

Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

13344



5 - SUMMARIES

000001

[REDACTED]
DISCHARGE SUMMARY

Name: [REDACTED]
Med Rec: [REDACTED]
Admission: 01/18/99
Discharge: 01/21/99

ATTENDING PHYSICIAN: [REDACTED] M.D.
REFERRING PHYSICIAN:

REASON FOR ADMISSION: Unresponsive episode.

PRINCIPAL DIAGNOSIS: Unintentional overdose of Hydroxycut, which includes caffeine and Ephedra, and toxic doses in combination with cold medicines causing a toxic psychosis.

BRIEF HISTORY: The patient is a 55-year-old white male, who was previously healthy who presented to the [REDACTED] emergency department after a day of "acting funny" and a seizure-like episode while he was on a bus on his way home from skiing at [REDACTED] ski resort. According to his family, he had been taking an over-the-counter metabolism enhancer called Hydroxycut for a few weeks. His family also reports he has no history of drug abuse and occasional alcohol use, but in general no alcohol abuse. There is no family history of seizures or patient history of seizures. His father said that three days prior to admission, he complained of headache, fatigue and did not come to work, but decided to attend the ski trip over the weekend. He also complained of not feeling well and feeling weird and having shaky hands prior to the ski trip. According to his girlfriend, on the ski trip, he was not himself all day and did not eat at all over the course of the day, and on the way home on the bus, he stood up, grabbed his head, yelled out in pain and then became unresponsive with increased secretions from his mouth. The rescue squad was called, who found him combative and responsive only to tactile stimuli, but not verbal stimuli. He was brought to the emergency room where he was combative and had dilated pupils. At that time, he was sedated and intubated for airway protection. He was paralyzed and received charcoal and IV fluids, underwent a CT scan that was negative and an LP to rule out meningitis and encephalitis, which was also negative. In talking to his family and his roommate, it seems that he had been taking Hydroxycut which included caffeine, ma huang which is Ephedra, cavarone which is another caffeine derivative, hydroxacen, willow bark extract which is converted to salicylates, L-Carnitine and chromium picolinate.

PAST MEDICAL HISTORY: Broken nose times two. In prior surgeries for his broken nose, he is exquisitely sensitive to anesthetic agents and takes approximately three days to wake up after anesthesia.

ALLERGIES: No known drug allergies.

MEDICATIONS: Hydroxycut as previously described, 12+ tablets per day.

SOCIAL HISTORY: He lives with a friend in [REDACTED] works for his father. He is very active in sports, a hockey player and baseball specifically and is a ski club president. He drinks

JAN 27 1999

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only occasional alcohol and has no known drug abuse and does not smoke.

FAMILY HISTORY: Positive for heart disease in his paternal side. No seizures.

REVIEW OF SYSTEMS: Unattainable.

PHYSICAL EXAMINATION ON ADMISSION: Blood pressure 140/72. Pulse 83. Respirations 12. Saturations were 100%. Temperature 36.3. In general, he was a sedated, intubated white male who was very pale-appearing. HEENT: Normocephalic/attraumatic. PERRLA. His pupils were 5 mm bilaterally and minimally reactive. NG tube was in place. ET tube was in place. His neck was supple with no lymphadenopathy, no JVD and his trachea was midline. Chest: He had equal expansion bilaterally and he was clear to auscultation bilaterally. Cardiac exam revealed a regular rate and rhythm with a normal S1, S2, no murmurs, rubs or gallops. Abdomen was soft, nontender, nondistended, positive bowel sounds, no hepatosplenomegaly. Extremities showed 2+ distal pulses, no clubbing, cyanosis or edema. Rectal exam was guaiac-negative, normal tone. Neurologic exam: He was unresponsive to verbal stimuli, moved all four extremities spontaneously, however, was responsive to tactile stimuli by being slightly combative and withdrawing.

LABORATORY ON ADMISSION: Sodium 143, potassium 3.2, chloride 104, bicarbonate 26, BUN 9, creatinine 1.0, glucose 147, calcium 8.6, magnesium 1.9, phosphorus 1.8. Albumin 4.4, total bilirubin 0.7, alkaline phosphatase 115, AST 23, ALT 32, CK was 324, osmolality serum was 293, calculated was 297, anion gap was 13, coags were normal. White blood cell count 6.2, hematocrit 41.9, platelets 305, alcohol less than 10, acetaminophen level less than 10, salicylates were 0. Toxicology screen was negative for any drugs of abuse. ABG on 100% FIO2 was 7.45/38/558. Chest x-ray with no acute cardiopulmonary disease or any other cardiopulmonary disease detected. CSF: Glucose was 72, protein 56. Tube #1 had 34 red blood cells, 4 white blood cells with 4% segmented leukocytes and 18% lymphocytes. Tube #4 had 1 red blood cell and 1 white blood cell. Head CT showed no evidence of subarachnoid hemorrhages and no masses. EKG was normal sinus rhythm.

BRIEF HOSPITAL COURSE: The patient was admitted and started on IV fluids to try and diurese off his metabolites from his Hydroxycut. Given the fact that his pupils were dilated, it was felt that organophosphate poisoning was not likely. In addition, with a normal EKG and normal labs, we felt that other toxic ingestions were not likely and most likely his state was due to the Hydroxycut. He was started on an Ativan drip for sedation and continued on mechanical ventilation, was started on sorbitol for gut decontamination and Pepcid. Overnight his Ativan was weaned off in the hopes to extubate

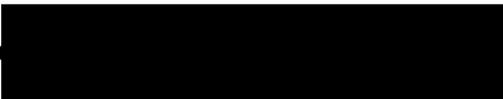
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him the following day. However, on the next hospital day, he was not able to be aroused and, therefore, it was decided to have neurology come see him to determine whether there was another cause for this. Neurology saw him and ordered an emergent EEG that showed no epileptiform activity and an MRI/MRA was ordered to rule out CNS vasculitis being caused by the caffeine/ephedrine as well as effects of the TheraFlu he had been taking for what he presumed to be a cold. The MRI/MRA was done and was not read initially and, therefore, he was started on Solu-Medrol 125 q. 6 as early treatment for CNS vasculitis. However, the decision to start Cytoxan was held until the MRI/MRA was read which was read as normal. The following morning, he woke up and, therefore, the Solu-Medrol was stopped and it was determined that most likely this was just a drug overdose as opposed to a CNS vasculitis. He was maintained on his IV fluids and was extubated on the morning of 1/20/99. However, he had intermittent spells of somnolence so, therefore, it was decided to watch him overnight to determine that he was okay to go home as far as his mental status. In addition, it was most likely felt that given the fact that he took so long to come out of anesthesia that a large part of his affect was most likely due to his Ativan that he had received while on the mechanical ventilation. By the morning of 1/21/99, he was fully awake and conversant with no complaints of pain and no memory of the previous few days. He was, however, suffering from short-term memory loss and had difficulty remembering new people he had met as well as anything that had happened which the team felt was most likely secondary to residual effects of the Ativan as well as residual effects of the Hydroxycut. He had no complaints the following morning and addictions was consulted to discuss with him his use of any further muscle building drugs.

PHYSICAL EXAMINATION ON DISCHARGE: He was afebrile. Vital signs were stable. In general, he is a very well-developed, well-nourished white male in no acute distress, awake and talkative, alert and oriented. HEENT: Normocephalic/attraumatic. PERRLA. Neck was supple without lymphadenopathy or thyromegaly. Chest was clear to auscultation bilaterally. Cardiac exam revealed a regular rate and rhythm with no murmurs, rubs or gallops. Abdomen was soft, nontender, nondistended, positive bowel sounds. Extremities showed 2+ distal pulses and no edema or cyanosis. Neurologic exam: He had normal strength throughout. DTRs were 2+ throughout and downgoing Babinski's. Normal sensory exam.

LABORATORY ON DISCHARGE: He had a normal chemistry, a normal CBC. His LFTs remained normal. TSH was 0.92, T4 3.4, T3 reuptake 45% which we thought was consistent with euthyroid syndrome.

MEDICATIONS ON DISCHARGE: None.

DISCHARGE INSTRUCTIONS: He is to follow up with his primary care physician, Dr. [REDACTED] in one week for followup of his short-term

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memory loss which should clear with washout of the Ativan he got during intubation. He is to return to medical care if he develops any mental status changes or severe headache. He is to resume a regular diet and avoid stimulant ingestion and he has been discharged to home in his parents' care where he has been instructed to stay for the next four or five days to be sure that his mental status clears and that he can return to his own home.

Dictated by:

Signed by:

[REDACTED]

[REDACTED]
M.D.

Job: [REDACTED]
Revision Date: [REDACTED]

D: 01/21/99 T: 01/24/99

cc: [REDACTED]

000005

CONSULTATION REQUEST

Second Page

ISO:

(continued from page one)

24 y.o. R#207 was in [redacted] of health today
Sleeping, then on w/s became agitated, combative, and
"foaming at mouth." I - ER pupils dilated but
reactive, combative, pt intubated for sedation for
way protection. Given etomidate 20mg IV, succ 100 IV
fentanyl 200, versed 4mg, vecuronium 10, chloroal/50.

Hx per step mother - 2 weeks "cold," last 3 days hands
shaking, body felt "weird."

PMHx

phi head trauma
phi SZ
phi medical problems.

meds

"Hydroxyent" - herbal preparation
guarana extract
"22% caffeine"

EMHx
- CAD, HTN
all to denul.
- psychiatric

Soc Hx

phi smoking
"social drinker"
lives in cheapeake = roommate
in apartment

Signed

Consultant

000007

CONSULTATION REQUEST

Second Page

AGE: 98

ISO:

(continued from page one)

(50 min. p paralysis)

363

194

99

105

98%

Gen pt intubated

Heads - unresponsive, myoclonic shiver

Neck - flaccid, rigid

lungs CTA

CVS RA

abd soft, ⊕ BS

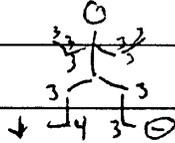
not periton, warm

neuro MS - pt aroused manually + physical stim by moving an extremity

CV - pupils equal and manually reactive to light, discs sharp, absent ocm, ⊕ w. reals, ⊕ gag

M - moves all extremities - at least anti-gravity mildly ↑ tone (rigidity)

R -



ⓑ crossed adductors

ATRA 7.45 / 38 / 558 / 26

143 / 107 / 19 / 147

8.4

1.9

1.8

EGTT <10

ASA 0

tylenol <10

8.2 / 26 / 1.0

Ht | Wt | AIT | ALT | alb
-7 | 115 | 23 | 32 | 4.7

6.2 / 14.4 / 41.9 / 305

OSM 293

PT 14.5 MT 28.2

UA 2WBC 9RBC } CSF glvc 72
nod crystals }
cxa ⊕ }
ct ⊕ }
pwt 56
tbc #1 4
tbc #4 1

Signed

Consultant

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