Background information

For several years, two formulations of melatonin tablet have been available in OHFT to prescribe to young people for the treatment of sleep difficulties that have not responded to sleep hygiene methods – Circadin MR 2mg tablets and Biomelatonin 3mg tablets.

**Circadin MR**

Until now Circadin MR had been the only product that OHFT had approved for use with a UK Product Licence. However, the licence is very narrow (for short term treatment of primary insomnia in > 55 year olds only) and therefore use in <18 year olds remains “off-label” / unlicensed. Circadin is a modified release formulation of melatonin and may be more suitable when staying asleep is the main problem. The current arrangement for prescribing Circadin MR in OHFT is on hospital FP10s.

**Bio-Melatonin**

Bio-Melatonin is an immediate release formulation of melatonin and may be preferred when falling asleep is the main problem. Bio-Melatonin does not have a UK Product Licence for any indication, however it is manufactured by Pharma Nord to pharmaceutical control standards with a guaranteed purity of 100% and it is licensed elsewhere in the EU.

Also available to OHFT prescribers is a liquid formulation of melatonin 1mg/ml (Kid Naps).

What is “Melatonin Pharma Nord”?

The manufacturer of Bio-Melatonin (Pharma Nord) has recently been granted a UK product licence for their new melatonin product called “Melatonin Pharma Nord”.

****This product is exactly the same (except in name, pack size and licensing) as Biomelatonin.****

The product licence has been granted for the following indication: “short-term treatment of jet lag in adults”.

Therefore, any prescribing of Melatonin Pharma Nord for indications other than jet lag or in <18 year olds (i.e. the indications used in CAMHS) is still “off-label” / unlicensed. However, as there is now a UK licensed product, there is no good reason to continue to source the version that is licensed in the EU (Biomelatonin). Using a UK licensed product “off-label” is preferred to using a product with no UK Product Licence, and this is specified within MHRA Guidance Note 14 (The Supply of Unlicensed Medicinal Products).

An additional benefit of switching to the UK licensed “Melatonin Pharma Nord” is that it has a fixed price, so there is also no need to prescribe on a hospital outpatient prescription.

So, what should prescribers do now?

<table>
<thead>
<tr>
<th>Current arrangement:</th>
<th>Circadin MR prescribed on FP10</th>
<th>Bio-Melatonin prescribed on hospital outpatient prescription</th>
<th>Melatonin 1mg/ml liquid on hospital outpatient prescription</th>
<th>Any other unlicensed special melatonin on hospital outpatient prescription</th>
</tr>
</thead>
<tbody>
<tr>
<td>New arrangement:</td>
<td>No change</td>
<td>When the next prescription is required prescribe “Melatonin Pharma Nord” <strong>on FP10</strong></td>
<td>No change</td>
<td>No change</td>
</tr>
</tbody>
</table>
**Prescribing information**
The manufacturer’s product literature (SPC) for Melatonin Pharma Nord is available on the [eMC](https://www.medicines.org.uk/EMC/).  

**What about shared care arrangements?**
The Buckinghamshire SCP currently includes modified release melatonin, Circadin MR. This protocol will be reviewed, however until this has taken place, any prescriptions for the immediate release formulation, Melatonin Pharma Nord, must be provided by OHFT on a hospital FP10.

No shared care agreements have been approved in Oxfordshire or SWB yet, but this is under review.

**What does the product and packaging look like?**
The packaging is similar to Bio-Melatonin – see below. The pack size of Melatonin Pharma Nord is smaller – there are 30 tablets in a box compared with 60 in a box of Bio-Melatonin.

**Melatonin Pharma Nord:**

![Image of Melatonin Pharma Nord packaging]

**Bio-Melatonin:**

![Image of Bio-Melatonin packaging]

The tablets in both products look the same – round, 7.5mm, film-coated, biconvex, white to off-white.

**What information is available for patients/parents/carers?**

An Oxford Health information leaflet about the switch has been written and can be used to support discussions about the new product, if considered appropriate.

As Melatonin Pharma Nord is not being used in an age group or for an indication that is covered by the UK product licence, you may wish to support your discussions about unlicensed or “off-label” use with some additional information. The MHRA recommends: “where current practice supports the use of a medicine outside the terms of its licence, it may not be necessary to draw attention to the licence when seeking consent. However, it is good practice to give as much information as patients or carers require or which they may see as relevant.” The information about Product Licensing contained in the Oxford Health’s Melatonin Pharma Nord information leaflet may be considered sufficient, however if you would like to provide any additional information, a leaflet written by the Royal College of Paediatrics and Child Health, Neonatal and Paediatric Pharmacy Group, and Well Child may be useful (see link on right).

**CLICK FOR LINKS:**

- OHFT’s Switch from Bio-Melatonin to Melatonin Pharma Nord information leaflets:
  - Detailed PIL
  - Brief PIL
- Unlicensed Medicines – information for parents and carers (NPPG, RCPCH and WellChild 2011)
- OHFT melatonin PILS
- Melatonin Pharma Nord manufacturer’s patient information leaflet / package insert

**Need more information/advice?**
Please contact the Medicines Advice Service: 01865 904365 or medicines.advice@oxfordhealth.nhs.uk