MONTELUKAST AND NEUROPSYCHIATRIC EVENTS

Australian Paediatric Surveillance Unit

Please contact the APSU (02) 9845 3005 or SCHN-APSU@health.nsw.gov.au if you have any questions about this form

APSU Office Use Only	
Study ID #:	

Instructions: Please answer each question by ticking the appropriate box or writing your response in the space provided. DK=Don't Know; NA = Not Applicable.

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REPORTING CLINICIAN'S DETAILS:

1. APSU Dr Code/Name: ☐☐☐☐/_____ **2**. Date questionnaire completed: __ __ / __ __ / __ __ __ __*(dd/mm/yyyy)*

PATIENT DETAILS:

3. First 2 letters of first name: ☐☐ **4.** First 2 letters of surname: ☐☐ **5.** Date of Birth: __ __ / __ __ / __ __ __ __*(dd/mm/yyyy)*

6. Sex: ☐ Male ☐ Female **7.** Postcode of family: ☐☐☐☐

If this patient is primarily cared for by another physician who you believe will report the case, please complete the questionnaire details above this line and return to the APSU. Please keep the patient's name and other details in your records.

If no other report is received for this child we will contact you for information requested in the remainder of the questionnaire.

The primary clinician caring for this child/young person is: ***Name:*** ***Hospital:***

NEUROPSYCHIATRIC EVENTS:

8. Which of the following events did the child experience **after** commencing montelukast? *(please tick all that apply)*

☐ agitation ☐ anxiety ☐ tremor

☐ restlessness ☐ irritability ☐ disorientation

☐ low mood/depression ☐ aggressive behaviour ☐ dream abnormalities/nightmares

☐ suicidal ideation or behaviour ☐ sleep disturbance *(please specify):* _____

☐ other *(please specify):* _____

Please desribe any additional details of note of the neuropsychiatric event: _____

_____

_____

_____

9. What was the date of commencement of montelukast : __ __ / __ __ / __ __ __ __ *(dd/mm/yyyy)*

10. What was the date of onset of the neuropsychiatric event? __ __ / __ __ / __ __ __ __ *(dd/mm/yyyy)*

11. What was the prescribed dose of montelukast? _____

12. What was the indication for use of montelukast? *(please tick all that apply)*

☐ asthma as first line preventer ☐ prevention of exercise induced asthma

☐ other *(please specify):* _____

13. Did the child have a history of any of the following psychiatric or behavioural disorders **prior** to presciption of montelukast? *(please tick all that apply)*

☐ anxiety ☐ ADHD ☐ aggressive behaviour

☐ depression ☐ Autistic spectrum disorder ☐ sleep disorder

☐ none ☐ obsessive compulsive disorder ☐ other *(please specify):* _____

_____

14. Please list any other medications the child was taking at the time of montelukast prescription:

_____

_____

_____

_____

_____

MANAGEMENT:

15. Did the child discontinue montelukast as a result of the neuropsychiatric event? ☐ Yes ☐ No ☐ DK

15a. If yes, did the neuropsychiatric symptoms resolve with cessation of montelukast? ☐ Yes ☐ No ☐ DK

15b. How long did the symptoms take to resolve? _____hours _____days_____months ☐ Don't Know

16a. If the child **continued** the montelukast**,** did the neuropsychiatric symptoms resolve? ☐ Yes ☐ No ☐ DK

16b. How long did the symptoms take to resolve? _____hours _____days_____months ☐ Don't Know

17. As a result of the neuropsychiatric symptoms which of the following did the child require?

☐ observation/monitoring only

☐ hospital admission

☐ investigations *(please specify):* _____

☐ referral to psychiatrist

☐ referral to neurologist

☐ referral to other specialist *(please specify)*

18. Have you reported this case to the Therapeutic Goods Administration (TGA) ? ☐ Yes ☐ No

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Thank you for your help with this research project.
Please return this questionnaire to the APSU via email to SCHN-APSU@health.nsw.gov.au
or fax to 02 9845 3082
or mail to Australian Paediatric Surveillance Unit, Kids Research, Locked Bag 4001, Westmead NSW 2145
- even if you don't complete all items.

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and Faulty of Medicine and Health, The University of Sydney.
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This study has been approved by a Human Research Ethics Committee properly constituted under NHMRC guidelines.

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