

Questionnaire for Reporting a suspected adverse drug reaction – Human Medicine

Heel Canada Inc.

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1. Name, specialty and address of the reporting therapist
(Practice stamp)

2. Pat. initials	3a. Date of birth	3b. Age
4. Sex <input type="checkbox"/> m <input type="checkbox"/> f	5. Weight	6. Size
7. Activity/occupation	8. Ethnicity	

9. Special features

- | | | |
|--|---|---|
| <input type="checkbox"/> diet | <input type="checkbox"/> physical therapy | <input type="checkbox"/> pregnancy (week?) _____ |
| <input type="checkbox"/> contraceptives | <input type="checkbox"/> drug abuse | <input type="checkbox"/> allergies (which one?) _____ |
| <input type="checkbox"/> metabolic defects | <input type="checkbox"/> pacemaker implants | <input type="checkbox"/> other (which one?) _____ |
| <input type="checkbox"/> regular consumption of nicotine | <input type="checkbox"/> radiotherapy | <input type="checkbox"/> change of the private environment
(e. g. change of employment,
separation from lifetime companion) _____ |
| <input type="checkbox"/> regular consumption of alcohol | <input type="checkbox"/> chemotherapy | |

10. Name of the Heel Remedy which is supposed to have caused the side-effect

11. Batch No.

12. Form of application

- | | | | |
|----------------------------------|---|-------------------------------------|---|
| <input type="checkbox"/> tablets | <input type="checkbox"/> ampoules | <input type="checkbox"/> nose drops | <input type="checkbox"/> suppositories |
| <input type="checkbox"/> drops | <input type="checkbox"/> drinkable amp. | <input type="checkbox"/> ointment | <input type="checkbox"/> other, please specify: |

13. Kind of application

- | | | | | |
|--|------------------------------|-------------------------------|--|---|
| <input type="checkbox"/> oral | <input type="checkbox"/> i.m | <input type="checkbox"/> i.c. | <input type="checkbox"/> peri-articular | <input type="checkbox"/> other, please specify: |
| <input type="checkbox"/> local/topical | <input type="checkbox"/> i.v | <input type="checkbox"/> s.c. | <input type="checkbox"/> intra-articular | |

14. Dosage

15. Primary disease against which the Heel Remedy has been applied

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16. Additional drugs for the treatment of the primary disease(s)?

no yes, please specify:

17. Was a disinfectant used?

no yes, please specify:

18. Was a local anaesthetic used?

no yes, please specify:

19. Have different solutions been mixed (drops, ampoules)?

no yes, please specify:

20. Additional (e.g. physical) therapies for treatment of primary disease(s)?

no yes, please specify:

21. Accompanying diseases?

no yes, please specify:

22. Additional drugs for the treatment of accompanying disease(s)?

no yes, please specify:

23. How did the side-effect manifest itself? Duration?

symptom/s, diagnose/s	duration (hours/days/weeks)
1.	
2.	
3.	
4.	

24. Have laboratory values changed?

unknown no yes, please specify:

25. Duration of treatment

_____ day(s) _____ week(s) _____ month(s)

26. Date of onset of the side-effect ____ / ____ / ____

27. Interval between start of treatment and the occurrence of the side-effect

_____ hour(s) _____ day(s) _____ week(s)

28. Interval between last application and the occurrence of the side-effect

_____ hour(s) _____ day(s) _____ week(s)

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29. Was the application of the Heel Remedy discontinued because of the side-effect(s) or was the dosage changed?

- no dosage increased _____ (please specify!)
 yes dosage reduced _____ (please specify!)
-

30. Did the side-effect disappear?

- no yes
-

31. Did a re-exposure take place?

- no yes
-

32. Did the side-effect re-appear?

- no yes
-

33. Treatment of the side-effect?

- no yes, please specify:
-

34. Earlier treatment with the suspected remedy?

- no yes
-

35. Did any side-effect appear at that time, too?

- no yes, please specify:
-

36. Consequence of the side-effect?

- none prolongation of a stay in hospital
 disablement danger to life
 handicap death of the patient
 stay in hospital other, please specify:
-

37. Outcome of the side-effect

- recovered unknown
 recovering fatal
 not recovered recovered with sequelae, please specify:
-

38. Do you see any causal relationship between the side-effect and the Heel Remedy?

- certain possible no relationship
 probable unlikely non-assessable
-

(Date)

(Seal)

(Signature)
