

Individual Safety Report



3562028-3-00-01

PHILADELPHIA, PA 19101

DWATCH

PRODUCTS REPORTING PROGRAM

Approved by the FDA on 09/24/1999

Mfr report # HQ9448304AUG2000

UF/Dist report #

FDA Use Only

Page 1 of 2

A. Patient information

1. Patient Identifier UNK	2. Age at time of event: or UNK Date of Birth:	3. Sex <input type="checkbox"/> female <input type="checkbox"/> male	4. Weight UNK lbs or UNK kgs
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B. Adverse event or product problem

1. Adverse event Product problem (e.g., defects/malfunctions)

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

<input type="checkbox"/> death (mo/day/yr)	<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"/> recovered	<input checked="" type="checkbox"/> other: medically important

3. Date of event (mo/day/yr) UNK

4. Date of this report (mo/day/yr) 08/28/2000

5. Describe event or problem

Follow-up information 23-AUG-2000 has been received from the physician regarding a patient (unidentified) who has been receiving RAPAMUNE SOLUTION (sirolimus solution) (dose and therapy dates unknown). Additional suspect medication included ACETAMINOPHEN and GANCICLOVIR. Medical history was not reported. Initially a pharmacist reported that the patient experienced hepatitis. In follow-up information, the physician reported that the patient experienced transaminitis (Hepatic function abnormal NOS). He indicated that the event was not related to Rapamune therapy, and that the patient remains on Rapamune now without transaminitis. The physician indicated the transaminitis was related to acetaminophen, alcohol and high dose ganciclovir, not Rapamune. This case has been downgraded from a 15 Day report due to follow-up information.

6. Relevant tests/laboratory data, including dates

None Provided.

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

UNK



C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

1 RAPAMUNE SOLUTION

2 ACETAMINOPHEN (cont'd)

2. Dose, frequency & route used

1 unspecified, Oral

2 Dose unspecified, Oral

3. Therapy dates (if unknown, give duration)

1 Continues

2 UNK

4. Diagnosis for use (indication)

1 UNK

2 UNK

5. Event abated after use stopped or dose reduced

1 yes no doesn't apply

2 yes no doesn't apply UNK

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 UNK

9. NDC # - for product problems only (if known)

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

G. All manufacturers

1. Contact office - name/address

WYETH LABS (RA)
240 N Radnor-Chester
St. Davids, PA 19087

Jill Robinson

2. Phone number

6109024647

3. Report source. (check all that apply)

foreign

study

literature

consumer

health professional

user facility

company representative

distributor

other:

4. Date received by manufacturer (mo/day/yr)

08/23/2000

5. (ANDA 21-083)

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 # 1

8. Adverse event term(s)

Hepatic function abnormal NOS

9. Mfr. report number

HQ9448304AUG2000

E. Initial reporter

1. Name & address phone #

Dr. [redacted] US

P.O. Box [redacted]

AUG 30 2000

DSS

AUG 31 2000

2. Health professional? yes no

3. Occupation Nephrologist

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

FDA Form 3500A (facsimile) Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

AUG 29 2000 DATE SENT TO FDA

Individual Safety Report



3562028-3-00-02

LADELPHIA, PA 19101

MEDWATCH

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Box C - Suspect medication(s) (Continuation)

1. Name (Given labeled strength & mfr/labeler, if known)

3.1 GANCICLOVIR

2. Dose, frequency & route used

3.1 Dose unspecified, Oral

3. Therapy dates (if unknown, give duration)

3.1 UNK

4. Diagnosis for use (indication)

3.1 UNK

5. Event abated after use stopped or dose reduced

3.1 UNK

6. Lot # (if known)

3.1

7. Exp date (if known)

8. Event reappeared after reintroduction

3.1 UNK

AUG 30 2000

DSS
AUG 31 2000