

AE Reporting Tool : Entry # 93

1. Date report filed (YYYY/MM/DD)

2015/08/09

2. Patient initials

AJ

3. Patient age

37

4. Patient sex

- Female

5. Race

- White

6. Date of Adverse Event (AE) (YYYY/MM/DD)

2015/08/04

7. Dates range of TCHM intake

2015/06/14 - 2015/08/04

8. How soon after start of TCHM intake AR appeared

7 weeks

9a. Adverse Reaction (AR) observed

- Other - describe in # 9b

9b. Description of other symptoms associated with AR (continuation of Question #9a)

Tunnel vision, panic attack

10. Describe Adverse Event in chronological order

The day of the event was stressful and busy, did not have much food, had 3 Red Bull drinks on the go. Took 2nd daily portion of Xiao Chai Hu Tang modified, 20 min after that started having tunnel vision and panic attack. All symptoms self resolved in about 30 min.

11. Known allergies

gluten

12. Medications taken concurrently

AE Reporting Tool : Entry # 93

none

13. Supplements taken concurrently

Multi vitamin (Sentrum),
Omega 3 (Nordic Naturals)

14. Patient weight

135 pounds

15. Patient chief health complaint

Alternating bowel movements

16. Accompanying symptoms and signs

Abdominal discomfort, alternating bowels, alternating body temperature, irregular periods, fatigue - (3 small children), low-grade anxiety.

17. Patient health history, including pre-existing medical conditions

F41.1: Generalized Anxiety Disorder

18. Concomitant medical therapy, including dates

Wholistic Psychologist

19. All laboratory test done during TCHM intake, (Include reference range)

none

20. Tongue observation

Pink, moderate white coat

21. Pulse examination

Thin, string-like

22. Western Medical Diagnosis addressed

ICD-10: K30 Functional dyspepsia

23. TCM Pattern(s)

SF57 Liver qi stagnation pattern (TM1)

24. TM Treatment Principle

Relieve abdominal discomfort, promote smooth movement of Liver Qi, harmonize Liver and Spleen, calm the Mind.

25. Suspected TCHM product name

Xiao Chai Hu Tang modified

AE Reporting Tool : Entry # 93

26. List all TCHM formula ingredients, include each ingredient amount

Chai Hu Bupleurum 25.00%
Ban Xia (Zhi) Pinellia ginger-cured 15.00%
Huang Qin Scutellaria 10.00%
Ren Shen (Hong) (5:1) Ginseng 9.00%
Sheng Jiang Ginger (Fresh) 9.00%
Zhi Gan Cao Licorice (Baked) 5.00%
Da Zao (Hong) red Jujube - dates (Red) 9.00%
Bai He Lily Bulb 9.00 %
Dang Gui (Shen) Tangkuei Root 9.00%

27. Daily intake dose in grams

2 grams 3 times a day

28. Product prescriber

- Prescribed by Licensed Acupuncturist

29. Product acquisition source

- 3rd party compounding dispensary

30. Form of herbal preparation

- Custom mixed loose 5:1 granule measured at home

31. Product manufacturer name and website

KPC - <https://www.kpc.com/>

32. Compounding facility name and website

Crane Herb Pharmacy. <https://www.craneherb.com>

33. Product Lot # if patent or Rx # if custom

Rx number: 123456

34. Substance suspected to cause Adverse Reaction

Ren Shen (Ginseng)

35. Remediation measures taken

The Xiao Chai Hu Tang modified was stopped for a few days. The patient was monitored closely for a few days, no more panic; level of anxiety went back to base.

36. Comment: what by your opinion could be a cause of this AE?

AE Reporting Tool : Entry # 93

Ren Shen (Ginseng) is a known CNS stimulant most likely combined with caffeine contained in Red Bull and taken on an empty stomach with preexisting anxiety diagnosis has caused a panic attack with tunnel vision.

37. AE Reporter First & Last name

Galina V. Roofener (Acupuncture Physician)

38. AE Reporter contact email

galinaroofener@gmail.com

I hereby agree that data entered will be stored electronically, and will be processed and used for TCHM safety reference and research purposes. Reporter name and contact are collected for AE clarification only and will be excluded from the database.

- I agree