more isolated, paranoid, scared, and was hiding. She was now afraid of common noises in the hallway, such as a door closing. She was clenching her hands and holding her blanket and sippy cup very tightly.
CONTINUED. See p2

6. Relevant tests/laboratory data, including dates
Neurological exam. Strep test - result unknown, reporter states staff are looking for an out - other reasons for events.

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)
Race: White. Ht/Wt: 3'8" / 35 lbs. No known drug allergies. No other relevant pre-existing medical conditions. No history of renal or hepatic dysfunction.

C. Suspect medication(s)

1. Name (give labeled strength & manufacturer, if known)
#1 Miralax
#2 Mfd by Braintree Labs

2. Dose, frequency & route used
#1 see item B5
#2

3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1 started 9/20/00-11 days
#2

4. Diagnosis for use (indication)
#1 constipation
#2

5. Event abated after use stopped or dose reduced
#1 ☐ yes ☒ no ☐ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

6. Lot # (if known)
#1
#2

7. Exp. date (if known)
#1 /
#2

8. Event reappeared after reintroduction
#1 ☐ yes ☐ no ☒ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

9. NDC # (for product problems only)
– –

10. Concomitant medical products and therapy dates (exclude treatment of event)
None

D. Suspect medical device

1. Brand name

2. Type of Device

3. Manufacturer name & address

4. Operator of device
☐ health professional
☐ lay user/patient
☐ other: ____

5. Expiration Date (mo/day/yr)

6.
model # ____
catalog # ____
serial # ____
lot # ____
other # ____

7. If implanted, give date (mo/day/yr)

8. If explanted, give date (mo/day/yr)

9. Device available for evaluation? (Do not send to FDA)
☐ yes ☐ no ☐ returned to manufacturer on ____ (mo/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name & Address
phone # 815-356-8945

Jeanie Ward
586 Somerset Ln Apt 5
Crystal Lake IL 60014-7787

2. Health professional? ☐ yes ☒ no

3. Occupation: N/A

4. Also reported to
☒ manufacturer
☐ user facility
☐ distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an " X " in this box. ☐

FDA

Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787

or FAX to: 1-800-FDA-0178

FDA Form 3500 (1/96)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event

Taken By Telephone

Attachment

5. **Describe event or problem (Continued)**

She became "spacey" - staring at a picture and not responding. She couldn't concentrate on a book. Compulsive behaviors arose. She had to sit in just one spot. She had to line up her toys just so. She would chew on her fingers and her toys. She never did that before. She also complained of cramping on her right side. And was keeling over towards her right side. She started to have unreal fears of her one year old baby sister. She typically spoke like a 6 year old, but at times her speech turned mumbo jumbo. She also had night sweats every night. The bedsheet would be wet. Eerily, her back would be cold and she was under the covers. The reporter took her temperature one night. It was 98.7 degrees F. She usually didn't sleep on her stomach, but she did so during this time. She would also sleep and sit in a fetal position. Perhaps it could be said she exhibited manic/depressive behaviors. She was sad and told the reporter this 15 times a day. Events peaked on 9/29 and 10/1 She went into state that is hard to describe, other than completely panicked or freaking. She seemed to be doing everything in her power to amuse/entertain herself to make herself normal. Her fingers were moving rapidly, and her tongue was rapidly moving left to right, right to left. She couldn't sleep and was up for hours, until 1:30 AM. The next night, she was up until 2:30 AM. She had also shed 4 bowel movements in a 60 - 90 minute period. The reporter stopped the drug. Concerned about the shaking and other events, they were instructed to take her to the ER on 10/04. She was discharged by accident. When the reporter called the provider's office to ask a question, they asked why are you at home? She was advised to return to the ER and she was admitted for observation and to be seen by a neurologist. She was hospitalized from 10/4 to 10/7. Her diagnosis was "Drug reaction to Miralax, neurological changes". She has improved somewhat since being hospitalized. Her throat symptoms are gone. She is not lining up her toys as much. She still hides. The cramping has gone. Her appetite is slowly coming back. She still daydreams and does not respond when addressed. She'll sleep with her hands clenched. Her speech is 90% better. She will say strange things though. She is still afraid of loud noise, like the blow dryer, and the television.

NOVEMBER 7, 2000 - Reporter faxed in a rewritten Section B5. See attached.

6. **Relevant tests/laboratory data, including dates (Continued)**

7. **Other relevant history, including preexisting medical conditions** (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) **(Continued)**

PATIENT INFORMATION

MiraLax™ (Polyethylene Glycol 3350, NF Powder) is a prescription only laxative which has been prescribed by your doctor to treat constipation. This product should only be used by the person for whom it was prescribed.

How to take

The dose is 17 grams each day or as directed by physician. It should always be taken by mouth. Measure the dose using the measuring cap (or use one heaping tablespoon of powder), stir and dissolve in a glass (8 oz) of water. Taking more than the prescribed dose may cause loss of fluid due to severe diarrhea.

How will it work

MiraLax softens the stool and increases the frequency of bowel movements by retaining water in the stool. Your first bowel movement will usually happen in **two to four days**, although results may vary for individual patients.

How long should I take it

MiraLax achieves its best results when used between one and two weeks. You may discontinue taking the drug after you have had several satisfactory bowel movements. Should unusual cramps, bloating, or diarrhea occur, consult your physician. MiraLax is intended for up to a two week course of therapy. You should not use for a longer time unless directed by your doctor.

Next Steps

After successfully completing the MiraLax therapy (usually between one and two weeks) please discuss with your doctor lifestyle changes which may produce more regular bowel habits (adequate dietary and fluid intake, regular exercise).

Who Should NOT take MiraLax

MiraLax should not be used by children. It should not be used by pregnant women unless prescribed by a physician.

Side Effects/Drug Reactions

Occasionally, MiraLax may cause nausea, stomach fullness, cramping, diarrhea and/or gas. Do not take if you have symptoms such as nausea, vomiting, abdominal pain or distention, which may be due to bowel obstruction. On rare occasions hives and skin rashes have been reported which are suggestive of an allergic reaction. If you get an allergic reaction you should discontinue the medication and call your doctor.

If you are allergic to polyethylene glycol, do not use this drug.

MiraLax™
Polyethylene Glycol 3350, NF
Powder

DESCRIPTION

A white powder for reconstitution. MiraLax (polyethylene glycol 3350, NF) is a synthetic polyglycol having an average molecular weight of 3350. The actual molecular weight is not less than 90.0 percent and not greater than 110.0 percent of the nominal value. The chemical formula is $HO(C_2H_4O)_nH$ in which n represents the average number of oxyethylene groups. Below 55°C it is a free flowing white powder freely soluble in water.

MiraLax is an osmotic agent for the treatment of constipation.

CLINICAL PHARMACOLOGY

Pharmacology: MiraLax is an osmotic agent which causes water to be retained with the stool.

Essentially, complete recovery of MiraLax was shown in normal subjects without constipation. Attempts at recovery of MiraLax in constipated patients resulted in incomplete

Pregnancy: Category C. Animal reproductive studies have not been performed with MiraLax. It is also not known whether MiraLax can cause fetal harm when administered to a pregnant woman, or can effect reproductive capacity. MiraLax should only be administered to a pregnant woman if clearly needed.

Pediatric Use: Safety and effectiveness in pediatric patients has not been established.

Geriatric Use: There is no evidence for special considerations when MiraLax is administered to elderly patients.

In geriatric nursing home patients a higher incidence of diarrhea occurred at the recommended 17 gram dose. If diarrhea occurs MiraLax should be discontinued.

ADVERSE REACTIONS

Nausea, abdominal bloating, cramping and flatulence may occur. High doses may produce diarrhea and excessive stool frequency, particularly in elderly nursing home patients.

Patients taking other medications containing polyethylene glycol have occasionally developed urticaria suggestive of an allergic reaction.

OVERDOSAGE

There have been no reports of accidental overdosage. In the event of overdosage diarrhea would be the expected major event. If an overdose of drug occurred without concomitant ingestion of fluid, dehydration due to diarrhea may result. Medication should be terminated and free water administered. The oral LD_{50} is >50 gm/Kg in mice, rats and rabbits.

DOSAGE AND ADMINISTRATION

The usual dose is 17 grams (about 1 heaping tablespoon) of powder per day (or as directed by physician) in 8 ounces of water. Each bottle of MiraLax is supplied with a measuring cap marked to contain 17 grams of laxative powder when filled to the indicated line.

Two to 4 days (48 to 96 hours) may be required to produce a bowel movement.

HOW SUPPLIED

In powdered form, for oral administration after dissolution in water. MiraLax is available in two package sizes; a 14 oz. container of 255 grams of laxative powder and a 26 oz. container of 527 grams of laxative powder.

The cap on each bottle is marked with a measuring line and may be used to measure a single MiraLax dose of 17 grams (about 1 heaping tablespoon).

Rx only

STORAGE

Store at 25 degrees C (77 degrees F); excursions permitted to 15-30 degrees C (59-86 degrees F). See USP "Controlled Room Temperature."

Distributed by Braintree Laboratories, Inc.,
Braintree, MA 02185

D 8/99

WARNINGS

Patients with symptoms suggestive of bowel obstruction (nausea, vomiting, abdominal pain or distention) should be evaluated to rule out this condition before initiating MiraLax therapy.

PRECAUTIONS

General: Patients presenting with complaints of constipation should have a thorough medical history and physical examination to detect associated metabolic, endocrine and neurogenic conditions, and medications. A diagnostic evaluation should include a structural examination of the colon. Patients should be educated about good defecatory and eating habits (such as high fiber diets) and lifestyle changes (adequate dietary fiber and fluid intake, regular exercise) which may produce more regular bowel habits.

MiraLax should be administered dissolved in approximately 8 ounces of water.

Information for Patients: MiraLax softens the stool and increases the frequency of bowel movements by retaining water in the stool. It should always be taken by mouth after being dissolved in 8 ounces of water. Should unusual cramps, bloating, or diarrhea occur, consult your physician.

Two to 4 days may be required to produce a bowel movement. This product should be used for 2 weeks or less or as directed by a physician. Prolonged, frequent or excessive use of MiraLax may result in electrolyte imbalance and dependence on laxatives.

Laboratory Tests: No clinically significant effects on laboratory tests have been demonstrated.

Drug Interactions: No specific drug interactions have been demonstrated.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Long term carcinogenicity studies, genetic toxicity studies and reproductive toxicity studies in animals have not been performed with MiraLax.

of MiraLax in constipated patients [illegible]
and highly variable recovery. In vitro study showed indirectly that MiraLax was not fermented into hydrogen or methane by the colonic microflora in human feces. MiraLax appears to have no effect on the active absorption or secretion of glucose or electrolytes. There is no evidence of tachyphylaxis.

CLINICAL TRIALS

In one study, patients with less than 3 bowel movements per week were randomized to MiraLax, 17 grams, or placebo for 14 days. An increase in bowel movement frequency was observed for both treatment groups during the first week of treatment. MiraLax was statistically superior to placebo during the second week of treatment.

In another study, patients with 3 bowel movements or less per week and/or less than 300 grams of stool per week were randomized to 2 dose levels of MiraLax or placebo for 10 days each. Success was defined by an increase in both bowel movement frequency and daily stool weight. For both parameters, superiority of the 17 gram dose of MiraLax over placebo was demonstrated.

INDICATIONS AND USAGE

For the treatment of occasional constipation. This product should be used for 2 weeks or less or as directed by a physician.

CONTRAINDICATIONS

MiraLax is contraindicated in patients with known or suspected bowel obstruction and patients known to be allergic to polyethylene glycol.

WARNINGS

Patients with symptoms suggestive of bowel obstruction (nausea, vomiting, abdominal pain or distention) should be evaluated to rule out this condition before initiating MiraLax therapy.

PRECAUTIONS

General: Patients presenting with complaints of constipation should have a thorough medical history and physical examination to detect associated metabolic, endocrine and neurogenic conditions, and medications. A diagnostic evaluation should include a structural examination of the colon. Patients should be educated about good defecatory and eating habits (such as high fiber diets) and lifestyle changes (adequate dietary fiber and fluid intake, regular exercise) which may produce more regular bowel habits.

MiraLax should be administered dissolved in approximately 8 ounces of water.

Information for Patients: MiraLax softens the stool and increases the frequency of bowel movements by retaining water in the stool. It should always be taken by mouth after being dissolved in 8 ounces of water. Should unusual cramps, bloating, or diarrhea occur, consult your physician.

Two to 4 days may be required to produce a bowel movement. This product should be used for 2 weeks or less or as directed by a physician. Prolonged, frequent or excessive use of MiraLax may result in electrolyte imbalance and dependence on laxatives.

Laboratory Tests: No clinically significant effects on laboratory tests have been demonstrated.

Drug Interactions: No specific drug interactions have been demonstrated.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long term carcinogenicity [illegible]

Jeanie Ward
586 Somerset Unit 5
Crystal Lake IL
60014

Dockets Management Branch
5630 Fishers Lane Room 1061
Rockville MD 20852