# Prescribing Support Document
# Melatonin in Neurodevelopmental Disorders in patients aged 2 to under 18 years.

## Change History

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|---|---|
| Version | V3.0 |
| Date ratified | V3.0 February 2024 HWE APC, V1.0 September 2020 HMMC and V2.1 February 2022 MOPB, V2.0 February 2021 MOPB, V1.0 December 2020 MOPB |
| Superseded version | V3.0 Merger of prescribing documents for Herts and west Essex- removal of information advocating use of specific products and to refer to the lowest cost melatonin product options document, removal of information under section 5: supporting information on melatonin, relating to Circadin® tablets and Ascomel® liquid, removal of section 9 of old documents relating to contact details for specialists/CCG & removal of Appendix 5- patient letter for Ascomel. |

# Prescribing Support Document
# Melatonin for Neurodevelopmental Disorders in patients aged 2 to under 18 years

## 1. Introduction

The document aims to support prescribing of melatonin for the following patients with neurodevelopmental disorders:

I. Formal confirmed diagnosis of Autism Spectrum Disorder (ASD)
II. Formal confirmed diagnosis of attention deficit hyperactivity disorder (ADHD)

The clinical management of patients with ASD and ADHD in Hertfordshire and West Essex Integrated Care System (HWE ICS) is the responsibility of the following organisations: Hertfordshire Community NHS Trust, Hertfordshire Partnership University NHS Foundation Trust (HPFT), West Hertfordshire Teaching Hospitals NHS Trust, East and North Hertfordshire NHS Trust and HCRG Care Group (Essex Child and Family Wellbeing Service).

Melatonin is prescribed for the treatment of insomnia and dysregulation of the sleep cycle in children with ASD and ADHD. It is prescribed as part of a management plan including clinical assessment of sleep disturbances following the implementation of environmental, behavioural and educational approaches.

There is now agreement between HWE ICB and the providers detailed above, for appropriate patients who are maintained on a stable dose of melatonin to be transferred to primary care for on-going prescribing.

The aim of this guideline is to ensure that the transfer of care of children and young people prescribed melatonin for sleep disturbance to primary care is safe and appropriate by providing the following information:

- Clinical information on melatonin for sleep disturbances
- The roles and responsibilities of the secondary care specialist team, GP, ICB and the patient/carer
- Monitoring/review requirements for patients on melatonin
- Criteria for the transfer of prescribing of melatonin to primary care
- Criteria for when melatonin should be stopped
- Secondary care contact details for support and back-up advice

## 2. Criteria for transfer of prescribing to primary care

The following must apply before the GP is asked to accept on-going prescribing responsibility for melatonin:

The ***inclusion*** criteria:

- The patient has a confirmed formal diagnosis of ASD or ADHD and is aged 2 to under 18 years
- The patient is taking more than 2 hours to fall asleep on a regular basis **and** sleep disturbance is causing significant family disturbance
- The patient must have undergone the appropriate assessments and shown a beneficial response to treatment
- The patient is stable on a maintenance dose of melatonin for at least 3 months
- The patient meets the continuation criteria for on-going melatonin prescribing
- The specialist will ensure on-going review of melatonin including treatment holidays to ensure continued benefit of medication

The ***exclusion*** criteria:

- Sleep disturbance in patients without a formal confirmed diagnosis of ASD or ADHD
- Children aged less than 2 years of age and young people over the age of 18 years

## 3. Areas of responsibility

| SPECIALIST RESPONSIBILITIES | |
|---|---|
| **1.** | The specialist team will have undertaken sleep hygiene measures, environmental stimulus control and adjustment of stimulant medication prior to melatonin prescribing as follows:<br>▪ Non-pharmacological interventions must be trialled for a minimum of at least 4 weeks before considering melatonin. These include:<br>o Fixed bedtime routine<br>o Reduce light levels in the bedroom<br>o Avoid extremes of temperature<br>o Avoid sources of distraction in the bedroom<br>o Avoid using screens and electronics at least two hours before bedtime<br>o Ensure that the bed is for sleeping. Avoid reading, working, watching television in bed as this will stimulate the brain rather than prepare the mind for sleep<br>o Avoid strenuous physical activity or exercise before bedtime<br>o Avoid caffeine-containing drinks in the hours leading to bedtime<br>▪ Melatonin must only be considered when the child or young person is taking more than 2 hours to fall asleep on a regular basis **and** sleep disturbance is causing significant family disturbance.<br>▪ Behavioural sleep interventions should be continued even when melatonin is prescribed.<br>▪ A sleep diary (example in Appendix 1) must be used to determine the baseline sleep pattern prior to any intervention and following any change in treatment in order to inform decisions on changing dose and stopping treatment. |
| **2.** | The initiating specialist is responsible for discussing treatment with melatonin as well as its side effects with the service user/parent/carer and obtaining informed consent to treatment. Where melatonin is being prescribed 'off-label', they will be responsible for explaining the off-license use. A written patient/parent/carer information leaflet on melatonin is available from the Medicines for Children website: https://www.medicinesforchildren.org.uk/medicines/melatonin-for-sleep-disorders/. |
| **3**. | Following initiation of melatonin, a trial is given for 3 months and continuation of treatment will only be considered if the specialist considers a significant improvement has been made. Significant improvement is considered as follows:<br>▪ When melatonin results in the young person having a reduction in sleep latency of at least 40 minutes<br>and/or<br>▪ Increase in total sleep duration of at least 40 minutes or more<br>and/or<br>▪ Qualitative improvement in sleep quality where young person wakes up feeling rested and refreshed<br>and/or<br>▪ Qualitative positive impact on the quality of life of the young person and positive impact on family life as described by carers<br>The Melatonin Clinic Review Form (Specialist Service) can be used for assessment (see Appendix 2). |
| **4.** | Monitoring of growth and sexual development is recommended i.e. to check height, weight and pubertal development. |
| **5.** | Initiate and stabilise treatment with melatonin. The specialist is responsible for choosing the most appropriate brand and formulation of melatonin. Please see HWE ICS guidance document on the lowest cost melatonin product options; clinicians should select the least expensive clinically appropriate option. |
| **6.** | Service users that require long term treatment of melatonin should be instructed by the specialist to withdraw use of melatonin for a period of time known as a 'drug-holiday' in order to assess the need for on-going treatment. |

| | |
|---|---|
| | Approximately every 12 months, patients should try a drug-free holiday for between 7 and 14 days. Patients and their carers can choose a suitable time to undertake a drug-free holiday and do not have to inform their GP or specialist. An opportunity to undertake the drug-free holiday could be two-four weeks before the specialist's annual review; recording the outcomes on and off melatonin on a sleep diary (example in Appendix 1). Alternatively, patients could try having a drug-free holiday during the school holidays to avoid adverse effects on school days and their sleep diary reviewed at their next specialist review.<br><br>If the break from melatonin has resulted in no deterioration in sleep cycle, the young person can remain off melatonin. If withdrawal of medication has impacted the young person's sleep cycle, parents should start again at the same dose the young person was stable on. The specialist and GP should be informed if the drug withdrawal trial has been successful and that melatonin is no longer required. The outcome of any treatment break should be recorded in the patient's notes.<br><br>Patients should be informed that if a trial withdrawal is not attempted on the advice of the specialist then melatonin prescriptions will be discontinued.<br><br>In those requiring long-term treatment, consider a reduction in dose after several months if patients have a regular sleep pattern. |
| **7.** | If melatonin is no longer effective after months or years of effective treatment, or a lower treatment effect is seen with melatonin after titration to a higher dose of melatonin, consider a down-titration to a lower dose, or a 2 – 3 week period off melatonin followed by re-starting at the lowest dose again. If this is not effective, consider complete discontinuation of treatment.<br><br>Melatonin can be stopped abruptly. No discontinuation effects are documented. Melatonin is not generally considered to produce tolerance, rebound insomnia or dependence. |
| **8.** | A review of melatonin will be undertaken 3 months after initiation. The specialist is responsible for carrying out 6 monthly reviews to monitor the young person's height and weight and ensure that on-going treatment is warranted and improvements (as per continuation criteria above) are still being maintained. |
| **9.** | Children and young people prescribed melatonin preparations other than the products recommended in the HWE ICS guidance document on the lowest cost melatonin options should be reviewed for a switch to the preferred options. The preparation of melatonin must be reviewed at each appointment to ensure the most cost effective preparation is prescribed. |
| **10.** | Write to the GP to transfer prescribing once the patient is stable on a maintenance dose (for at least 3 months). **Information that needs to be provided to the GP is set out in Section 4 of this document.** |
| **11.** | Ensure the patient has 4 weeks supply of medication prior to transfer to GP. |
| **12.** | Specialist to ensure that patient/carer is informed and made aware of their responsibilities (see patient/carer responsibilities). This includes the importance of attending review appointments with the specialist; failure to attend appointments will result in GP being asked to stop prescribing melatonin. |
| **13.** | Contact GP if patient does not attend review appointments, or drug withdrawal trial not attempted (to advise GP to stop prescribing melatonin). |
| **14.** | Children and young people approaching the age of 18 years of age must have a medication review and melatonin stopped as GPs will not be expected to continue melatonin prescribing into adulthood. |
| **15.** | The specialist team to inform service users/parents/carers (at initiation of melatonin and/or on transfer to GP prescribing) that GPs will not be expected to prescribe melatonin once service users reach the age of 18 years (i.e. melatonin is not prescribable under NHS commissioned services in Hertfordshire and West Essex for adults). Service users to be advised that they will have a medication review with their specialist to stop the melatonin when they approach 18 years of age. |

| GP RESPONSIBILITIES | |
|---|---|
| **1.** | Review the request from the specialist to take on prescribing of melatonin. Acceptance is assumed. Promptly communicate to the specialist if prescribing responsibility is not accepted (within 2 weeks), including the clinical reason. Responsibility cannot be declined on grounds of cost of medication. |
| **2.** | Check sufficient information has been provided to take on the responsibility for continued prescribing see Section 4 of this document. Request any missing information to be provided from the specialist before taking on the prescribing in primary care. Transfer of care can be refused by GP if information is insufficient. |
| **3.** | Prescribe melatonin at the maintenance dose recommended. |
| **3.** | Link melatonin to indication on GP prescribing system. |
| **4.** | Seek advice from the specialist on any aspect of patient care of concern to the GP that may affect treatment. |
| **5.** | Check for possible drug interactions when newly prescribing or stopping concurrent medication. |
| **6.** | Discontinue treatment where drug holidays have been successful or on the advice of the specialist. |
| **7.** | Refer patient back to secondary care when appropriate, see Section 8 'Triggers for referral to secondary care'. |
| **8.** | Discontinue melatonin if advised by the specialist that patient has not attended review appointments, or drug withdrawal trial not attempted. |

| PATIENT/CARER RESPONSIBILITIES | |
|---|---|
| **1** | Report to their specialist if they do not have a clear understanding of or have any concerns with their treatment with melatonin. |
| **2.** | Following the transfer of prescribing, obtain further prescriptions for melatonin from the GP and not the specialist. |
| **3.** | Inform their GP of any over the counter products (the GP will know the patients prescribed medications). Inform the community pharmacist that they are prescribed melatonin when buying over the counter medications. |
| **4.** | Report any adverse effects to the GP whilst taking melatonin. |
| **5.** | Report any changes in sleep disturbance to the GP or specialist. |
| **6.** | Approximately every 12 months, patients should try a drug-free holiday for between 7 and 14 days. Patients and their carers can choose a suitable time to undertake a drug-free holiday and do not have to inform their GP or specialist. An opportunity to undertake the drug-free holiday could be two-four weeks before the specialist's annual review; recording the outcomes on a sleep diary (Example in Appendix 1) on and off treatment. Alternatively, patients could try having a drug-free holiday during the school holidays to avoid adverse effects on school days and their sleep diary reviewed at their next specialist review.<br><br>If the break from melatonin has resulted in no deterioration in sleep cycle, the young person can remain off melatonin. If withdrawal of medication has impacted the young person's sleep cycle, parents should start again at the same dose the young person was stable on. The specialist and GP should therefore be informed if the drug withdrawal trial has been successful and that melatonin is no longer required.<br><br>If a drug withdrawal trial is not attempted on the advice of the specialist then melatonin prescriptions will be discontinued. |
| **7.** | Attend review appointments with specialist as requested; if patients miss appointments GPs will be unable to continue to supply melatonin. |

| ICB RESPONSIBILITY | |
|---|---|
| **1** | The ICB will review the prescribing support document when new information becomes available. |

## 4. Communication and Handover from Secondary to Primary care

The following information should be provided by the specialist when requesting the transfer of prescribing of melatonin to the GP (see Appendix 3 for a GP letter template):

- Clear diagnosis and care plan including information that has been discussed with patient and carer
- Confirmation that sleep hygiene measures have been implemented
- Confirmation that the continuation criteria for melatonin prescribing have been met
- Details of melatonin preparation and dose
- Confirmation that the patient is stable on a maintenance dose
- At least four weeks supply of melatonin from last appointment
- Specialist team contact details for GPs to obtain advice and support
- For East and North Hertfordshire NHS Trust - Provision of a Letter for Carers explaining the use of melatonin (see Appendix 4)

## 5. Supporting Information on Melatonin

For full details, please refer to the current individual drug Summary of Product Characteristics (SmPC) and BNFc.

Please see HWE ICS guidance document on the lowest cost melatonin product options; clinicians should select the least expensive clinically appropriate option. Also includes advice on administration (e.g. crushing/halving tablets).

| **DOSAGE AND ADMINISTRATION OF MELATONIN** |
|---|
| Children up to 18 years initially 2mg at night increased if necessary after 1-2 weeks in increments of 2mg up to 4-6mg; max daily dose 10mg.[2] (Note: if a dose of 6mg is not effective higher doses are unlikely to be effective).<br><br>When children are escalated to the maximum dose of 10mg, their response should be reviewed and, if they have not made a significant improvement, then melatonin should be stopped or reduced to the minimum dose that achieves the same response. |

| **Absolute Contraindications to melatonin[1]** | |
|---|---|
| Hypersensitivity | To the active substance or any of the excipients. |
| Liver Disorders | Melatonin is not recommended for use in patients with hepatic impairment. There is no experience of the use of melatonin in patients with liver impairment. Published data demonstrates markedly elevated endogenous melatonin levels during daytime hours due to decreased clearance in patients with hepatic impairment. The manufactures of melatonin recommended avoiding use in patients with hepatic impairment. |
| Autoimmune disease | No clinical data exist concerning the use of melatonin in individuals with autoimmune diseases. Therefore, melatonin is not recommended for use in patients with autoimmune diseases. |

| **Cautions – to be used with caution in the following[1]** | |
|---|---|
| Melatonin may cause drowsiness | Melatonin may cause drowsiness. Therefore, the product should be used with caution if the effects of drowsiness are likely to be associated with risk to safety. |
| Renal impairment | The effect of any stage of renal impairment on melatonin pharmacokinetics has not been studied. Caution should be used when melatonin is administered to such patients. |
| Rare hereditary glucose tolerance disorders | Some brands of melatonin contain lactose. Patients with rare hereditary problems of galactose intolerance. LAPP lactase deficiency or glucose malabsorption should not take preparations containing lactose. |

| **Adverse effects of melatonin[1]**<br>**Melatonin is generally well tolerated and adverse reactions reported are at a similar level to those reported with placebo** | | |
|---|---|---|
| ***Adverse effects*** | ***Symptoms/signs*** | ***Frequency*** |
| Psychiatric disorders | Irritability, nervousness, restlessness, insomnia, abnormal dreams, nightmares, anxiety | Uncommon |
| | Mood altered, aggression, agitation, crying, stress symptoms, disorientation, early morning awakening, libido increased, depressed mood, depression | Rare |
| Nervous system disorders | Migraine, headache, lethargy, psychomotor hyperactivity, dizziness, somnolence | Uncommon |
| | Syncope, memory impairment, disturbance in attention, dreamy state, restless legs syndrome, poor quality sleep, paraesthesia | Rare |
| Vascular disorders | Hypertension | Uncommon |
| | Hot flush | Rare |
| Gastrointestinal disorders | Abdominal pain, abdominal pain upper, dyspepsia, mouth ulceration, dry mouth, nausea | Uncommon |
| | Gastro-oesophageal reflux disease, gastrointestinal disorder, oral mucosal blistering, tongue ulceration, gastrointestinal upset, vomiting, bowel sounds abnormal, flatulence, salivary hypersecretion, halitosis, abdominal discomfort, gastric disorder, gastritis | Rare |
| Hepatobiliary disorders | Hyperbilirubinaemia | Uncommon |
| Skin and subcutaneous tissue disorders | Dermatitis, night sweats, pruritus, rash, pruritus generalised, dry skin | Uncommon |
| | Eczema, erythema, hand dermatitis, psoriasis, rash generalised, rash pruritic, nail disorder | Rare |
| | Angioedema, oedema of mouth, tongue oedema | Unknown |
| Musculoskeletal and connective tissue disorders | Pain in extremity | Uncommon |
| | Arthritis, muscle spasms, neck pain, night cramps | Rare |
| Renal and urinary disorders | Glycosuria, proteinuria | Uncommon |
| | Polyuria, haematuria, nocturia | Rare |
| Reproductive system and breast disorders | Menopausal symptoms | Uncommon |
| | Priapism, prostatitis | Rare |
| | Galactorrhoea | Unknown |
| General disorders and administration site conditions | Asthenia, chest pain | Unknown |
| | Fatigue, pain, thirst | Rare |
| Blood and lymphatic system disorders | Leukopenia, thrombocytopenia | Rare |
| Infections and infestations | Herpes zoster | Rare |
| Cardiac disorders | Angina pectoris, palpitations | Rare |
| Ear and labyrinth disorders | Vertigo positional, vertigo | Rare |
| Eye disorders | Visual acuity reduced, vision blurred, lacrimation increased | Rare |
| Immune system disorders | Hypersensitivity reaction | Unknown |

| | | |
|---|---|---|
| Investigations | Liver function test abnormal, weight increased | Uncommon |
| | Hepatic enzyme increased, blood electrolytes abnormal, laboratory test abnormal | Rare |

If the patient has a suspected adverse reactions report it to the specialist and also report the adverse reaction via the Yellow Card Scheme: www.mhra.gov.uk/yellowcard.

| **Drug Interactions**[1] | | |
|---|---|---|
| **Pharmacokinetic Interactions** | | |
| **Medication** | **Effect** | **Action** |
| Fluvoxamine* | Plasma concentration of melatonin significantly increased | Avoid – potentially serious interaction |
| 5 and 8-methoxypsoralen (psoralen) | Plasma concentration of melatonin increased | Review / reduce dose of melatonin |
| Cimetidine | Plasma concentration of melatonin increased | Review / reduce dose of melatonin |
| Oestrogens (e.g. contraceptive or hormonal replacement therapy) | Plasma concentration of melatonin increased | Review / reduce dose of melatonin |
| Quinolones | Plasma concentration of melatonin may be increased | Review / reduce dose of melatonin if quinolones prescribed for long term use |
| Carbamazepine and rifampicin | Plasma concentration of melatonin may be decreased | Review / increase dose of melatonin |
| Cigarette smoking | Plasma concentration of melatonin may be decreased | Review if there is a change in smoking habit |
| **Pharmacodynamic Interactions** | | |
| **Medication** | **Effect** | **Action** |
| Alcohol | Reduces effectiveness of melatonin on sleep | Advise alcohol will reduce effectiveness of melatonin |
| Hypnotics and CNS depressants | Melatonin may enhance the sedative properties of other drugs acting on the CNS | Monitor for over sedation and review |
| Sedative antipsychotics* | Increased sedative effects | Monitor for over sedation - Advise and review |

* potentially serious interactions

| **Pregnancy and breast feeding**[1] | |
|---|---|
| **Pregnancy** | **Breast feeding** |
| In view of the lack of clinical data, use in pregnant women and by women intending to become pregnant is not recommended. | Breastfeeding is not recommended in women under treatment with melatonin. |

**Long term effects of melatonin:**

The long-term effects of melatonin in children are unknown. A NICE Key Therapeutic Topic on Hypnotics states that the risks associated with the long-term use of benzodiazepine and 'Z-drug hypnotics' have been well recognised for many years. Recent data also suggest a similar safety concern with melatonin.[2] An observational study discussed in NICE's medicines evidence commentary on fracture risk associated with melatonin and other hypnotics found that in people aged 45 years and over, receiving 3 or more melatonin prescriptions were associated with an increased risk of fracture compared with no use of any hypnotic drugs.[2] There is uncertainty over what effects exogenous melatonin has on other circadian rhythms including endocrine or reproductive hormone secretion. Whilst there is no clinical data so far supporting the risk of hormonal disturbances or effects on pubertal development by melatonin treatment, long-term studies are warranted.[3]

## 6. Monitoring requirements

| Secondary Care monitoring | |
|---|---|
| 6 monthly reviews of the patient by the specialist to: | |
| **1.** | Ensure that on-going treatment is warranted and improvements as per continuation criteria have been maintained. |
| **2.** | Monitoring of growth and sexual development is recommended i.e. to check height, weight and pubertal development. |
| **3.** | Ensure that the patient has undertaken a 'drug-holiday' from melatonin at least once a year. |
| **Primary Care monitoring** | |
| Monitor for adverse effects and drug interactions (see Section 5 for details). Contact specialist for advice where necessary. | |

## 7. Stopping Medication

- Melatonin should be stopped in patients who do not continue to benefit from its use or experience intolerable side effects. Melatonin should be stopped if treatment holidays are successful. Children and young people approaching the age of 18 years of age must have a medication review with the aim of stopping melatonin as GPs will not be expected to continue melatonin prescribing.

## 8. Triggers to refer to secondary care

- Difference of opinion between primary care team and carer about stopping medication.
- If there is no benefit from treatment with melatonin and there are ongoing sleep problems.
- Patient is experiencing side effects.
- If there is delayed sexual development or failure to gain weight and height for the expected age and familial characteristics.

## 9. References


1. Medicines.org.uk. (2023). Adaflex 2mg tablets. *Summary of Product Characteristics (SmPC) - (eMC)*. [online] Available at: https://www.medicines.org.uk/emc/product/13629 [Accessed 13 Dec. 2023]
2. National Institute for Health and Care Excellence (NICE). Key therapeutic topic (KTT6): Hypnotics. 2015. Last updated September 2019. Available: https://www.nice.org.uk/advice/ktt6/chapter/Evidence-context
3. European Medicines Agency. Assessment report for Slenyto. July 2018. Available from: https://www.ema.europa.eu/en/documents/assessment-report/slenyto-epar-public-assessment-report_en.pdf

**Appendix 1 – Sleep diary** **Week beginning ……./……./…….**

**Child's name:** **Date of birth:**

| | Monday | Tuesday | Wednesday | Thursday | Friday | Saturday | Sunday |
|---|---|---|---|---|---|---|---|
| Time put to bed/bedtime | | | | | | | |
| Time fell asleep | | | | | | | |
| Did anything help to fall asleep | | | | | | | |
| Night-time waking (number of times/how long) | | | | | | | |
| Details of night-time waking *Explain why child woke up e.g. nightmare, environment* | | | | | | | |
| Time awoke | | | | | | | |
| How many daytime naps and length of time | | | | | | | |

**Appendix 2**

**Insert trust logo**

## Melatonin Clinic Review (Specialist Service)

**Date:**

**Address Label**

1. **Name of child:** **Date of birth:**
2. **Name of Melatonin used:** **Date of last prescription:**
3. **Type of Melatonin prescribed:**

4. **Are tablets crushed before use?**
   **Yes** **No**

5. **Dose prescribed:** **Time given:**

4. **Has your child experienced any side effects from Melatonin?**
   **Yes** **No** **don't know**
   **If yes, please state which side effects:**

5. **Is the Melatonin effective helping your child to fall sleep?**
   **Yes** **No** **don't know**
   **Time to fall sleep** **<1 hour ❑** **1-2 hours ❑** **>2hours ❑**
6. **Does your child wake up frequently at night?**
   **Yes** **No** **don't know**

7. **How long has your child been off Melatonin if you're doing a 'wash out'?**

   **Please remember also to fully complete a 2 week sleep diary and mail to your Specialist or take to your next appointment.**

_____

**Will be completed by your doctor on receipt of above information**

a. **Repeat Melatonin prescription justified**
   **Yes❑** **No ❑** **State reasons …….**
   **……**

b. **Dose changed** **Yes** **❑** **No** **❑**

   **If Yes, state new dose and type of Melatonin:**
   _____

c. **Date of new prescription issue: _____**

d. **Name of doctor _____**

e. **Signature _____**

Updated by Dr S Ozer/ Dr N Bajaj March 2020

**Appendix 3**

**Insert trust logo**

## Template Letter to GP

Ref:

Team Details:

Date:

Tel No:

Address:

Dear Dr…….

**Re:……**

**NHS No. ……**

**DOB:……..**

**Diagnosis: ……**

**Care plan for the management of insomnia: ……**
**……**

I have seen ……. in clinic today.

……..(insert name)…….has been stable on melatonin for over three months and I kindly request that you take over the prescribing on melatonin in primary care.

Melatonin preparation prescribed:

……. Dose…….mg at night.

I can confirm prior to initiating melatonin non-pharmacological interventions were trialled for a minimum of at least 4 weeks. Despite sleep hygiene measures implemented melatonin was initiated.

……..(insert name)…….has demonstrated proven benefit to being on melatonin and continues to have (*please tick):*

☐ A reduction in sleep latency of at least 40 minutes and/or

☐ Increase in total sleep duration of at least 40 minutes or more

and/or

☐ Qualitative improvement in sleep quality where young person wakes up feeling rested and refreshed

and/or

☐ Qualitative positive impact on the quality of life of the young person and positive impact on family life as described by carers

……..(insert name)…….parents/carers have been instructed to withdraw use of melatonin for a period of time known as a 'drug-holiday' at least once a year in order to assess the need for on-going treatment.

Today I have supplied them with 4 weeks of melatonin.

Further information on the use of melatonin for patients with neurodevelopmental disorders can be found in the Hertfordshire melatonin prescribing support document (available on the Hertfordshire CCG websites). Please feel free to contact me should you wish to discuss any of the afore-mentioned issues further.

With best regards.

Yours sincerely

Specialist sign off here

Date of next review _____

## Melatonin Letter for Carers

Dear Parent/Carer

**RE**: **MELATONIN PRESCRIPTIONS FOR CHILDREN AND YOUNG PEOPLE WITH ADHD and ASD**

**1. Why your child has been prescribed Melatonin by your Specialist.**

Your child has been prescribed Melatonin for a short period to help establish/support a normal sleep pattern as much as possible. It is important you continue to implement good sleep hygiene even though your child is on melatonin. Please read carefully the leaflet on Melatonin given to you by your Paediatrician or Chemist before you give your child the medication.

**2. Melatonin Evidence.**

Research has shown that even though Melatonin is a relatively safe drug in children, its safety or usefulness hasn't been well established beyond 3 months.
There is limited evidence that some types of Melatonin may improve sleep onset at bed time by up to half an hour and may /may not have any effect on early wakening or total sleep time.

**3**. **What to do if you need a repeat prescription for Melatonin.**

- Please note that repeat prescriptions for Melatonin will not be automatically issued without evidence of a 'trial off' the medication ('wash out period'). 'Wash out' periods are 3-6 monthly depending on the indication for Melatonin. It is advisable to do 'wash outs' during school holidays to minimise disruption to your child and family.
- Fully complete a 2 week sleep diary, sleep questionnaire and melatonin review questionnaire during your child's 'wash out' period. You can contact your Consultant's secretary for the forms if you do not have any.
- To avoid delay **fully** complete the sleep diary and questionnaires and then mail your responses to your Clinician or ADHD Nurse Specialist who will have a discussion with you on the telephone or next available clinic.
- **Remember to continue implementing good sleep hygiene. You may also discuss sleep hygiene with your school nurse/health visitor or GP.**
- **Please note that completing the sleep diary/questionnaire does not mean your child will automatically be issued with a prescription. Your responses will help us signpost you to the right support for your child's sleep difficulties.**

**4. Where to take your Melatonin prescriptions (if shared care has not been initiated)**

All melatonin prescriptions can be obtained at the hospital pharmacy (Lister hospital, Stevenage and the QE2 hospital Welwyn Garden City pharmacies).

**Useful addresses**

For Melatonin prescriptions please go to:

**North Hertfordshire**
Lister Hospital Outpatient Pharmacy (ENHPharma)
Coreys Mill Lane,

Stevenage, Hertfordshire,
SG1 4AB.
01438314333 (Main switchboard)

**East Hertfordshire**
Queen Elizabeth II Hospital Pharmacy
Howlands, Welwyn Garden City,
Hertfordshire
AL7 4HQ
01707 328111 (Main switchboard)

Best Wishes,
Community Paediatricians (East and North Hertfordshire NHS Trust)

March 2020

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