**SUMMARY REPORT FOR PUBLICATION**

**July 2019: Promotion of Melatonin solution by Colonis Pharma**

Nine healthcare professionals complained about a letter sent by Colonis Pharma to healthcare professionals in June 2019. The complainants alleged that the letter advertised off-label use of the product.

MHRA upheld the complaint. Colonis withdrew the mailing and issued the following corrective statement to all recipients of the original letter:

**Important information: Correction to Promotional Mailing for Melatonin 1mg/ml Oral Solution PL 41344/0050**

The MHRA have asked Colonis Pharma to provide a corrective statement regarding the promotion of Melatonin 1mg/ml Oral Solution to clarify the licensed indication and safety restrictions for use in certain patient populations.

* Melatonin 1mg/ml Oral Solution is indicated for short-term treatment of jet-lag in adults.1
* Melatonin 1mg/ml Oral Solution should not be used in children and adolescents aged 0 - 18 years due to safety and efficacy concerns. [Click here to view the SmPC for further information.](https://urldefense.proofpoint.com/v2/url?u=http-3A__news.colonis-2Dproduct-2Dlaunch.co.uk_3A04C741CA54C699C3A821D480D76AB38AAA7B69E1B71B7A1617BFA06E5193E6_B50A3F6FC030FEA99FBA61B140182B5A_LE35&d=DwMFaQ&c=bXyEFqpHx20PVepeYtwgeyo6Hxa8iNFcGZACCQj1uNM&r=qI80tqjaL8pFnQztNVN8hh63HwlwQiyEt-SntsexySE&m=FnLsdi_ThSmU-yJzLCg5xXWo-snY9sRGyHWlj0pa6Fc&s=u_ufcz_crukhYyZTDKOH2mwTet-YKqF6oEXdTKVUuC8&e=)[1](https://urldefense.proofpoint.com/v2/url?u=http-3A__news.colonis-2Dproduct-2Dlaunch.co.uk_6918525DD86AA55C95AF4C27401A1874790F2DF0AF0E949177F9D568871AD097_B50A3F6FC030FEA99FBA61B140182B5A_LE35&d=DwMFaQ&c=bXyEFqpHx20PVepeYtwgeyo6Hxa8iNFcGZACCQj1uNM&r=qI80tqjaL8pFnQztNVN8hh63HwlwQiyEt-SntsexySE&m=FnLsdi_ThSmU-yJzLCg5xXWo-snY9sRGyHWlj0pa6Fc&s=RSNA6iBsyKkRNXMnBJYCvM71dBWg2RiUctUwTxVWCdU&e=)
* Melatonin 1mg/ml Oral Solution is not recommended for use in patients with severe renal or moderate or severe hepatic impairment. [Click here to view the SmPC for further information.1](https://urldefense.proofpoint.com/v2/url?u=http-3A__news.colonis-2Dproduct-2Dlaunch.co.uk_62140AF0EED9B5C4AA28ED699701DFA70A1C399B5C79A1058576C1ECB70686C6_B50A3F6FC030FEA99FBA61B140182B5A_LE35&d=DwMFaQ&c=bXyEFqpHx20PVepeYtwgeyo6Hxa8iNFcGZACCQj1uNM&r=qI80tqjaL8pFnQztNVN8hh63HwlwQiyEt-SntsexySE&m=FnLsdi_ThSmU-yJzLCg5xXWo-snY9sRGyHWlj0pa6Fc&s=4AVu6-aox5_v2pFP4udkCPxbVXK7N6dLVluj_pqyyAc&e=)

In addition, we have noticed that the incorrect Prescribing Information (i.e. that for Melatonin 3mg Film-Coated Tablets) was included in the original mailing in error. We would like to take this opportunity to apologise for any confusion this may have caused. [Click here to view the SmPC for further information.1](https://urldefense.proofpoint.com/v2/url?u=http-3A__news.colonis-2Dproduct-2Dlaunch.co.uk_A508650C694450906A4680E8D2476747EFF33C7C327F2F3E9DCC1B2BBDFEEFD7_B50A3F6FC030FEA99FBA61B140182B5A_LE35&d=DwMFaQ&c=bXyEFqpHx20PVepeYtwgeyo6Hxa8iNFcGZACCQj1uNM&r=qI80tqjaL8pFnQztNVN8hh63HwlwQiyEt-SntsexySE&m=FnLsdi_ThSmU-yJzLCg5xXWo-snY9sRGyHWlj0pa6Fc&s=Br8m1pLxaSJjOBZgx4tUMMxuwVHFx_s8I203WiWkApY&e=)

Finally, the reference used in the original mailing citing the **West Essex CCG** was in no way intended to suggest they had endorsed our product, which they do not. We wish to apologise to **West Essex CCG** for referring to their document without their express permission and more widely for any inconvenience the original mailing may have caused any other recipients.

We can confirm this was a single use promotional mailing and has now been formally withdrawn from use.

For further information please contact [medinfo@colonis.co.uk](mailto:medinfo@colonis.co.uk)

or telephone **01892 739 403**.