

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

ARMS#

13499



3 - OUTPATIENT

000001

01-05-99: [REDACTED]

S: The patient is quite anxious and nervous about a peculiar syndrome that she vaguely describes as a sensation of tremulousness and tremor, not present currently, but bothering her for the last three to four weeks. She initially noted it after she began using some herbs that did have stimulants within them. Subsequently to stopping the stimulants, she has continued to have difficulty. She denies any change in her stress level. She feels as if she is having changes in her skin, that it is more dry than usual and even thinning of her hair. Her mother does have a hereditary thyroid disease which she has not had problems with in the past.

O: NECK - examination shows that thyroid does not appear to be enlarged. HEART - regular rate and rhythm. VITAL SIGNS - P 72. There is no obvious anatomical findings. No obvious tremor currently.

A: 1. Tremulousness, etiology unclear. May be anxiety partly superimposed on reaction to the herbal medicines she was trying.

P: 1. Keep off all herbal remedies.
2. Avoid caffeine.
3. Base line serum chemistries including, thyroid-stimulating hormone (TSH), CBC, and comprehensive metabolic panel.
4. Recheck next week regarding the above and to discuss the laboratory test results.

[REDACTED] M.D. [REDACTED]

D: 1-05-99
T: 1-07-99

01-11-99: [REDACTED]

S: The patient is a 48-year-old female who is here for a recheck. She had the sensation of tremulousness that she had associated initially with the use of a Chinese herbal metabolic product that she was taking, but even when stopping the metabolic product, she continued to feel that way. Her signs and symptoms were somewhat suggestive of a possible thyroid disease, but blood work which included a thyroid-stimulating hormone (TSH), was all within normal limits. She is now seen here for a recheck one week later and she reports that her signs and symptoms have all cleared. She is not under any undue stress.

O: HEART - regular rate and rhythm. LUNGS - clear to auscultation and percussion.

A: 1. Tremulousness, etiology unclear, but has completely resolved.

P: 1. Observation.

[REDACTED]

D: 1-11-99
T: 1-12-99

INTERNAL MEDICINE CONSULTATION

PATIENT: [REDACTED]
MEDICAL RECORD #: [REDACTED]
DATE: March 11, 1999
REFERRING PHYSICIAN: [REDACTED] M.D.

HISTORY OF PRESENT ILLNESS:

The patient is a 48-year-old white female, who presents for complaints of tremors and muscle pain since November.

The patient states that in November she was using a herbal diet pill, containing primarily caffeine and Moiwan. She did well losing weight on this regimen. She was also drinking 2-3 cups of caffeine a day along with 2-4 coca colas a day. The patient states that she began developing tremors, agitation, and difficulty sleeping. This was associated with fatigue and some numbness in the bilateral fingertips.

The patient was initially evaluated and stopped on her herbal medication and the symptoms eventually went away. Slowly, however, over the past month the symptoms have returned. She continues with her routine of coffee as well as cokes, although she did not take the diet pill at this time. She states she is still somewhat agitated inside, and although she does not feel that she is having tremors, she is still tremulousness inside herself.

The patient also has been having complaints of temperature changes, feeling intermittently hot and cold. She has not had any hot flashes per-se. She was on birth control pills for the past seven years and stopped approximately four days per her OB/GYN. She has not had a period yet.

PAST MEDICAL HISTORY:

- MEDICAL:
1. Mitral valve prolapse
 2. History of labyrinthitis

INTERNAL MEDICINE CONSULTATION

PATIENT:

[REDACTED]

MEDICAL RECORD #:

[REDACTED]

DATE:

March 11, 1999

REFERRING PHYSICIAN:

[REDACTED]

M.D.

SURGICAL:

Unremarkable

CURRENT MEDICATIONS:

She is currently taking Ortho-Novum 777, but stopped four days ago, Dyazide and multivitamins.

SOCIAL HISTORY:

No tobacco or alcohol use.

REVIEW OF SYSTEMS:

No chest pain, paroxysmal nocturnal dyspnea (PND), or orthopnea. She did admit to occasional palpitations and tremulousness, no shortness of breath, cough, wheezing, hemoptysis, abdominal pain, melena, hematochezia, diarrhea, constipation or new neurological symptoms, except was described above.

PHYSICAL EXAMINATION:

GENERAL:

Well-developed, well-nourished white female, in no apparent distress.

VITAL SIGNS:

Blood pressure 120/74, pulse 80, respiration 18, temperature 98.

HEENT:

Pupils are equal, round, and reactive to light and accommodation. Extraocular muscles are intact. Tympanic membranes clear. Pharynx clear.

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INTERNAL MEDICINE CONSULTATION

PATIENT: [REDACTED]
MEDICAL RECORD #: [REDACTED]
DATE: March 11, 1999
REFERRING PHYSICIAN: [REDACTED] M.D.

NECK: Supple, no jugular venous distention (JVD), no bruits. No lymphadenopathy or thyromegaly.

CARDIOVASCULAR: Regular rate and rhythm, no murmurs were appreciated.

LUNGS: Clear to auscultation.

ABDOMEN: Soft, non-tender, positive bowel sounds, no masses.

LOWER EXTREMITIES: No edema.

NEUROLOGIC: She appeared to be non-focal. She did have a mild resting tremor.

ASSESSMENT/PLAN:

- 1. Hyper-stimulation

DISCUSSION: Likely secondary to caffeine intake.

PLAN: I recommended that the patient slowly taper her caffeine intake down and that she may have rebound affects as well as withdrawal affects, which is probably causing some of her fatigue and sensation of agitation, headaches, and disorientation. At that time the patient was reassured that it does not appear that she has some neurological disease and that we will, at this point attempt to taper her off the caffeine and then evaluate should there be further symptoms.

INTERNAL MEDICINE CONSULTATION

PATIENT: [REDACTED]
MEDICAL RECORD #: [REDACTED]
DATE: March 11, 1999
REFERRING PHYSICIAN: [REDACTED] M.D.

2. Hot and cold flashes

DISCUSSION: Etiology unclear.

PLAN: Recommended following advice to stay off birth control pills. If need be, we will re-evaluate with a hormonal study in one month. TSH was normal. The patient will follow-up in two weeks and one month for recheck.

[REDACTED]

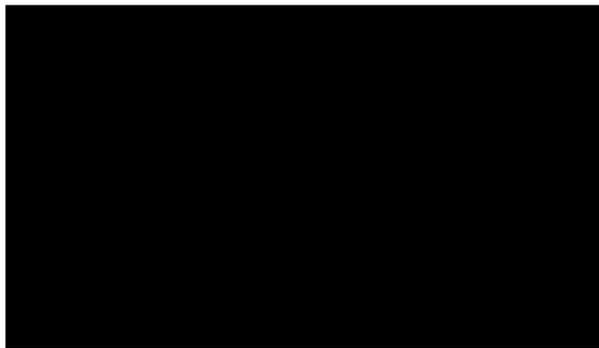
[REDACTED]

[REDACTED]

CFSAN Project #13499; patient [REDACTED]
@ USFDA/LOS-DO; collected on 4-21-99

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CFGAN Project
13499



000008

LABORATORY REPORT

MICROFILM#

PATIENT NAME		PATIENT ID		ROOM NO.	AGE	SEX	PHYSICIAN	
[REDACTED]		[REDACTED]			48	F	[REDACTED]	
PAGE	REQUISITION NO.	ACCESSION NO.	LAB REF. #	COLLECTION DATE & TIME		LOG-IN-DATE	REPORT DATE	& TIME
1	[REDACTED]	[REDACTED]	[REDACTED]	01051999 1020		01051999	01061999	7:06AM

REMARKS

PULL CHART	REVIEW COMPLETE
DATE	INITIALS

PACIFIC TIME

REPORT STATUS	TEST	RESULT	UNITS	REFERENCE RANGE	SITE CODE
FINAL		IN RANGE OUT OF RANGE			

Date of Birth: [REDACTED]
 COMPREHENSIVE METABOLIC

PANEL WITHOUT CO2

GLUCOSE	86	MG/DL	70-115
UREA NITROGEN (BUN)	10	MG/DL	7-25
CREATININE	0.7	MG/DL	0.5-1.4
BUN/CREATININE RATIO	14	(CALC)	6-25
SODIUM	141	MEQ/L	135-146
POTASSIUM	4.2	MEQ/L	3.5-5.3
CHLORIDE	103	MEQ/L	95-108
CALCIUM	9.3	MG/DL	8.5-10.3
PROTEIN, TOTAL	7.8	G/DL	6.0-8.5
ALBUMIN	4.2	G/DL	3.2-5.0
GLOBULIN	3.6	G/DL (CALC)	2.2-4.2
ALBUMIN/GLOBULIN RATIO	1.2	(CALC)	0.8-2.0
BILIRUBIN, TOTAL	0.7	MG/DL	0.0-1.3
ALKALINE PHOSPHATASE	45	U/L	20-125
AST (SGOT)	29	U/L	0-42

CBC (INCLUDES DIFF/PLT)

WHITE BLOOD CELL COUNT	6.0	THOUS/MCL	3.8-10.8
RED BLOOD CELL COUNT	4.37	MILL/MCL	3.90-5.20
HEMOGLOBIN	13.6	G/DL	12.0-15.6
HEMATOCRIT	39.7	%	35.0-46.0
MCV	90.6	FL	80.0-100.0
MCH	31.2	PG	27.0-33.0
MCHC	34.4	%	32.0-36.0
RDW	12.8	%	9.0-15.0
PLATELET COUNT	267	THOUS/MCL	130-400
ABSOLUTE NEUTROPHILS	4140	CELLS/MCL	1500-7800
NEUTROPHILS	69.0	%	
ABSOLUTE LYMPHOCYTES	1218	CELLS/MCL	850-4100
LYMPHOCYTES	20.3	%	
ABSOLUTE MONOCYTES	510	CELLS/MCL	200-1100
MONOCYTES	8.5	%	
ABSOLUTE EOSINOPHILS	102	CELLS/MCL	50-550
EOSINOPHILS	1.7	%	
ABSOLUTE BASOPHILS	36	CELLS/MCL	0-200
BASOPHILS	0.6	%	

THYROID STIMULATING HORMONE

2.0

MICRO IU/ML 0.4-5.5

>> REPORT CONTINUED ON NEXT PAGE <<

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CFSAN Project #13499; pt

USFDA/LOS-DO; 4-21-99