



CDER

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

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

Form Approved OMB No. 0910-0291 Expires 12/31/94 See OMB statement on reverse

FDA Use Only (AHFS)

Trace and sequence #	107721
DEATH - FAX	

Page ___ of ___

CDER

A. Patient information

1 Patient identifier: 161209
90
In confidence

2 Age at time of event: 36
or Date of birth:

3 Sex: female
 male

4 Weight: 96 lbs
or ___ 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 6-25-99
 life-threatening
 hospitalization - initial or prolonged
 disability
 congenital anomaly
 required intervention to prevent permanent impairment/damage
 other

3 Date of event: 4/19/99
4 Date of this report: 7/23/99

5 Describe event or problem:
 PT ingested ≈ 45 LORTAB TABLETS, PRESENTED TO HOSPITAL WITH acute hepatic failure, renal failure. TX with MUCOMYST, NARCAN, Thiamine, glucose, VITs, Folic ACID, INTUBATED. PT proceeded onto Pulmonary hepatic failure, renal failure. PT status continued to decline. made O.R. + died short time later. TX with mucomyst for acetaminophen overdose.

6 Relevant tests/laboratory data, including dates:
 ON ADMISSION: INR=3.6, TRAMINASTAT ≈ 6000, BUN 49, BS=42, Na 130, K=5.8, NH4=175, TB=4.2, TPT Level 14.
 Time of death BUN 177, Scr 12.3, Na 157, TB 5.3, PT 9.35

7 Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.):
 NKA, Alcoholism x 12YR - Quit 7YR AGO, SP TAH/BSO multiple suicide attempts. Home med: LORTAB, SUMA, Prozac, quinine, TRAZADOL

C. Suspect medication(s)

1 Name (give labeled strength & manufacturer if known):
 #1 LORTAB OVERDOSE
 #2

2 Dose, frequency & route used:
 #1 ≈ 45 LORTAB
 #2 PAST

3 Therapy dates (if unknown, give duration) (month/year):
 #1 6/19/99 - 6/25/99
 #2

4 Diagnosis for use (indication):
 #1 LORTAB OD,
 #2 Liver, renal failure, MOE

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):
 Hx depression ALCOHOL + prescripts
 Rx abuse

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 (month/year)

6 model # REC'D.
 catalog #
 serial # AUG 11 1999

7 If implanted, give date (month/year)

8 If explanted, give date (month/year)

9 Device available for evaluation? (Do not send to FDA)
 yes no returned to manufacturer on ___/___/___

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

E. Reporter (see confidential) M.D.

1 Name, address & phone #
 [Redacted]
 [Redacted] University
 [Redacted] Phone [Redacted]

2 Health professional? yes no

3 Occupation: M.D.

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.



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

or FAX TO:
 1-800-FDA-0178

FDA Form 3500 (6/93)

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

AUG 13 1999

CTU107721

107721

Show demographics | Lab links | Pre-clear | Prepare for printing | Edit problem list | In-Box | LOGOUT

Patient name or MR#: Previous searches:

MR#

24HLabs	Coag	TransfInfo	MostCommon	OtherChem	Immunopath	Endocrine	MiscLabs	From:	07/16/
CBC	BasicMetab	UABasic	APath/Cyto	OtherHeme	SPEP	DrugLevels	Flows	to:	07/23/1999
Different	CompMetab	UAMicrosc	Micro/Viro	OtherCoag	BloodBank	Toxicology	Pending	3days	7days
Abbr.Diff	RoutChems	BloodGases	ChemPanels	OtherScrol	BodyFluids	MolecDiag	AllResults		0

06/25/1999 DS DEATH NOTE	ALL TYPES	1997MJJASOND	1998MJJASOND	1999MJJASOND
06/21/1999 RAD USREN ¹	Problems
06/19/1999 HP HISTORY AND PHYS	Anat.Path
06/19/1999 HP HISTORY AND PHYS	Disc.Sum.	1
06/19/1999 RAD CHST5	Notes	2
06/19/1999 RAD CHST5	Lab**	*
06/19/1999 RAD CHST5	Radiology2	4
06/19/1999 RAD CHST5	Reports
	Letters

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MR#

Report Type HP - HISTORY AND PHYSICAL
 Date 06/19/1999
 Physician M.D.
 Attending Phys.... M.D. Date of Adm 06/19/1999
 Status **Unverified transcription**
 Draft signed by.. 1999/06/21 07:51

HISTORY AND PHYSICAL
 INPATIENT

ROOM NO:

Primary Care Provider: Dr.
 Staff: Dr. and Dr. Fellow: Dr.

Informant(s): The patient's family and records from outside hospital.

CHIEF COMPLAINT: Status post multiple drug overdose.

HISTORY OF PRESENT ILLNESS:
 This is a 36-year-old white female with a long-standing history of depression and alcohol abuse (apparently went through alcohol rehabilitation one year ago no alcohol since), abuse of prescription drugs including Soma and Lortab, who was brought to the Hospital in by her husband this evening with altered mental status.

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Apparently history of present illness dates back to approximately June 17, when the patient's husband noticed that the patient seemed rather sleepy. He reported that the patient from time to time will take multiple tablets of her Lortab, Soma, trazodone, Phenergan, and Prozac, and become sleepy without apparent intention of harming herself. The patient's husband thought that the patient may have taken too much of her medication and therefore held her medication. He also noted that the patient was rather sleepy but had normal cognitive function. The following day, on June 18, the patient was somewhat more sleepy, less interactive, and had an episode of coffee-grounds emesis. The patient's husband tried to coerce the patient into going to the emergency department at that time; however, she refused.

On the evening of admission, the patient was much more somnolent, and therefore the patient's husband called the ambulance. When the ambulance arrived, the patient was found to have a systolic blood pressure in the 60s. She was taken directed to the [REDACTED] Medical Center in [REDACTED] at which time the presumptive diagnosis of drug overdose was made. There, in the emergency department, the patient was given 3 L of fluid with increase in her blood pressure to the 90s to 100s systolic. In addition, the patient had a blood sugar of 42 and was therefore given an amp of D50 with improvement. Urine drug screen at the outside hospital was positive for benzodiazepines and opiates. Tylenol level was 14. Salicylate level was normal.

It was noted that the patient was in hepatic failure with an INR of 3.6 and transaminases in the 6,000 range. In addition, she was noted to have a BUN of 49, glucose of 42, sodium of 130, potassium of 5.8, bicarb of 24, hematocrit of 35, platelets of 61,000, and an ammonia level of 175. The patient was treated with subcutaneous vitamin K, thiamine, and folate in addition to Narcan, and subsequently transferred to [REDACTED] Medical Center for further management of her fulminate hepatic failure.

Upon further discussion with the patient's husband and mother, it appears that the patient often takes "handfuls" of Tylenol for chronic leg cramps. In addition, the patient's husband is unable to quantitate how much of these various medications the patient has taken and that she apparently has hidden bottles. In addition, when questioned where the patient gets these medications, she apparently buys them off the street from time to time. The patient's mother thinks that the patient has taken 45 Lortab in the last three to four days.

PAST MEDICAL HISTORY:

1. Remarkable for hypertension per the patient's husband; however, she has been on no medications for this.
2. Status post TAH/BSO and is on Premarin.
3. A history of alcoholism for 12 years, quit approximately one year ago.
4. Denies a history of seizures.
5. Questionable street drugs. Husband has no knowledge of intravenous drug use.
6. Denies diabetes, coronary disease, CVA.
7. Depression. Husband denied history of previous suicide attempts. No previous history of drug overdose.

MEDICATIONS:

Home medications include Lortab 5, one tablet b.i.d.; Soma one tablet q.i.d.; trazodone one at h.s.; Prozac 20 mg per day; Phenergan 25 mg p.r.n.; quinine sulfate p.r.n.

ALLERGIES:

Husband reports questionable allergy to Medrol dosepak, although cannot state what this allergy was.

FAMILY MEDICAL HISTORY:

Unremarkable.

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SOCIAL HISTORY:

She is married, has two children, and lives in [redacted] with her husband. Does not work. She spends most of her day in bed from her depression. Heavy tobacco abuse, approximately one to two packs a day per mother.

REVIEW OF SYSTEMS: Unable to be obtained.

PHYSICAL EXAMINATION:

HEIGHT 96 kg WEIGHT approximately 5 feet 10 inches
TEMP The patient is afebrile BP 120/53 HR 100
RR approximately 18 to 20 with saturations of 97% on 2 L

GENERAL: The patient is somnolent. She responds to simple commands such as opening eyes, squeezing hand, and deep breathing.

HEENT: Pupils are approximately 6 mm bilaterally and equal and reactive to light. Extraocular movements appear to be intact. Oropharynx: There is some dried, brownish material on the lips and mouth. Poor dentition.

NECK: Supple. No lymphadenopathy, no JVD, no bruits.

RESPIRATORY: Lungs clear to auscultation anteriorly, bilaterally.

CARDIOVASCULAR: Nondisplaced PMI, tachycardia, normal S1 and S2, no murmurs, rubs, or gallops.

GI: Abdomen is obese, distended, with bowel sounds. There is diffuse tenderness. No rebounding.

EXTREMITIES: Trace bilateral lower and upper extremity edema. She has good dorsalis pedis pulses and radial pulses. There are multiple areas of ecchymoses in the antecubital areas of her arms from attempts at IV placement.

NEUROLOGIC: Moving all extremities. The patient cannot cooperate to assess for asterixis. There are four beats of myoclonus in the left foot. Reflexes are brisk, 2+ throughout.

LABORATORIES:

From the outside hospital include: White count 2.7, hematocrit 35.5, platelets 61,000, 69 segs, 18 bands, 7% lymphocytes. Sodium 130, potassium 5.8, chloride 98, bicarb 24, BUN 49, creatinine 3.7. Bilirubin 4.2, SGOT 10,000, SGPT 6,000, alkaline phosphatase 216, albumin 2.9. Drug screen positive for benzodiazepines and opiates. Tylenol level is 14. Ammonia level is 176. PT 41, INR 3.6.

EKG from the outside hospital reveals normal sinus rhythm with a heart rate of approximately 100, normal axis, no ST-T wave changes, normal intervals.

Chest x-ray is pending.

PROBLEM LIST

1. Fulminate hepatic failure including coagulopathy, encephalopathy, elevated transaminases.
2. Acute renal failure. Possibly prerenal picture versus toxic metabolic.
3. History of polysubstance abuse.
4. History of alcoholism.

ANALYSIS OF ADMITTING PROBLEMS:

This is a 36-year-old white female with a history of depression, history of alcohol abuse and prescription drug abuse, who presents greater than 48 hours after ingestion of unknown quantities of Lortab, acetaminophen, Soma, who has evidence of acute hepatic failure with coagulopathy, encephalopathy, in addition to renal failure.

Have discussed the patient's case with Dr. [redacted] in Toxicology who recommendations still giving Mucomyst IV, given the severity of her hepatic dysfunction.

1. Acute hepatic failure with coagulopathy and encephalopathy: Will treat patient with IV Mucomyst per protocol. Will place NG tube and give the patient lactulose for encephalopathy. Will correct coagulopathy with FFP and vitamin K. Will follow up a Tylenol level and repeat urine drug screen here.

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2. Continue supportive treatment, follow mental status closely, worrying about cerebral edema should her mental status decline further. In addition, the patient appears to be able to protect her airway at present but would have low threshold for intubation for airway protection.

3. Acute renal failure. Possibly multifactorial including prerenal azotemia related to the patient's hypotension in addition to toxic metabolic effects of Tylenol toxicity. Will check urine sodium, creatinine, and calculate FENa. In addition, will check urine electrolytes. Will try fluid challenge. In addition, will consider renal ultrasound as well as obtain renal consult in the morning.

4. History of alcohol abuse. Will give the patient thiamine, folate, and multivitamin.

CONSULTATIONS:

Toxicology.

T: 06/19/99 1009
D: 06/19/99 0523
Job #: 6736
MD#:

Signature of Physician
M.D.
RESIDENT, MEDICINE



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Patient name or MR#: [redacted] Previous searches: [redacted] OK

[redacted] MR#: [redacted]

24HLabs	Coag	TransInfo
CBC	BasicMetab	UABasic
Differentl	CompMetab	UAMicrosc
Abbr.Diff	RoutChems	BloodGases

MostCommon	OtherChem	Immunopath	Endocrine	MiscLabs
APath/Cyto	OtherHeme	SPEP	DrugLevels	Flows
Micro/Viro	OtherCoag	BloodBank	Toxicology	Pending
ChemPanels	OtherSerol	BodyFluids	MolecDiag	AllResults

From: 07/16/ to: 07/23/1999 3days 7days [O]

06/25/1999 DS DEATH NOTE	ALL TYPES	1997MJJASOND	1998MJJASOND	1999MJJASOND
06/21/1999 RAD USREN	Problems			
06/19/1999 HP HISTORY AND PHYS	Anat.Path			
06/19/1999 HP HISTORY AND PHYS	Disc.Sum.			1
06/19/1999 RAD CHST5	Notes			2
06/19/1999 RAD CHST5	Lab	*	*	*
06/19/1999 RAD CHST5	Radiology	2		4
06/19/1999 RAD CHST5	Reports			
	Letters			

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[redacted] MR#: [redacted]

Report Type DS - DEATH NOTE Date 06/25/1999 Physician [redacted] M.D. Attending Phys.... [redacted] M.D. Date of Adm 06/19/1999 Date of Disch. ... 06/25/1999 Signed by [redacted] 1999/07/20 16:13

BRIEF HISTORY: The patient is a 36-year-old white female with a longstanding history of depression, alcohol and prescription drug use who was transferred from [redacted] Medical Center in [redacted] with fominant hepatic failure and renal failure secondary to acetaminophen ingestion. It is undetermined whether the acetaminophen ingestion was an intentional suicide attempt or an unintentional overdose. Medications ingested were Lortab and Soma.

HOSPITAL COURSE: Since arrival at [redacted] Medical Center, the patient has had a declining course that has been notable for requirement of mechanical ventilation secondary to decreased mental status, increasing BUN and creatinine. The final values measured were on June 23, 1999, with a BUN of 177, a creatinine of 12.3, and an increasing total bilirubin with a final value measured on June 23, 1999, of 15.9. The patient was treated aggressively for the first several days of admission with N-acetyl-cysteine and lactulose for elevated ammonia. The patient's status continued to decline during that time and it was decided on June 23, 1999, that she would be made DNR. At approximately 3:30 a.m. the morning of June 25, 1999, she experienced cardiopulmonary arrest and was pronounced dead at that time. Medical Examiner's Office was notified and it was determined that this would be a Medical Examiner's case. The Medical Examiner that was spoken to was [redacted] and the case number assigned was [redacted]

On physical examination at time of death, patient was noted to have no spontaneous movement. She was markedly jaundiced, motionless in bed. Her

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pupils were fixed and dilated. There was no corneal reflex, no gag; there were no breath sounds, no heart sounds, no pulse, no response to deep painful stimuli and she was pronounced dead at 3:30 a.m., June 25, 1999.

T: 06/25/99 06:39
D: 06/25/99 04:16
Job #: 8352
MD#:

Signature of Physician
M.D.
RESIDENT, INTERNAL MEDICINE



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Patient name or MR#: Previous searches:

MR#:

24HLabs	Coag	TransInfo	MostCommon	OtherChem	Immunopath	Endocrine	MiscLabs	From:	<input type="text"/>
CBC	BasicMetab	UABasic	APath/Cyto	OtherHeme	SPEP	DrugLevels	Flows	to:	<input type="text"/>
Differentl	CompMetab	UAMicrosc	Micro/Viro	OtherCoag	BloodBank	Toxicology	Pending		
Abbr.Diff	RoutChem	BloodGases	ChemPanels	OtherSerol	BodyFluids	MolecDiag	AllResults	3 days	7 days <input type="checkbox"/>

06/25/1999 DS DEATH NOTE	ALL TYPES	1997MJJASOND	1998MJJASOND	1999MJJASOND
06/21/1999 RAD USREN	Problems
06/19/1999 HP HISTORY AND PHYS	Anat.Path
06/19/1999 HP HISTORY AND PHYS	Disc.Sum.	1
06/19/1999 RAD CHST5	Notes	2
06/19/1999 RAD CHST5	Lab***
06/19/1999 RAD CHST5	Radiology24
06/19/1999 RAD CHST5	Reports
	Letters

Error - Warning - a spreadsheet has more than 600 lines. Extra lines will not be displayed.

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MR#:

CBC	WBC	Hgb	PCV	Plt-Ct	RBC	MCV	MCH	MCHC	R
Ref. range:	4-11	12-16	37-44	150-400	4.0-5.5	82-100	27-31	32-36	11.5-
Units:	thou/uL	g/dL	%	thou/uL	mil/uL	fL	pg	%	
06/21/99 14:00	---	---	27.0*	---	---	---	---	---	---
06/21/99 03:45	---	---	27.0*	---	---	---	---	---	---
06/20/99 18:30	---	---	27.0*	---	---	---	---	---	---
06/20/99 13:30	---	---	24.0*T	---	---	---	---	---	---
06/20/99 04:30	4.4	10.5*	32.0*	83*	3.27*	96	32.0*	33.2	15
06/19/99 20:05	5.3	10.9*	33.0*	70*	3.42*	95	31.8*	33.3	15
06/19/99 03:45	3.7*	10.0*	30.0*	57*U	2.97*	99	33.7*	34.0	13

Differentl	CBCPDF	Diff	PltSuf	AutoNt	Neut	Lym	Monocy	Eos	Lu
Ref. range:					42-77	25-40	2-10	0-5	0
Units:				%	%	%	%	%	
06/19/99 03:45	:	:	LOW	86	86*T	9*	2	1	

Coag	Pat-PT	PT-inr	PTT-pt	PTTctr	Fbrngn	FiSpPr
Ref. range:	12-15		25-36		185-400	<= 5
Units:	sec		sec	sec	mg/dL	mcg/mL
06/23/99 04:10	23.3*	1.9	---	---	---	---
06/21/99 04:20	24.8*	2.0	---	---	---	---
06/21/99 03:45 T	---	---	---	---	---	---
06/20/99 15:10	27.5*	2.3	34.0	34.0	194	>20
06/20/99 13:30	26.7*	2.2	---	---	---	---
06/20/99 04:30	32.0*	2.8	---	---	---	---
06/19/99 19:50	36.3*	3.3	35.2	34.0	185	---
06/19/99 06:45	36.2*	3.3	---	---	---	---

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06/19/99 03:45	53.3*	5.3	--	--	--	--	
BasicMetab	Na	K	Cl	CO2	BUN	Creat	Gluc
Ref. range:	135-145	3.5-5.0	95-105	23-30	5-25	0.7-1.5	70-110
Units:	mEq/L	mEq/L	mEq/L	mmol/L	mg/dL	mg/dL	mg/dL
06/23/99 04:10	157*	3.8	103	17*	177*T	12.3*	121*
06/22/99 04:30	156*	3.7	105	17*	146*	11.1*	132*
06/21/99 18:00	148*	3.1*	99	19*	120*	9.6*	145*
06/21/99 03:45	145	3.1*	99	20*	116*	8.2*	109
06/20/99 04:30	144	3.8	102	25	77*	7.3*	122*
06/19/99 17:00	135	4.4	96	27	63*	6.1*	124*
06/19/99 05:20	136	4.0	101	28	50*	5.4*	214*
06/19/99 03:45	: T	: T	: T	: T	: T	: T	: T

CompMetab	Na	K	Cl	BUN	Creat	Gluc	Ca	TProt	A
Ref. range:	135-145	3.5-5.0	95-105	5-25	0.7-1.5	70-110	8.5-10.	6-8	3.5-5
Units:	mEq/L	mEq/L	mEq/L	mg/dL	mg/dL	mg/dL	mg/dL	g/dL	g/
06/23/99 04:10	157*	3.8	103	177*T	12.3*	121*	9.2	5.2*	2
06/22/99 04:30	--	--	--	--	--	--	8.3*	--	--
06/21/99 03:45	--	--	--	--	--	--	8.3*	--	--
06/20/99 04:30	--	--	--	--	--	--	7.1*	--	2
06/19/99 05:20	136	4.0	101	50*	5.4*	214*	6.0*	4.5*	2
06/19/99 03:45	: T	: T	: T	: T	: T	: T	: T	: T	: T

RoutChems	CBil	Mg	CaIo	pHCaIo	Phos	Amm	SGPT	LDH
Ref. range:	0.0-0.3	1.8-2.4	4.48-5.	7.35-7.	2.5-4.5	11-35	4-40	310-620
Units:	mg/dL	mg/dL	mg/dL		mg/dL	mcmol/L	U/L	U/L
06/23/99 04:10	--	--	--	--	--	38*	--	--
06/22/99 04:30	--	--	--	--	2.8	--	--	--
06/21/99 03:59	--	--	4.45*	7.43	--	--	--	--
06/21/99 03:45	--	--	--	--	--	104*	--	--
06/20/99 05:27	--	--	3.88*	7.45	--	--	--	--
06/20/99 04:30	5.3*	--	--	--	--	--	3245*	--
06/19/99 17:00	--	--	--	--	2.9	--	--	--
06/19/99 15:00	--	--	3.60*	7.36	--	--	--	--
06/19/99 06:48	--	--	3.16*	7.36	--	--	--	--
06/19/99 05:20	--	2.9*	--	--	3.3	--	--	--
06/19/99 03:45	: T	: T	--	--	: T	--	: T	: T

Note: Product Std Vol: RBCs (350ml); Plasma (200ml); Plts (50ml); Apher Plts (200ml)
 Actual volumes are recorded on the chart (Transfusion Slip).

TransfInfo	RBC/WB	FFPCRY
06/20/99 20:34	--	FFP Transfd
06/20/99 20:34	--	FFP Transfd
06/20/99 11:37	--	FFP Transfd
06/20/99 11:37	--	FFP Transfd
06/19/99 04:53	RCL Transfd	--
06/19/99 04:44	--	FFP Transfd
06/19/99 04:44	--	FFP Transfd
06/19/99 04:44	--	FFP Transfd
06/19/99 04:44	--	FFP Transfd

DSS
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UABasic	UColor	UChar	USpGr	UpH	UGluc	UALb	UKeto	UBili	UUr
Ref. range:			1.015-1	5.0-6.5	NORM=NE	NORM=NE	NORM=NE	NORM=NE	0.1-1
Units:									Ehrli
06/19/99 09:00	BROWN	CLOUDY	1.024	5.0	NEG.	2+	: T	: T	1

UAMicrosc UWBC URBC UBact USqEpi Eos-UA



C7U 107721