

MONTELUKAST AND NEUROPSYCHIATRIC EVENTSND NEUROPSYCHIATRIC EVENTS

Australian Paediatric Surveillance Unit

APSU Office Use Only

Study ID #:

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

Version 1.1_20/11/2019

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.

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)

- | | | |
|---|--|---|
| <input type="checkbox"/> agitation | <input type="checkbox"/> anxiety | <input type="checkbox"/> tremor |
| <input type="checkbox"/> restlessness | <input type="checkbox"/> irritability | <input type="checkbox"/> disorientation |
| <input type="checkbox"/> low mood/depression | <input type="checkbox"/> aggressive behaviour | <input type="checkbox"/> dream abnormalities/nightmares |
| <input type="checkbox"/> suicidal ideation or behaviour | <input type="checkbox"/> sleep disturbance (please specify): _____ | |
| <input type="checkbox"/> other (please specify): _____ | | |

Please describe 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)

- | | |
|---|--|
| <input type="checkbox"/> asthma as first line preventer | <input type="checkbox"/> prevention of exercise induced asthma |
| <input type="checkbox"/> other (please specify): _____ | |

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

- | | | |
|-------------------------------------|--|--|
| <input type="checkbox"/> anxiety | <input type="checkbox"/> ADHD | <input type="checkbox"/> aggressive behaviour |
| <input type="checkbox"/> depression | <input type="checkbox"/> Autistic spectrum disorder | <input type="checkbox"/> sleep disorder |
| <input type="checkbox"/> none | <input type="checkbox"/> obsessive compulsive disorder | <input type="checkbox"/> 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

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.

The APSU is affiliated with the Royal Australasian College of Physicians (Paediatrics and Child Health Division) and Faculty of Medicine and Health, The University of Sydney.

The APSU is funded by the Australian Government Department of Health.

This study has been approved by a Human Research Ethics Committee properly constituted under NHMRC guidelines.

