Medicines & Healthcare products Regulatory Agency

Public Assessment Report

National Procedure

Temazepam 10 mg Tablets
Temazepam 20 mg Tablets

temazepam

PL 48836/0003-0004

Osgen Pharmaceuticals Limited

This Public Assessment Report reflects the reason for the non-approval of Temazepam 10 mg and 20 mg Tablets. The procedure was finalised on 25 March 2024.

I INTRODUCTION

Based on the review of the quality, safety and efficacy data, the MHRA has refused to grant marketing authorisations for Temazepam 10 mg and 20 mg Tablets, from Osgen Pharmaceuticals Limited.

The indications applied for are*:*
The short term treatment of insomnia, only where the condition is severe, disabling or subjecting the individual to extreme distress.
Temazepam tablets are indicated for pre-medication before minor surgery or other procedures especially in the case of outpatients.

The marketing authorisation applications were submitted under Regulation 54 of The Human Medicines Regulation 2012, as amended, in the United Kingdom (UK).

II OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

The marketing authorisations could not be granted, in line with The Human Medicines Regulations 2012, as amended, the applicant did not submit the further information requested by the MHRA in the given period, during the assessment of this application.

Under paragraph 3 of Schedule 11 to the Human Medicines Regulations 2012 as amended, the MHRA has the authority to refuse to grant the marketing authorisation applied for, if information requested in connection with the application is not provided within 6 months of the first request or within 3 months of subsequent requests, and when the MHRA has not agreed to extend the period on justified grounds.