

## **Package leaflet: Information for the patient**

### **HETLIOZ 20 mg hard capsules** tasimelteon

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

1. What HETLIOZ is and what it is used for
2. What you need to know before you take HETLIOZ
3. How to take HETLIOZ
4. Possible side effects
5. How to store HETLIOZ
6. Contents of the pack and other information

#### **1. What HETLIOZ is and what it is used for**

HETLIOZ contains the active substance tasimelteon. This type of medicine is called a “melatonin agonist” that acts as a regulator of daily body rhythms.

It is used to treat Non-24-Hour Sleep-Wake Disorder (Non-24) in adults who are totally blind.

#### **How HETLIOZ works**

In sighted people, the change in light levels between day and night helps to synchronise internal body rhythms, including feeling sleepy at night and being active during the day. The body controls these rhythms through many pathways including increases and decreases in the production of the hormone melatonin.

Patients with Non-24 who are totally blind cannot see light, so their body rhythms shift out of alignment with the 24-hour world, resulting in periods of feeling sleepy during the day and the inability to sleep at night. The active substance in HETLIOZ, tasimelteon, is able to act as a time-keeper for the body rhythms and resets them each day. It aligns body rhythms with the usual 24-hour day and night cycle and so improve sleep patterns. Because of individual differences in each person’s body rhythms, it could take weeks or up to 3 months for an improvement in symptoms to be noticed.

#### **2. What you need to know before you take HETLIOZ**

##### **Do not take HETLIOZ if**

You are allergic to tasimelteon or any of the other ingredients of this medicine (listed in section 6).

##### **Warnings and precautions**

After taking HETLIOZ, you should get ready to go to bed and only carry out activities that you would normally do before going to bed.

#### **Children and adolescents**

Do not give HETLIOZ to children under the age of 18 years. This is because HETLIOZ has not been tested in people under 18 years of age and the effects are unknown.

### **Other medicines and HETLIOZ**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes:

- medicines known to reduce the activity of an enzyme called 'CYP1A2'. An example is fluvoxamine, which is used to treat depression and obsessive compulsive disorder (OCD).
- medicines known to reduce the activity of an enzyme called 'CYP3A4'. An example is ketoconazole, which is used to treat fungal infections.
- medicines known to increase the activity of an enzyme called 'CYP3A4'. An example is rifampicin, which is used to treat tuberculosis (TB).
- medicines known to reduce the activity of an enzyme called 'CYP2C19'. An example is omeprazole, which is used to treat heartburn and gastroesophageal reflux disease (GERD).
- medicines called "beta blockers" used to treat high blood pressure and other heart problems. Some examples include atenolol, metoprolol, and propranolol.

If any of the above applies to you (or you are not sure), talk to your doctor or pharmacist before taking HETLIOZ.

### **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. As a precautionary measure, it is preferable to avoid the use of tasimelteon during pregnancy. If you become pregnant while taking HETLIOZ, consult your doctor immediately as it is recommended not to take HETLIOZ while you are pregnant or breast feeding.

### **HETLIOZ contains lactose**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

### **HETLIOZ contains Orange Yellow S (E110)**

Tell your doctor if you have an allergy to Orange Yellow S (E110). HETLIOZ contains Orange Yellow S (E110) which may cause allergic reactions.

### **HETLIOZ contains sodium**

This medicinal product contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

## **3. How to take HETLIOZ**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

### **How much to take**

The recommended dose is one capsule every night, taken one hour before you go to bed. Try to take the medicine at the same time every night. Because of individual differences in each person's body rhythms, it could take weeks or months for you to notice an improvement in your symptoms. Therefore, your doctor may ask you to take HETLIOZ for up to 3 months before checking if it is working for you.

### **Taking HETLIOZ**

- Take the medicine by mouth.
- Swallow the capsule whole.

- It is best to take HETLIOZ on an empty stomach as food can reduce the amount of the medicine that is absorbed into your body. If you eat a high-fat meal close to the time you would normally take the medicine, it is best to wait 2 hours before taking HETLIOZ.
- To open the bottle, push the cap down and turn counter-clockwise.

#### **If you take more HETLIOZ than you should**

If you accidentally take more HETLIOZ than your doctor recommended, contact your doctor at once or contact the nearest hospital for advice. Keep the bottle with you so that you can easily describe what you have taken.

#### **If you forget to take HETLIOZ**

- Skip the missed dose. Take your next dose at the usual time the next day. Do not take a double dose.

#### **If you stop taking HETLIOZ**

Do not stop taking HETLIOZ without talking to your doctor.

- If HETLIOZ is not taken every night, the body rhythms will lose alignment with the usual 24-hour day and night cycle again. This means that symptoms will come back.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine.

**Very common:** may affect more than 1 in 10 people

- headache

**Common:** may affect up to 1 in 10 people

- change in sleeping pattern
- difficulty in sleeping
- dizziness
- dry mouth
- tiredness
- indigestion
- feeling sick in the stomach
- blood tests which show changes in the way the liver is working (alanine aminotransferase)
- unusual dreams
- sleepiness

**Uncommon:** may affect up to 1 in 100 people

- abnormal or change in taste
- blood tests which show changes in the way the liver is working (aspartate aminotransferase and gamma-glutamyl transferase)
- increase in daytime urination
- nightmares
- ringing in the ears
- feeling foggy in the head

#### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in [Appendix V](#). By reporting side effects, you can help provide more information on the safety of this medicine.

### **5. How to store HETLIOZ**

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the bottle and the carton after EXP. The expiry date refers to the last day of that month.
- This medicine does not require any special temperature storage conditions.
- Store in the original container and keep the bottle tightly closed in order to protect from moisture and light.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What HETLIOZ contains**

- The active substance is tasimelteon. Each hard capsule contains 20 mg of tasimelteon.
- The other ingredients are lactose anhydrous, microcrystalline cellulose, croscarmellose sodium, silica, colloidal anhydrous, and magnesium stearate.
- The hard capsule shell consists of gelatin, titanium dioxide, Brilliant Blue FCF, Erythrosine, and Orange Yellow S (E 110).
- The white printing ink contains shellac, propylene glycol, sodium hydroxide, povidone and titanium dioxide.

### **What HETLIOZ looks like and contents of the pack**

HETLIOZ hard capsules are opaque dark blue printed with “VANDA 20 mg” in white. Each bottle has a child-resistant cap and contains 30 hard capsules.

### **Marketing Authorisation Holder**

Vanda Pharmaceuticals Netherlands B.V.  
Prins Bernhardplein 200  
1097 JB Amsterdam  
The Netherlands

### **Manufacturer**

AcertiPharma B.V.  
Minervum 7333  
4817 ZD Breda  
The Netherlands

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

#### **Deutschland**

Vanda Pharmaceuticals Netherlands B.V.  
Tel: +49 (0)30 800 98845

#### **France**

Vanda Pharmaceuticals Netherlands B.V.  
Tél: +49 (0)30 800 98845

#### **España**

Vanda Pharmaceuticals Netherlands B.V.  
Tel: +49 (0)30 800 98845

#### **Italia**

Vanda Pharmaceuticals Netherlands B.V.  
Tel: +49 (0)30 800 98845

**This leaflet was last revised in June 2021**

### **Other sources of information**

Detailed information on this medicine is available on the European Medicines Agency web site:  
<http://www.ema.europa.eu>.