

# Agomelatine for the treatment of REM behaviour disorder (RBD)

This leaflet will provide you with some information about agomelatine, which has been prescribed to treat your sleep disorder. If you have any questions or concerns, please speak to the doctor, pharmacist or nurse caring for you.

## What is RBD?

RBD happens during rapid eye movement (REM) sleep. This is usually the phase of sleep when we dream, and our muscles are temporarily paralysed so we cannot move.

People who have RBD are able to move their muscles while they dream, which means they can act out the content of their dreams.

This can lead to episodes of intense shouting or speaking, and violent movement or behaviour which can result in injury to you or your bed partner.

## What is agomelatine?

Agomelatine is an anti-depressant normally used to help treat depression. However, it also works to make you sleepy and regulate your body clock. This means that agomelatine is now being used to treat sleep disorders that can cause abnormal events during sleep.

## Taking an unlicensed medicine

The use of agomelatine for the treatment of RBD is unlicensed, which means that the manufacturer of the medicine has not specified it can be used in this way. However, there is evidence that it works to treat this particular condition. The leaflet, **Unlicensed medicines – a guide for patients**, has more information about unlicensed medicines. If you would like a copy, please ask your doctor, nurse or pharmacist. Alternatively you can call the Pharmacy Medicines Helpline (details are at the end of this leaflet).

## How do I take the medicine?

For the treatment of RBD, agomelatine should be taken once a day at night, one hour before bedtime. It may be taken with or without food. Swallow the tablet(s) with a drink of water.

Keep taking the tablets until your doctor tells you otherwise. Stopping suddenly can cause problems and your doctor will want you to reduce your dose gradually if you need to stop treatment.

## What should I do if I forget to take the medicine?

If you forget to take a dose of agomelatine, don't worry. Take the next dose when it is due. **Do not take an extra dose the following night to make up for the missed dose.**

## Are there any side effects?

In addition to their desired effects, most medicines can cause unwanted side effects, but not everyone gets them. The following are examples of some of the side effects reported by patients taking agomelatine. The unwanted effects often fade as your body adjusts to the new medicine, but speak with your GP or pharmacist if any of the following continue or become troublesome.

Side effect	What should I do if it happens?
<b>Common (between one in 100 and one in 10)</b>	
Headache	Take your usual painkiller (for example, paracetamol)
Feeling dizzy, tired or sleepy	Take dose one hour before bedtime. Do not drive and do not use tools or machines until these effects have worn off. Do not drink alcohol.
Feeling sick (nausea), diarrhoea	Stick to simple foods. Avoid rich or spicy meals
Constipation, stomach pain	Try to eat a well-balanced diet containing fresh fruit and vegetables. Drink plenty of water
Difficulty sleeping, increased sweating, back pain	These effects are usually mild and soon pass, but if any become troublesome, speak with your doctor

**Important:** if you experience any of the following rare, but possibly serious, symptoms, stop taking agomelatine and contact your doctor for advice **straight away**.

- Dark urine, light coloured stools, yellowing of your skin or the whites of your eyes (jaundice), unexpected bruising, tummy pain, itchy skin, and feeling unusually tired. These may be signs that your liver is not working as it should.
- Changes to your mood (such as feeling anxious, nervous or agitated), behaviour, or thinking (forgetful). You may also have thoughts about harming yourself or ending your life.

For further information on side effects, please see the manufacturer's leaflet that comes with the medicine.

## Is there anything else I need to know?

It can take a week or two after starting this treatment before the effect builds up, and up to four weeks before you feel the full benefit. It is important that you keep taking it, even if you feel that it is not helping.

To make sure that your liver is staying healthy, you will need to have a blood test every few weeks for six months, and then when necessary. You can discuss how often they are required with your consultant and doctor when you are settled on your medication.

Alcohol can affect the liver, as can agomelatine. Alcohol can also worsen the symptoms of RBD. Do not drink alcohol while taking agomelatine.

Smoking can affect the amount of agomelatine in your body. Let your doctor know if you either start or stop smoking while you are taking agomelatine.

If you are a driver, please be aware that agomelatine may affect your reactions and ability to drive. It is an offence to drive while your reactions are impaired. Even if your driving ability is not impaired, if you drive, you are advised to carry some evidence with you which shows that the medicine has been prescribed for you – a repeat prescription form or the patient information leaflet from the packet is generally considered suitable.

If you are having an operation or dental treatment, tell the person carrying out the treatment which medicines you are taking in case there are any drug interactions.

Agomelatine should be kept out of reach of children. If anyone other than you takes this medicine, then you, they, or their parent/carer should contact NHS 111 for advice. If they are unwell, they should call for an ambulance.

The expiry date is printed on the container. Do not use the medicine after this date. The remainder should be returned to your local pharmacy to be thrown away.

### **Pregnancy and breast feeding:**

We do not recommend the use of this medicine if you are pregnant or breastfeeding. You should let your consultant know if you are planning a pregnancy so that a management plan can be agreed. If you discover that you are pregnant, please contact your consultant for advice as soon as possible.

**Sleep hygiene:** Taking agomelatine is not a replacement for a good sleep routine. It is still important to aim to get around seven to eight hours of sleep at night if possible. It is advisable to go to bed when tired, and get up at about the same time each day. Maintain a normal total sleep time. Sleep deprivation will increase RBD. Monitor for any sleepiness.

### **Bedroom safety precautions for RBD**

- Move objects away from your bedside. This includes night stands, lamps, or other objects that could cause injury.
- Move your bed away from the window.
- Encourage your bed partner to report any worsening or changes in your night-time behaviour.

## **Can I take agomelatine with other medicines?**

Agomelatine may interact with some medicines. It is important to let us know about any medicines that you are currently taking, so that we can check agomelatine is suitable for you. If you are buying any medicines over the counter from a pharmacy, always mention that you have been prescribed agomelatine. Seek advice from a pharmacist when buying herbal or homeopathic remedies. It is safe to take paracetamol or ibuprofen with this medicine.

## How will my treatment be reviewed?

Your treatment will be reviewed on an ongoing basis at the Sleep Disorder Centre, and the dose adjusted in response to your symptoms. This will be a long-term treatment if it is of benefit. Your consultant will want to check to make sure that the treatment is helping.

## How do I get a repeat prescription?

Guy's Sleep Disorder Centre will provide you with a repeat prescription for your agomelatine, which will be dispensed by Lloyd's Outpatient Pharmacy which is in the hospital.

### Contact us

If you have any questions or concerns about your sleep disorder, please contact the Sleep Disorder Centre, **t:** 020 7188 3430, Monday to Friday, 9am to 5pm.

Out of hours, please leave a message and a member of staff will call you back in working hours, or contact your GP or NHS 111.

For more information leaflets on conditions, procedures, treatments and services offered at our hospitals, please visit [www.guysandstthomas.nhs.uk/leaflets](http://www.guysandstthomas.nhs.uk/leaflets)

### Pharmacy Medicines Helpline

If you have any questions or concerns about your medicines, please speak to the staff caring for you or call our helpline.

**t:** 020 7188 8748 9am to 5pm, Monday to Friday

### Your comments and concerns

For advice, support or to raise a concern, contact our Patient Advice and Liaison Service (PALS). To make a complaint, contact the complaints department.

**t:** 020 7188 8801 (PALS)      **e:** [pals@gstt.nhs.uk](mailto:pals@gstt.nhs.uk)

**t:** 020 7188 3514 (complaints)      **e:** [complaints2@gstt.nhs.uk](mailto:complaints2@gstt.nhs.uk)

### Language and Accessible Support Services

If you need an interpreter or information about your care in a different language or format, please get in touch.

**t:** 020 7188 8815      **e:** [languagesupport@gstt.nhs.uk](mailto:languagesupport@gstt.nhs.uk)

### NHS 111

Offers medical help and advice from fully trained advisers supported by experienced nurses and paramedics. Available over the phone 24 hours a day.

**t:** 111

### NHS website

Online information and guidance on all aspects of health and healthcare, to help you take control of your health and wellbeing.

**w:** [www.nhs.uk](http://www.nhs.uk)

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