



Bristol-Myers Squibb Company  
Medical Research Institute

Approved by FDA: 09 April 1999
Mfr report # <b>10305357</b>
UP/Dist report #
FDA Use Only

# MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 2

<b>A. Patient information</b>			
1. Patient Identifier	2. Age at time of event: or Date of birth: <b>07/17/1915</b>	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight <b>MT</b> lbs or kg
In confidence			
<b>B. Adverse event or product problem</b>			
1. <input checked="" type="checkbox"/> Adverse event and/or <input type="checkbox"/> Product problem			
2. Outcomes attributed to adverse event (check all that apply)			
<input checked="" type="checkbox"/> death <b>03/27/2000</b>			
<input type="checkbox"/> life-threatening			
<input checked="" type="checkbox"/> hospitalization-initial or prolonged			
<input type="checkbox"/> disability			
<input type="checkbox"/> congenital anomaly			
<input type="checkbox"/> required intervention to prevent permanent impairment/damage			
<input type="checkbox"/> other:			
3. Date of event <b>12/15/1999</b>	4. Date of this report <b>04/28/2000</b>		
5. Describe event or problem			
A consumer reported that another 85 year old female consumer experienced a hospitalization due to liver cirrhosis and hemolytic anemia. The event occurred during the consumer's use of Glucophage(metformin) 500 mg tablets taken twice daily for the treatment of diabetes. The consumer does have medical history that includes a thyroid disorder and congestive heart failure and receiving parenteral nutrition at the time of reporting. Also at the time of reporting the patient had been hospitalized for 24 days and was diagnosed with scar tissue in the liver leading to cirrhosis. The consumer's M.D. was reported to have described the event as "liver shut down." The hemolytic anemia is being treated with prednisone. The consumer was on both Lasix and Glucophage prior to hospitalization. Insulin was reported as a concomitant medication. Additional information will be requested.			
Supplemental information was received from the consumer's physician 17 April 2000. Lasix(furosemide), Tylenol(acetaminophen), and EtOH(ethyl alcohol) were also considered suspect drugs. Hospitalization was due to liver failure and not liver cirrhosis as previously reported. Scar tissue in the liver was not proven by biopsy. Liver function tests in January 1999 were slightly elevated. Hemolytic anemia was noted 15 December 1999. The hematocrit level improved after the treatment with prednisone 60 mg daily. Glucophage, and Lasix were discontinued on 05 January 2000. The patient (Continued)			
6. Relevant test/laboratory data			
HBV Positive			
LIVER FUNCTION TEST High			
7. Other relevant history, including preexisting medical conditions			
Diabetes mellitus NOS , Thyroid disorder NOS , Cardiac failure congestive			

<b>C. Suspect medication(s)</b>			
1. Name			
#1 <b>GLUCOPHAGE(metformin hcl)</b>			
#2 <b>LASIX(furosemide)</b>			
2. Dose, frequency & route used		3. Therapy dates	
#1 500 Milligram, 2/1 Day ORAL		#1 10/00/1997-01/05/2000	
#2 NI		#2 UNK-01/05/2000	
4. Diagnosis for use		5. Event stated after use stopped or dose reduced	
#1 Diabetes mellitus NOS		#1 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
#2 NI		#2 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
6. Lot #		7. Exp. date	
#1 NI		#1 NI	
#2 NI		#2 NI	
8. NDC #		8. Event repeated after reintroduction	
#1 NI		#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
#2 NI (Continued)		#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
10. Concomitant medical products			
insulin STEROID ALDOCTONE HERBAL PREPARATION ADWIL ALVITE			
<b>D. Manufacturer</b>			
1. Contact office - name/address		2. Phone number	
Murray Barnhart Bristol-Myers Squibb Company Drug Safety & Pharmacovigilance Mail Location MW19-1.01 P.O. Box 5400 Princeton, NJ 08543-5400 United States		609-818-3737	
3. Report source (check all that apply)			
<input type="checkbox"/> foreign			
<input type="checkbox"/> study			
<input type="checkbox"/> healthcare			
<input checked="" type="checkbox"/> consumer			
<input checked="" type="checkbox"/> health professional			
<input type="checkbox"/> user facility			
<input type="checkbox"/> company representative			
<input type="checkbox"/> distributor			
<input type="checkbox"/> other:			
4. Date received by manufacturer		5. (AN)DA # <b>20-357</b>	
04/17/2000		IND # _____	
6. If IND, protocol #		PLA # _____	
7. Type of report (check all that apply)		pre-1938 <input type="checkbox"/> yes	
<input type="checkbox"/> 5-day <input checked="" type="checkbox"/> 15-day		OTC product <input type="checkbox"/> yes	
<input type="checkbox"/> 10-day <input type="checkbox"/> periodic			
<input type="checkbox"/> initial <input checked="" type="checkbox"/> follow-up <b>1</b>			
8. Adverse event term(s)			
10305357		#1 Hepatic failure	
		#2 Death NOS	
		#3 Hepatic encephalopathy	
		#4 Hemolytic anemia NOS	
		#5 Thrombocytopenia	
		#6 Hepatitis B	
<b>E. Initial reporter</b>			
Name of initial reporter [Redacted]			
MAY 01 2000			
2. Health professional?		3. Occupation	
<input checked="" type="checkbox"/> yes <input type="checkbox"/> no			
4. Initial reporter also sent report to FDA			
<input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> unk			



Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

Facsimile Form 3500A



Bristol-Myers Squibb Company  
Pharmaceutical Research Institute

Approved by FDA: 02 April 1999

Mfr report # **10305357**

UP/Dist report #

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# MED WATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

**A. Patient information**

1. Patient Identifier  
In confidence

2. Age at time of event:  
or  
Date of birth:

3. Sex  
 female  
 male

4. Weight  
\_\_\_\_ lbs  
or  
\_\_\_\_ kgs

**B. Suspect medication(s)**

1.  Adverse event and/or  Product problem

2. Outcomes attributed to adverse event (check all that apply)

death  
 life-threatening  
 hospitalization-initial or prolonged

disability  
 congenital anomaly  
 required intervention to prevent permanent impairment/damage  
 other:

3. Date of event

4. Date of this report **04/28/2000**

5. Describe event or problem

also experienced thrombocytopenia, and hepatic encephalopathy with ascites thought to have been consistent with liver failure. The thrombocytopenia did not improve. She was also found to have had a chronic hepatitis B infection noted by a positive HBsAg test. The patient's diabetes was not controlled. She then developed liver failure and died on 27 March 2000, with the cause of death reported as "multifactorial liver failure."

6. Relevant tests/laboratory data

7. Other relevant history, including preexisting medical conditions

**MAY 02 2000**

**C. Suspect medication(s)**

1. Name  
#3 **ETOH(ethyl alcohol)**  
#4 **TYLENOL(acetaminophen)**

2. Dose, frequency & route used  
#3 NI  
#4 NI

3. Therapy dates  
#3 NI  
#4 NI

4. Diagnosis for use  
#3 NI  
#4 NI

5. Event abated after use stopped or dose reduced  
#3  yes  no  doesn't apply  
#4  yes  no  doesn't apply

6. Lot #  
#3 NI  
#4 NI

7. Exp. date  
#3 NI  
#4 NI

8. Event reappeared after reintroduction  
#3  yes  no  doesn't apply  
#4  yes  no  doesn't apply

9. NDC #  
#3 NI  
#4

10. Concomitant medical products

**D. All manufacturers**

1. Contact office - name/address

2. Phone number

3. Report source (check all that apply)

foreign  
 study  
 literature  
 consumer  
 health professional  
 user facility  
 company representative  
 distributor  
 other:

4. Date received by manufacturer

5. (ANDA # \_\_\_\_\_  
IND # \_\_\_\_\_  
PLA # \_\_\_\_\_  
pre-1938  yes  
OTC product  yes

6. If IND, protocol #

7. Type of report (check all that apply)

5-day  15-day  
 10-day  periodic  
 initial  follow-up

8. Adverse event term(s)

**MAY 01 2000**

9. Mfr. report number  
**10305357**

**E. Initial reporter**

1. Name, address & phone number

2. Health professional?  
 yes  no

3. Occupation

4. Initial reporter also sent report to FDA  
 yes  no  unk



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