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Reckitt Seeks UK General Sale Status For Nuromol Paracetamol + Ibuprofen Combo

by David Ridley

Reckitt's application for a P-to-GSL switch of its Nuromol paracetamol and ibuprofen combination painkiller in the UK is out for consultation until 3 June.

Reckitt Benckiser Healthcare Ltd is looking to make its Nuromol painkiller brand available in UK grocery stores and supermarkets.

Currently out for consultation until 3 June, the pharmacy (P) to general sales list (GSL) switch of Nuromol (200mg ibuprofen and 500mg paracetamol) for oral use is proposed on the following conditions:

- Indicated for the temporary relief of mild to moderate pain, which has not been relieved by ibuprofen or paracetamol individually, such as migraine, headache, backache, period pain, dental pain, rheumatic and muscular pain, cold and flu symptoms, sore throat and fever in adults 18 years and over
- Maximum single dose of two tablets and a maximum daily dose of six tablets
- Maximum pack size of 16 tablets

The UK Medicines and Healthcare products Regulatory Agency said it welcomes views from the public and stakeholders on whether this product should become a GSL medicine.

“The MHRA is committed to making medicines easier to access, where it is safe to do so,” the regulator commented. “Therefore, it is vital that we hear what people have to say on this consultation.”

Good Safety Profile

Widening access to Nuromol in the UK has been recommended by the country's Commission on Human Medicines (CHM) – which advises the government on the safety, quality and effectiveness of medicines and vaccines – on the basis that it is safe for this product to potentially be made available as a GSK medicine, the MHRA pointed out.

"Six years of use of Nuromol as a P medicine in the UK did not identify any unknown and significant safety risks and data from New Zealand, where Nuromol has been classified as medicine that can be sold without prescription in non-pharmacy outlets, revealed that the incidence of Adverse Drug Reactions (ADRs) is low," the MHRA explained.

"Even at the conservative estimate of toxicity (100mg/kg) a 60kg adult would need to take 30 tablets at once to overdose," the regulator added.

With respect to the ability of people to choose and use Nuromol without the supervision of the pharmacist, the key issue that Reckitt had to address, according to the MHRA, is how people will be able to choose the product as second line (over paracetamol or ibuprofen alone) treatment for mild to moderate pain.

"The applicant proposed to address this by adding a prominent statement on the front of the pack indicating that the product should only be used after trying ibuprofen and paracetamol first," the MHRA reported.

"This proposal was accepted by CHM on the condition that there were additional measures in the Risk Management Plan to manage the risk of people not using the product as second line treatment, including an appropriate study carried out before approval of the reclassification application to demonstrate that the product would be used as second-line treatment for pain relief," the regulator continued.

"Consequently, the applicant undertook a pilot and pivotal study to demonstrate that the product will be used as second-line treatment for pain relief and undertook two user testing studies of the label to demonstrate that participants could differentiate and self-select Nuromol from other products according to the criteria which would need to be taken into account when buying the product in the absence of a pharmacist," the MHRA added.

"The pilot and pivotal study protocol were pre-approved by the Pharmacovigilance Expert Advisory Group," it said.