R.W. JOHNSON PHARM. RES. INST. USA

Individual Safety Report

3364475-1-00-01

For use by user-facilities, ...rs and manufacturers for ...NDATORY reporting

Approved by FDA on 09/25/95

MfR report # PRIUSA1999006293

UF/Distr report #

FDA Use Only

Page 1 of 2

A. Patient information

1. Patient identifier: ?-?
In confidence

2. Age at time of event: or 17 yr
Date of birth: ??/???/??

3. Sex: ☐ female ☐ male

4. Weight: UNK lbs or UNK 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
☐ 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: 09/30/99

5. Describe event or problem

A pharmacists reports that a 17 year-old female patient took 12 Extra Strength Tylenol Sinus (date prior to 12-Sep-99 not specified). On 12-Sep-99 she started norgestimate/ethinyl estradiol therapy and on 17-Sep-99 experienced nausea, pain in her right upper quadrant (liver) and jaundice.

She was admitted to the hospital for jaundice and subsequently transferred to a teaching hospital with the diagnosis of autoimmune hepatic disease.

6. Relevant tests/laboratory data, including dates

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

No Pat Profiles Rptd

unknown

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
#1 ORTHO TRI-CYCLEN(tablet)(NORGESTIMATE/ET-
#2 TYLENOL SINUS EXTRA STRENGTH(TYLENOL SINUS MEDICATION) (Cont.)

2. Dose, frequency & route used
#1 1 table, daily, oral
#2 1 table, 12 in 1 day(s), oral

3. Therapy dates (if unknown, give duration)
#1 09/12/99 - ??/???/??
#2 ??/???/??

4. Diagnosis for use (indication)
#1 CONTRACEPTIVE MANAGEMENT
#2 UNKNOWN

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 (if known)

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

No Concomitant Products Reported

G. All manufacturers

1. Contact office - name/address (& mfrng site for devices)

R.W. JOHNSON PHARM. RES. INST.
USA
DIV. OF ORTHO PHARMACEUTICAL CORP.
920 U.S. Route 202
P.O. Box 300
Raritan NJ 08869
USA
(Informing Unit)

2. Phone number: 908-704-4504

3. Report source (check all that apply)
☐ foreign
☐ study
☐ literature
☐ consumer
☒ health professional
☐ user facility
☐ company representative
☐ distributor
☐ other:

4. Date received by manufacturer: 09/22/99

5. (A)NDA # 19-697
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)
1) AUTO-ANTIBODY RESPONSE
2) JAUNDICE
3) NAUSEA
4) ABDOMINAL PAIN

9. Mfr. report number
PRIUSA1999006293

E. Initial reporter

1. Name, address & phone #
Mr. [redacted] Hospital
[redacted] Street
USA
Phone [redacted]

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2. Health professional? ☒ yes ☐ no

3. Occupation: Pharmacis

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

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.

OCT 6 1999

R.W. JOHNSON PHARM. RES. INST. USA
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920 U.S. Route 202
P.O. Box 300
Raritan NJ 08869
USA

Individual Safety Report

3364475-1-00-02

Continuation Sheet for FDA-3500A Form

Mfr. report # : PRIUSA1999006293

Date of this report : 09/30/99

C. Suspect medication (Cont...)

Seq No. : 1
C.1 Suspect medication : ORTHO TRI-CYCLEN(tablet)(NORGESTIMATE/ETHINYLESTRADIOL)

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