



ONCOLIFE-MT is an unlicensed medicine, manufactured on an individual patient basis at the request of a prescriber.

ONCOLIFE-MT comes in 60mg capsules and for administration by the oral route only. The active drug is Melatonin.

Melatonin is being investigated as an oncostatic - where growth suppression of some tumor types have been observed.(1)

USAGE of Oncolife MT

ONCOLIFE-MT may be useful as an alternative therapy in an increasing number of neoplastic conditions, determined after consultation with an appropriate health care practitioner.

Melatonin, the active drug, is licensed worldwide as a sleep aid, and regulator of circadian rhythm. In post marketing surveillance, it was found to have a wide spectrum of actions far exceeding the sleep assistance.

ONCOLIFE-MT has compulsory reporting, so in order to obtain this product a consultation must be completed with a suitably qualified prescriber.

Melatonin is usually taken at doses not exceeding 10mg, ONCOLIFE-MT is six times this dose (60mg) and not to be prescribed or taken purely for sleep disturbance. This is an unlicensed dose, only to be used in off-label therapy for cancer.

WARNINGS AND PRECAUTIONS

BEFORE you use ONCOLIFE-MT talk to your prescriber if you:

- have previously had a reaction to Melatonin
- are taking benzodiazepines
- are taking any blood thinners or blood pressure medicines

If you go into hospital you must tell the doctors all the medicines you are taking. This includes ONCOLIFE-MT.

Some drugs interact with Melatonin. Therefore it is important that prior to taking Melatonin you tell your prescriber if you are taking potent liver enzyme modifiers:

- · benzodiazepines such as temazepam, diazepam, lorazepam - may increase the drowsiness you experience on the day or the day after.
- clonidine and methoxamine where their effect may be inhibited
- warfarin, and coumadin based blood thinners where taking both together is contraindicated due to increase risk of bleed. Additional monitoring required.
- immunosuppressants melatonin stimulates the immune system so may counteract the effects (monitoring required).
- fluvoxamine and amitriptyline where the melatonin effect can be increased
- prescribers should visit https://bnf.nice.org.uk/interactions/melatonin/ before prescribing this high dose of melatonin

PROPER USE OF THIS PRODUCT

ONCOLIFE-MT is supplied as a pharmaceutical vegan capsule. The dose in 24 hours should not exceed 1 capsule. This is usually best taken 20 minutes before bed time.

ONCOLIFE-MT is designed to be instant release, allowing for the highest possible blood level as quickly as possible. Therefore avoid having a heavy meal one hour before taking.

If you forget to take a dose, take the next dose and carry on as before, do NOT double your dose.

Capsules can be opened, and dispersed in a little water or yoghurt for patients with swallowing difficulties.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Melatonin has a low side effect profile, and is generally well tolerated. As with all medicines individuals may experience side effects. These include, most commonly:

- dizziness / sleepiness
- headache
- nausea
- vomiting
- irritability the next day
- dry mouth
- constipation
- unusual dreams
- unusual pains in arms and legs
- dry or itchy skin

If these side effects do not resolve after taking ONCOLIFE-MT for a few weeks, speak to your doctor or pharmacist.

Patients taking OMCOLIFE-MT must have previously taken Melatonin at a lower dose of 10-30mg to ensure tolerability.

Patients who have never had melatonin before must not start ONCOLIFE-MT 60mg

INGREDIENTS AND STORAGE

ONCOLIFE-MT is formulated to be hypoallergenic. Capsules are vegan, and contain melatonin and an inert base such as microcrystalline cellulose. They are colour and preservative free. **Do not refrigerate or freeze.**

Any unused capsules should not be disposed of in domestic bins and <u>must be returned to a pharmacy for incineration</u>.

KEEP OUT OF SIGHT AND REACH OF CHILDREN STORE IN A SECURE PLACE DO NOT GIVE YOUR ONCOLIFE-MT TO ANYONE ELSE

MORE INFORMATION

ONCOLIFE-MT is manufactured by:

Rokshaw Laboratories 5a Rivergreen Industrial Estate Sunderland SR4 6AD (MS43743)

Regulatory compliance assured by: Thistle Pharma www.thistlepharma.co.uk

and supplied exclusively by:
Dickson Chemist 35 Mitchell Arcade, Rutherglen,
G73 2LS 0141 404 6545

REFERENCES

- 1. Wang L, Wang C, Choi WS. Use of Melatonin in Cancer Treatment: Where Are We? Int J Mol Sci. 2022 Mar 29;23(7):3779. doi: 10.3390/ijms23073779. PMID: 35409137; PMCID: PMC8998229.
- 2.Li Y, Li S, Zhou Y, Meng X, Zhang JJ, Xu DP, Li HB. Melatonin for the prevention and treatment of cancer. Oncotarget. 2017 Jun 13;8(24):39896-39921. doi: 10.18632/oncotarget.16379. PMID: 28415828; PMCID: PMC5503661.
- 3. Reiter RJ, Rosales-Corral SA, Tan DX, Acuna-Castroviejo D, Qin L, Yang SF, Xu K. Melatonin, a Full Service Anti-Cancer Agent: Inhibition of Initiation, Progression and Metastasis. Int J Mol Sci. 2017 Apr 17;18(4):843. doi: 10.3390/ijms18040843. PMID: 28420185; PMCID: PMC5412427.
- 4.Talib WH, Alsayed AR, Abuawad A, Daoud S, Mahmod AI. Melatonin in Cancer Treatment: Current Knowledge and Future Opportunities. Molecules. 2021 Apr 25;26(9):2506. doi: 10.3390/molecules26092506. PMID: 33923028; PMCID: PMC8123278.

PRESCRIBING INFORMATION

ONCOLIFE-MT should be prescribed in units of 28 not exceeding 3x28 (84) in one supply. This will maximise expiry. Generally capsules last 90 days from dispatch. For longer prescribing intervals please prescribe 28, with sufficient repeats to last the intended period.