Medicines & Healthcare products
Regulatory Agency

Public Assessment Report

National Procedure

Zopiclone 3.75 mg Film-Coated Tablets
Zopiclone 7.5 mg Film-Coated Tablets
Zopiclone

PL 15764/0184-0185

Strandhaven Limited trading as Somex Pharma

LAY SUMMARY

Zopiclone 3.75 mg Film-coated Tablets
Zopiclone 7.5 mg Film-coated Tablets
Zopiclone

This is a summary of the Public Assessment Report (PAR) for Zopiclone 3.75 mg and 7.5 mg Film-coated Tablets. It explains how these products were assessed and their authorisation recommended, as well as their conditions of use. It is not intended to provide practical advice on how to use these products.

These products will be referred to as Zopiclone film-coated tablets in this lay summary for ease of reading.

These applications were approved under the International Recognition procedure (IRP). The Reference Regulator (RR) was the EU/EEA (Denmark), with the procedure number DK/H/3300/001-002/DC. The procedure followed route A.

These applications were approved under Regulation 51B, of the Human Medicines Regulation 2012, as amended (previously Article 10(1) of Directive 2001/83/EC, as amended).

For practical information about using Zopiclone film-coated tablets, patients should read the Patient Information Leaflet (PIL) or contact their doctor or pharmacist.

What are Zopiclone film-coated tablets and what are it/they used for?
Zopiclone film-coated tablets are generic medicines. This means that these medicines are the same as, and considered interchangeable with the reference medicines, already authorised called Zimovane LS 3.75 mg Film-Coated Tablets and Zimovane 7.5mg Film-Coated Tablets, respectively.

Adults can use Zopiclone film-coated tablets for short-term treatment of insomnia when the insomnia is severe or disabling and causes pronounced problems.

How do Zopiclone film-coated tablets work?
Zoplicone film-coated tablets contain the active substance zopiclone, which belongs to a group of medicines called benzodiazepines. Zopiclone has a sleep-inducing and a calming effect.

How are Zopiclone film-coated tablets used?
The pharmaceutical form of these medicines is a film-coated tablet, and the route of administration is oral (taken by mouth).

Treatment with Zopiclone film-coated tablets will usually last for a maximum of 2 weeks and should be as short as possible. The treatment should not exceed 4 weeks, including tapering. It is important that the patient does not take more tablets than their doctor has prescribed, and the lowest effective dose should be used. Zopiclone film-coated tablets should be taken as a single dose and should not be taken again during the same evening. It is also important that the patient takes the tablets immediately before bedtime.

The patient should swallow the tablet with a drink of water and should not crush or chew the tablets.

The recommended dose is:
The tablet of 7.5 mg can be divided into two equal halves.

Adults: One tablet 7.5 mg zopiclone.

Use in children and adolescents:
Zopiclone film-coated tablets **should not be used in children and adolescents less than 18 years**. The safety and efficacy of this medicine in children and adolescents aged less than 18 years have not been established.

Elderly:
The patient should start with ½ tablet of 7.5 mg zopiclone or one tablet of 3.75 mg zopiclone. The dose may be increased to one tablet of 7.5 mg zopiclone. The patient should talk to their doctor.

Liver impairment:
The patient should start with ½ tablet of 7.5 mg zopiclone or one tablet of 3.75 mg zopiclone. The dose may be increased to one tablet of 7.5 mg zopiclone. The patient should talk to their doctor.

Chronic poor breathing:
The patient should start with ½ tablet of 7.5 mg zopiclone or one tablet of 3.75 mg zopiclone. The dose may be increased to one tablet of 7.5 mg zopiclone. The patient should talk to their doctor.

Kidney impairment:
The patient should start with ½ tablet of 7.5 mg zopiclone or one tablet of 3.75 mg zopiclone. If necessary, the patient should talk to their doctor.

The patient should make sure that they have the possibility for 7-8 hours of undisturbed sleep before taking Zopiclone film-coated tablets.

For further information on how Zopiclone film-coated tablets are used, refer to the PIL and Summaries of Product Characteristics (SmPCs) available on the Medicines and Healthcare products Regulatory Agency (MHRA) website.

These medicines can only be obtained with a prescription.

The patient should always take the medicine(s) exactly as their doctor/pharmacist has told them. The patient should check with their doctor or pharmacist if they are not sure.

What benefits of Zopiclone film-coated tablets have been shown in studies?
As Zopiclone film-coated tablets are generic medicines, studies in healthy volunteers have been limited to tests to determine that they are bioequivalent to the reference medicines. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects of Zopiclone film-coated tablets?
For the full list of all side effects reported with these medicines, see Section 4 of the PIL or the SmPCs available on the MHRA website.

If a patient gets any side effects, they should talk to their doctor, pharmacist or nurse. This includes any possible side effects not listed in the product information or the PIL that comes with the medicines. Patients can also report suspected side effects themselves, or a report can be made on their behalf by someone else who cares for them, directly via the Yellow Card scheme at https://yellowcard.mhra.gov.uk or search for 'MHRA Yellow Card' online. By reporting side effects, patients can help provide more information on the safety of these medicines.

As Zopiclone film-coated tablets are generic medicines and are bioequivalent to the reference medicines, their benefits and possible side effects are considered to be the same as the reference medicines.

Why were Zopiclone film-coated tablets approved?
It was concluded that, Zopiclone film-coated tablets have been shown to be bioequivalent to the reference medicines. Therefore, the MHRA decided that, as for the reference medicines, the benefits are greater than the risks and recommended that they can be approved for use.

What measures are being taken to ensure the safe and effective use of Zopiclone film-coated tablets?
As for all newly authorised medicines, a Risk Management Plan (RMP) has been developed for Zopiclone film-coated tablets. The RMP details the important risks of Zopiclone film-coated tablets, how these risks can be minimised, any uncertainties about Zopiclone film-coated tablets (missing information), and how more information will be obtained about the important risks and uncertainties.

The following safety concerns have been recognised for Zopiclone film-coated tablets:

Summary of safety concerns	
Important identified risks	• Respiratory depression • Anterograde amnesia • Psychiatry and paradoxical reactions • Tolerance and dependence • Withdrawal symptoms/insomnia • Psychomotor impairment
Important potential risks	• Abuse and diversion • Somnambulism and associated behaviours • Precipitation of encephalopathy in patient with severe hepatic insufficiency
Missing information	• Use in pregnancy and lactation

The information included in the SmPCs and the PIL is compiled based on the available quality, non-clinical and clinical data, and includes appropriate precautions to be followed by healthcare professionals and patients. Side effects of Zopiclone film-coated tablets are

continuously monitored and reviewed including all reports of suspected side-effects from patients, their carers, and healthcare professionals.

An RMP and a summary of the pharmacovigilance system have been provided with these applications and are satisfactory.

Other information about Zopiclone film-coated tablets
Marketing authorisations were granted in the United Kingdom on 25 March 2025.

The full PAR for Zopiclone film-coated tablets follows this summary.

This summary was last updated in May 2025.

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I. INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the Medicines and Healthcare products Regulatory Agency (MHRA) considered that the applications for Zopiclone 3.75 mg and 7.5 mg Film-coated Tablets (PL 15764/0184-0185) could be approved.

The products are approved for the following indication:

- the short-term treatment of insomnia in adults.

  Benzodiazepines or benzodiazepine-like agents are only indicated in cases where the insomnia is severe, disabling or subjecting the individual to extreme distress.

The products contain the active substance, zopiclone, which is a benzodiazepine-like hypnotic agent and belongs to the group of cyclopyrrolone compounds. Its pharmacological properties include anxiolytic, sedative, hypnotic, anticonvulsant and muscle-relaxant effects.

These effects are related to a specific agonist action at central receptors belonging to the 'GABA-omega (BZ1 and BZ2) macromolecular receptor"- complex modulating the opening of the chloride ion channel.

These applications were approved under International Recognition procedure (IRP). The Reference Regulator (RR) was the EU/EEA (Denmark) with the procedure number DK/H/3300/001-002/DC. The procedure followed route A.

For the scientific discussion of the quality, non-clinical and clinical assessment conducted by the reference regulator, please refer to the public assessment report on the relevant competent authority's website.

These applications were approved under Regulation 51B of the Human Medicines Regulation 2012, as amended (previously Article10(1) of Directive 2001/83/EC, as amended), claiming to be generic medicinal products of suitable originator products, Zimovane LS 3.75 mg Film-Coated Tablets and Zimovane 7.5mg Film-Coated Tablets, respectively, that have been licensed for a suitable time, in line with the legal requirements.

The MHRA has been assured that acceptable standards of Good Manufacturing Practice (GMP) are in place for these products at all sites responsible for the manufacture, assembly and batch release of these products.

A Risk Management Plan (RMP) and a summary of the pharmacovigilance system have been provided with these applications and are satisfactory.

Marketing authorisations were granted on 23 March 2025.

II. PRODUCT INFORMATION

SUMMARIES OF PRODUCT CHARACTERISTICS (SmPCs)

The SmPCs are in line with current guidelines and are satisfactory.

PATIENT INFORMATION LEAFLET (PIL)

The PIL is in line with current guidelines and is satisfactory.

LABEL
The labelling is in line with current guidelines and is satisfactory.

III. QUALITY ASPECTS
The MHRA considered that the quality data submitted for these applications is satisfactory. The grant of marketing authorisations were recommended.

IV. NON-CLINICAL ASPECTS
The MHRA considered that the non-clinical data submitted for these applications is satisfactory.

The grant of marketing authorisations were recommended.

V. CLINICAL ASPECTS
The MHRA considered that the clinical data submitted for these applications is satisfactory.

The grant of marketing authorisations were recommended.

VI. RISK MANAGEMENT PLAN (RMP)
The applicant has submitted an RMP, in accordance with the requirements of Regulation 182 of The Human Medicines Regulation 2012, as amended. The safety information in the proposed Product Information is aligned to the reference medicinal products. The applicant proposes only routine pharmacovigilance and routine risk minimisation measures for all safety concerns. This is acceptable.

VII. USER CONSULTATION
A full colour mock-up of the PIL was provided with the applications in accordance with legal requirements, including user consultation.

VIII. OVERALL CONCLUSION, BENEFIT/RISK AND RECOMMENDATION
The quality of the products is acceptable, and no new non-clinical or clinical safety concerns have been identified. Clinical experience with zopiclone is considered to have demonstrated the therapeutic value of the compound .The benefit/risk balance is, therefore, considered to be positive.

The SmPCs, PIL and labelling are satisfactory.

In accordance with legal requirements, the current approved UK versions of the SmPCs and PIL for these products are available on the MHRA website.

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Steps taken after the initial procedure with an influence on the Public Assessment Report (non-safety variations of clinical significance).

Please note that only non-safety variations of clinical significance are recorded below and in the annexes to this PAR. The assessment of safety variations, where significant changes are made, are recorded on the MHRA website or European Medicines Agency (EMA) website. Minor changes to the marketing authorisations are recorded in the current SmPCs and/or PIL available on the MHRA website.

Application type	**Scope**	**Product information affected**	**Date of grant**	**Outcome**	**Assessment report attached Y/N**