

Individual Safety Report



\*3748454-8-00-01\*

Glaxo Wellcome

Approved by the FDA (HF-2) on 3 Nov 93

Mfr report #	A0150825A
FDA report #	
FDA Use Only	

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

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A. Patient information			
1. Patient identifier	2. Age at time of event: 33Y or Date of birth: 15Sep1967	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male <input type="checkbox"/> unknown	4. Weight (lb) UNK
In confidence			
B. Adverse event or product problem			
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 type="checkbox"/> death	<input type="checkbox"/> disability	<input type="checkbox"/> congenital anomaly	
<input type="checkbox"/> life-threatening	<input type="checkbox"/> required intervention to prevent permanent impairment/damage		<input type="checkbox"/> other:
<input checked="" type="checkbox"/> hospitalization - initial or prolonged			
3. Date of event: 07Jun2001	4. Date of this report: 21Jun2001		
5. Describe event or problem			
A physician reported that a 33 year old female with a history of alcohol abuse and obesity received lamivudine/zidovudine (Combivir) tablets concurrently with nevirapine (Viramune) tablets for HIV post-exposure prophylaxis for 23 days. She presented with shortness of breath and fever. An MRI revealed hepatic steatosis. The patient was hospitalized following an abnormal hepatobiliary scan. A biopsy of the liver revealed hepatocellular necrosis and the patient was diagnosed with hepatic failure. The events were unresolved. The physician considered that the events were probably caused by the history of alcohol use, use of acetaminophen and nevirapine. He also considered that the events could possibly have been caused by lamivudine/zidovudine.			
6. Relevant tests/laboratory data, including dates			
Results: Hepatic steatosis on MRI. Abnormal hepatobiliary scan and biopsy of the liver revealed hepatic necrosis.			
7. Other relevant history, including preexisting medical conditions (eg. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc)			
History: Alcohol abuse and Tylenol use. No prior history of liver disease			

C. Suspect medication(s)			
1. Name (give labeled strength & mfr/labeler, if known) cont'd next page			
#1	Combivir Tablet (Combivir)		
#2	Nevirapine Tablet (Nevirapine)		
2. Dose / frequency / route used		3. Therapy dates	
#1	1 tablet / Twice per day / Oral	#1	16May01 - 07Jun01
#2	200 mg / Twice per day / Oral	#2	16May01 - 07Jun01
4. Diagnosis for use (indication)		5. Event abated after use stopped or dose reduced	
#1	Prophylaxis against HIV	#1	<input type="checkbox"/> yes <input checked="" type="checkbox"/> no <input type="checkbox"/> doesn't apply
#2	Prophylaxis against HIV	#2	<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply
6. Lot # (if known)	7. Exp. date (if known)	8. Event reappeared after reintroduction	
#1	None	#1	<input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
#2	None	#2	<input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
9. NDC # - for product problem's only (if known)			
10. Concomitant medical products and therapy dates (exclude treatment of event)			
Oral contraceptive UNK			

G. All manufacturers	
1. Contact office - name/address	2. Phone number
Glaxo Wellcome North American Product Surveillance PO Box 13398 Research Triangle Park NC 27709	1-888-825-5249 ext. 37070
4. Date received by manufacturer	5. (A)NDA #
11Jun2001	20-857
6. If IND, protocol #	IND #
	PLA #
7. Type of report	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 checked="" type="checkbox"/> Initial <input type="checkbox"/> follow-up #	
9. Mfr. report number	8. Adverse event term(s)
A0150825A	Hepatic failure Fatty liver Hepatic necrosis Shortness of breath Fever

E. Initial Reporter			
1. Name, address & phone #			
[Redacted]			
2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA?	
<input checked="" type="checkbox"/> yes <input type="checkbox"/> no	Physician	<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.



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UP/Dist report #	
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**A. Patient information**

Patient identifier	2. Age at time of event: or Date of birth	3. Sex <input type="checkbox"/> female <input type="checkbox"/> male <input type="checkbox"/> unknown	4. Weight (lb)
In confidence			

**B. Adverse event or product problem**

1.  Adverse event and/or  Product problem

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

<input type="checkbox"/> death	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other: _____

3. Date of event: \_\_\_\_\_

4. Date of this report: \_\_\_\_\_

5. Describe event or problem

6. Relevant tests/laboratory data, including dates

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

**C. Suspect medication(s)**

1. Name (give labeled strength & mfr/labeler, if known)  
#3 Paracetamol (formulation unknown) (Acetaminophen)  
#4 \_\_\_\_\_

2. Dose / frequency / route used  
#3 UNK / UNK / Unknown  
#4 \_\_\_\_\_

3. Therapy dates  
#3 UNK  
#4 \_\_\_\_\_

4. Diagnosis for use (indication)  
#3 UNK  
#4 \_\_\_\_\_

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

6. Lot # (if known)  
#3 None  
#4 \_\_\_\_\_

7. Exp. date (if known)  
#3 \_\_\_\_\_  
#4 \_\_\_\_\_

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

9. NDC # - for product problems only (if known)  
#3 \_\_\_\_\_  
#4 \_\_\_\_\_

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

**G. All manufacturers**

1. Contact office - name/address

2. Phone number  
1-888-825-5249 ext. 37070

3. Report source  
 foreign  
 study  
 literature  
 consumer  
 health professional  
 user facility  
 company representative  
 distributor  
 other: \_\_\_\_\_

4. Date received by manufacturer

5. (A)NDA # \_\_\_\_\_  
IND # \_\_\_\_\_  
PLA # \_\_\_\_\_  
pre-1938  yes  
OTC product  yes

6. If IND, protocol #

7. Type of report  
 5-day  15-day  
 10-day  periodic  
 Initial  follow-up # \_\_\_\_\_

8. Adverse event term(s)

9. Mfr. report number  
A0150825A

**E. Initial Reporter**

1. Name, address & phone #

2. Health professional?  
 yes  no

3. Occupation

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



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7. Other relevant history (cont'd)

Condition	Started	Ended	Continuing
Obese	Unknown	Unknown	Yes
Alcohol abuse	Unknown	Unknown	Unknown
Prophylaxis against HIV infection	Unknown	Unknown	Unknown