

Boehringer Ingelheim France
BI Trial No.: 1208.2

Final protocol – June 28th, 2004
Clinical Trial Protocol Revision A (including Amendments 1 and 2)

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APPENDIX 11.10 AMDP-5

Check one number that best describes the severity of each symptom

| | Absent | Mild | Moderate | Severe | Not Evaluated |
|-----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|-----------------------------|
| 1 Difficulty falling asleep | <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 98 |
| 2 Interrupted sleep | <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 98 |
| 3 Shortened sleep | <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 98 |
| 4 Early waking | <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 98 |
| 5 Drowsiness | <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 98 |

| | Absent | Mild | Moderate | Severe | Not Evaluated |
|----------------------|----------------------------|----------------------------|----------------------------|----------------------------|-----------------------------|
| 6 Decreased appetite | <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 98 |
| 7 Excessive appetite | <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 98 |
| 8 Excessive thirst | <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 98 |
| 9 Decreased libido | <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 98 |

| | Absent | Mild | Moderate | Severe | Not Evaluated |
|-----------------------|----------------------------|----------------------------|----------------------------|----------------------------|-----------------------------|
| 10 Hypersalivation | <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 98 |
| 11 Dry mouth | <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 98 |
| 12 Nausea | <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 98 |
| 13 Vomiting | <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 98 |
| 14 Gastric discomfort | <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 98 |
| 15 Constipation | <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 98 |
| 16 Diarrhea | <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 98 |

| | Absent | Mild | Moderate | Severe | Not Evaluated |
|---------------------------|----------------------------|----------------------------|----------------------------|----------------------------|-----------------------------|
| 17 Breathing difficulties | <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 98 |
| 18 Dizziness | <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 98 |
| 19 Palpitations | <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 98 |
| 20 Cardiac Pain | <input type="checkbox"/> 0 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 98 |

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| | Absent | Mild | Moderate | Severe | Not Evaluated |
|-----------------------------|--------|------|----------|--------|---------------|
| 21 Blurred vision | ☐ 0 | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 98 |
| 22 Increased perspiration | ☐ 0 | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 98 |
| 23 Seborrhea | ☐ 0 | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 98 |
| 24 Micturition difficulties | ☐ 0 | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 98 |
| 25 Menstrual difficulites | ☐ 0 | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 98 |

| | Absent | Mild | Moderate | Severe | Not Evaluated |
|--------------------------|--------|------|----------|--------|---------------|
| 26 Headache | ☐ 0 | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 98 |
| 27 Backache | ☐ 0 | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 98 |
| 28 Heaviness in the legs | ☐ 0 | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 98 |
| 29 Hot flashes | ☐ 0 | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 98 |
| 30 Chills | ☐ 0 | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 98 |
| 31 Conversion symptoms | ☐ 0 | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 98 |

| | Absent | Mild | Moderate | Severe | Not Evaluated |
|---------------------|--------|------|----------|--------|---------------|
| 32 Hypertonia | ☐ 0 | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 98 |
| 33 Hypotonia | ☐ 0 | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 98 |
| 34 Tremor | ☐ 0 | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 98 |
| 35 Acute dyskinesia | ☐ 0 | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 98 |
| 36 Hypokinesia | ☐ 0 | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 98 |
| 37 Akathisia | ☐ 0 | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 98 |
| 38 Ataxia | ☐ 0 | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 98 |
| 39 Nystagmus | ☐ 0 | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 98 |
| 40 Paresthesia | ☐ 0 | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 98 |

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| | Absent | Mild | Moderate | Severe | Not Evaluated |
|--------------------------------|----------------|----------------|----------------|----------------|------------------|
| 41 Increased dreams/nightmares | ☐ ₀ | ☐ ₁ | ☐ ₂ | ☐ ₃ | ☐ ₉₈ |
| 42 Allergic reactions | ☐ ₀ | ☐ ₁ | ☐ ₂ | ☐ ₃ | ☐ ₉₈ |
| 43 Tardive Dyskinesia | ☐ ₀ | ☐ ₁ | ☐ ₂ | ☐ ₃ | ☐ ₉₈ |
| 44 Dependent edema | ☐ ₀ | ☐ ₁ | ☐ ₂ | ☐ ₃ | ☐ ₉₈ |
| 45 Somatic anxiety | ☐ ₀ | ☐ ₁ | ☐ ₂ | ☐ ₃ | ☐ ₉₈ |
| 46 Increased Blood Pressure | ☐ ₀ | ☐ ₁ | ☐ ₂ | ☐ ₃ | ☐ ₉₈ |
| 47 Increased Hypertension | ☐ ₀ | ☐ ₁ | ☐ ₂ | ☐ ₃ | ☐ ₉₈ |