

MTN020

PROGRESSIVE NEUTROPENIA

318- 30037-8

PROGRESSIVE NEUTROPENIA

Introduction

- D.O.B. 20 JUL 81
- Single at screening on 26 Nov 12
- Has partner, using Jadelle, para 2
- Partner has several casual partners
- Incomplete secondary school, unemployed
- No alcohol, no cigarettes

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Baseline

- O/E at screening, normal
- normal screening results except lymphocytes
- Reduced lymphocytes, ungradable, NCS 1289 cells/mm³
- Normal range 1500 – 4000
- enrolled 13 Dec 12
- O/E at enrolment, normal

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Clinical Summary

- Pre-existing intermittent headache grade 1
- And intermittent allergic conjunctivitis grade 1
- Visit 1,2, 3 , 6, 7, 8, 9, 9.1, 9.2,10 & 11 no complaints
- Visit 4 & 5 c/o backache grade 1 GAE -1 page 001
- Visit 10.1 c/o chest pains grade 1 GAE-1 page 002

Progressive Neutropenia Summary

| DATE | COMPLAINTS | RESULTS | COMMENTS |
|-------------------|------------|---|---|
| 05 MAR 13 03.0 | NIL | Reduced Neutrophils 1043 WCC 3230 Low | GRADE 1. AE, related |
| 02 APR 13 04.0 | Backache | No blood draw * | GAE-1 Page 001 |
| 25 APR 13 05.0 | NIL | No blood draw * | Well |
| 23 MAY 13 06.0 | NIL | Neutrophils - 1429 Low Lymphocytes - 1400 Low WCC - 3270 Low | All un-gradable Resolved reduced neutrophils AE |

Progressive Neutropenia Summary

| DATE | COMPLAINTS | RESULTS | COMMENTS |
|-------------------|------------------------|--|--|
| 21 AUG 13 09.0 | NIL | Reduced Neutrophils 691 Reduced WCC 2540 | Grade 3 Product hold Grade 1 |
| 26 AUG 13 09.1 | NIL | Reduced Neutrophils 1159 | Grade 1 Resume product |
| 19 Sep 13 10 | NIL | Reduced Neutrophils 906 | Grade 2 |
| 23 SEP 13 10.1 | Chest pains Grade 1 | No blood draw | O/E Normal Given Rx |
| 17 OCT 13 11 | NIL | Reduced Neutrophils 1148 | Grade 1 |

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Discussion

- Related or not related
- All 4 AE-1 CRFs marked related
- Both GAEs attributed to strenuous activity
- Lifting heavy water containers
- Share site experiences
- Causes of reduced Neutrophils

Thank you

