


標準品との対比表

| | 後発品 | | 標準品 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------|--|---|--|------------------------|------------------|--------|--|-----|----|----|----|--------|---|-------------|----|---|----|----|------|----|-------------|----|---|----|---|------|----------------|----|---|---|---|------|-----|----------------|---|---|---|---|------|----|---------|---|---|---|---|------|-------|---|---|---|---|------|------------------|---|---|---|---|------|---|--|----|----|----|----|
| 販売名 | 日本薬局方 メコバラミン錠 メコバラミン錠 500 μ g「JG」 | | 日本薬局方 メコバラミン錠 メチコパール錠 500 μ g | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 販売元 (製造販売元) | 共創未来ファーマ株式会社 (日本ジェネリック株式会社) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 成分・含量 | 1錠中メコバラミン500 μ gを含有 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 薬効分類 | 末梢性神経障害治療剤 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 薬 価 | 5.70円/錠 | | 14.70円/錠 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 薬 価 差 | 9.00円/錠 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 効能・効果 | 標準品と同一 | 末梢性神経障害 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 用法・用量 | 標準品と同一 | 通常、成人は1日3錠(メコバラミンとして1日1,500 μ g)を3回に分けて経口投与する。 ただし、年齢及び症状により適宜増減する。 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 添加物 | 乳糖水和物、結晶セルロース、ヒドロキシプロピルセルロース、カルメロースカルシウム、ステアリン酸マグネシウム、酸化チタン、タルク、カルナウバロウ | | カルナウバロウ、含水二酸化ケイ素、結晶セルロース、酸化チタン、ステアリン酸、ステアリン酸カルシウム、精製白糖、タルク、沈降炭酸カルシウム、トウモロコシデンプン、乳糖水和物、白色セラック、ヒドロキシプロピルセルロース、プルラン、ポビドン、マクロゴール6000 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 製 剤 | 販売名 | 外 観(直径, 厚さ, 重量) | | 性 状 | 本体表示 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | メコバラミン錠 500 μ g「JG」 |  7.2mm 4.0mm 151mg | | 白色の フィルムコーティン グ錠 | メコバラミン 500 JG | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 標準品 | 500 μ g | 7.3mm 4.0mm 155mg | | 白色 糖衣錠 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 標準製剤との 同等性 | 生物学的同等性試験 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | <p>本製剤は標準製剤との生物学的同等性試験を行っていない。 臨床試験を実施し、その有効性を確認した。(旧処方製剤)</p> <table border="1"> <thead> <tr> <th colspan="2">疾患別分類</th> <th>症例数</th> <th>著効</th> <th>有効</th> <th>無効</th> <th>有効率(%)</th> </tr> </thead> <tbody> <tr> <td>I</td> <td>変形疾患に伴う神経障害</td> <td>43</td> <td>5</td> <td>21</td> <td>17</td> <td>60.5</td> </tr> <tr> <td rowspan="2">II</td> <td>A 外傷後末梢神経障害</td> <td>15</td> <td>1</td> <td>13</td> <td>1</td> <td>93.3</td> </tr> <tr> <td>B 末梢神経炎、末梢神経麻痺</td> <td>11</td> <td>4</td> <td>4</td> <td>3</td> <td>72.7</td> </tr> <tr> <td>III</td> <td>内科的疾患に伴う末梢神経障害</td> <td>3</td> <td>0</td> <td>1</td> <td>2</td> <td>33.3</td> </tr> <tr> <td rowspan="3">IV</td> <td>A 頸腕症候群</td> <td>4</td> <td>0</td> <td>1</td> <td>3</td> <td>25.0</td> </tr> <tr> <td>B 腱鞘炎</td> <td>2</td> <td>0</td> <td>1</td> <td>1</td> <td>50.0</td> </tr> <tr> <td>C その他(脊髄炎、癌転移など)</td> <td>4</td> <td>0</td> <td>3</td> <td>1</td> <td>75.0</td> </tr> <tr> <td colspan="2">計</td> <td>82</td> <td>10</td> <td>44</td> <td>28</td> <td>65.8</td> </tr> </tbody> </table> <p>有効率: 有効及び著効の割合</p> <p>また、処方変更製剤は旧処方製剤と生物学的に同等と評価されている。</p> | | | | | 疾患別分類 | | 症例数 | 著効 | 有効 | 無効 | 有効率(%) | I | 変形疾患に伴う神経障害 | 43 | 5 | 21 | 17 | 60.5 | II | A 外傷後末梢神経障害 | 15 | 1 | 13 | 1 | 93.3 | B 末梢神経炎、末梢神経麻痺 | 11 | 4 | 4 | 3 | 72.7 | III | 内科的疾患に伴う末梢神経障害 | 3 | 0 | 1 | 2 | 33.3 | IV | A 頸腕症候群 | 4 | 0 | 1 | 3 | 25.0 | B 腱鞘炎 | 2 | 0 | 1 | 1 | 50.0 | C その他(脊髄炎、癌転移など) | 4 | 0 | 3 | 1 | 75.0 | 計 | | 82 | 10 | 44 | 28 |
| 疾患別分類 | | 症例数 | 著効 | 有効 | 無効 | 有効率(%) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| I | 変形疾患に伴う神経障害 | 43 | 5 | 21 | 17 | 60.5 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| II | A 外傷後末梢神経障害 | 15 | 1 | 13 | 1 | 93.3 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | B 末梢神経炎、末梢神経麻痺 | 11 | 4 | 4 | 3 | 72.7 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| III | 内科的疾患に伴う末梢神経障害 | 3 | 0 | 1 | 2 | 33.3 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| IV | A 頸腕症候群 | 4 | 0 | 1 | 3 | 25.0 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | B 腱鞘炎 | 2 | 0 | 1 | 1 | 50.0 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | C その他(脊髄炎、癌転移など) | 4 | 0 | 3 | 1 | 75.0 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 計 | | 82 | 10 | 44 | 28 | 65.8 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 備考 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 連絡先 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |