|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Who may be eligible?**  **• Adult patient over 30 years with neurologist diagnosed idiopathic PD**  **• Chronic sleep difficulty** | | | | | | | | | | | | | | |
| **1. Today’s Date** |  |  | | |  | |  | | **2** | | **0** | |  |  |
| **2. Patient name** |  | | | | | | | | | | | | | |
| **3. Date of birth** |  | |  |  | |  | |  | |  | |  | | |
|  | *day* | | | *month* | | | | *year* | | | | | | |
| **4. Patient Phone number** |  | | | | | | | | | | | | | |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **5. INCLUSION CRITERIA** | | | | | |
| 5.1 Patient has idiopathic PD (diagnosed by neurologist) | | YES |  | NO |  |
| 5.2 Patient has been taking stable dose of Parkinson’s Disease or psychotropic medication for >= 1 month | | YES |  | NO |  |
| 5.3. Patient has claimed sleep difficulty | | YES |  | NO |  |
| **If all answers were ‘YES’ please continue to next section. If any answers are ‘NO’, Patient is ineligible, STOP HERE and sign back page and provide to the research nurse.** | | | | | |
| **8. EXCLUSION CRITERIA** | | | | | |
| 8.1 Moderate-severe abnormal kidney function or untreated kidney disease | | YES |  | NO |  |
| 8.2 Patient has significant active liver disease | | YES |  | NO |  |
| 8.3 Acquired brain injury | | YES |  | NO |  |
| 8.4 Active or untreated post-traumatic stress disorder | | YES |  | NO |  |
| 8.5 Uncontrolled psychosis or schizophrenia | | YES |  | NO |  |
| 8.6 Unstable seizure disorder (i.e. seizure in the last 12 months) | | YES |  | NO |  |
| 8.7 Other relevant medical diseases, malignancy or other progressive neurological disorder | | YES |  | NO |  |
| 8.8 Blood clotting disorder | | YES |  | NO |  |
| 8..9 Uncontrolled hormonal disorder | | YES |  | NO |  |
| **If any answers to exclusion criteria (10.1 – 10.13) are checked “YES”, the patient is NOT ELIGIBLE, STOP here, and SIGN at the end of the form. Otherwise please provide Hoehn & Yahr Score, SIGN and give to nurse.** | | | | | |
| 9. Modified Hoehn and Yahr Scale score (*If eligible*) | |  | | |  |
| **SIGN HERE** | **Date** | | | | |

**INSOM-PD ESSENTIAL CLINICAL INFORMATION**

The melatonin will be supplied by the trial pharmacy and is a 3 mg melatonin immediate release sublingual tablet sourced from Denmark (Pharmanord). Referring doctors need to fill out the details below.

Please make sure that you fill out all questions. If you have any queries, please contact Dr Jane Nikles on 0408 599 033.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **PATIENT’S DETAILS:** (If applicable affix Patient Identification Label and initial) | | | | |
| **Surname:** |  | | **UR No:**  **If applicable** |  |
| **Given Name:**  (first and middle name) |  | | **D.O.B:** |  |
| **Address:** |  | | | |
| **Date :** | | **Known Allergies/Adverse Reactions** | | |

|  |
| --- |
| **I am aware that this is an off-label indication for melatonin.** Melatonin is indicated as monotherapy for the short term treatment (up to 3 weeks) of primary insomnia characterized by poor quality of sleep in patients who are aged 55 or over.  *This trial is open to patients aged over 30 years and lasts for 14 weeks (12 weeks plus a 2 week open run-in).*  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |

**Script for Run in phase (Insom-PD) trial – Melatonin 3mg Sublingual Tablet**

Patient Initials \_\_\_\_\_\_\_\_ \_\_Registration number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**\_\_\_\_\_\_\_\_\_**

Study medication Melatonin 3mg Sublingual, daily for 14 days, 30 minutes before bed

Doctor’s signature: \_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_ Doctor’s name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Mobile phone/Pager: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Prescriber number \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Doctor’s address\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_