Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

ANNEX 1
Response document for MHRA public consultation on the proposal to make Nuromol Dual Action Pain Relief 200mg/500mg tablets available on General Sale

Ref: ARM 100

MHRA proposes to permit supply of Nuromol Dual Action Pain Relief 200mg/500mg tablets on general sale outside pharmacies because we consider that the evidence presented in this application demonstrates that the product meets the GSL criterion set out in the legislation. Your response should address why you agree or disagree with this conclusion and any additional safeguards you consider to be necessary. We will review all responses received to see if the evidence presented changes our conclusion that the product does meet the GSL criterion.

Your details

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Position (if applicable): Policy and Engagement Lead Royal Pharmaceutical Society in Wales

Organisation (if applicable): Royal Pharmaceutical Society

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1. Do you consider that Nuromol Dual Action Pain Relief 200mg/500mg tablets meets the criterion for a medicine to be classified as a medicinal product subject to general sale

No

Please provide any comments or evidence to support your response:

Pharmacy plays a vital role in ensuring individuals have access to medicines. The supply of P medicines provides a touchpoint with patients and enables a direct interaction to take place between the patient and the pharmacist potentially including an intervention around medicines or giving lifestyle advice. It is crucial that these important interactions are not lost and that appropriate opportunity for the patient to be supported with medicines and health advice tailored to their individual needs are maintained.

Regardless of the route of access the RPS believes that medicines supply should be:
1. safe
2. person-centred
3. timely
4. equitable
5. efficient & effective

We have concerns about the safety of making this combination product available as a general sales item. Ibuprofen is contraindicated in several patients, such as patients with previous hypersensitivity reactions, history

of gastrointestinal bleeding or perforation (related to previous NSAIDs therapy), severe renal failure, severe hepatic failure and severe heart failure [1].

There are also many times when it should be used with caution, for example in the first and third trimester [2].

We are concerned about the potential for people to confuse the product with paracetamol alone and take the standard paracetamol dose of two tablets four times a day. This has the potential to cause patient harm and is not considered in the consultation.

We also note that annually in the UK, paracetamol overdose results in approximately 100,000 Emergency Department presentations and 50,000 acute hospital admissions, and is the direct cause of death in around 150 people (ECM, HES)

The National Institute for Health and Care Excellence (NICE) clinical guidelines in the UK for the treatment of mild-moderate pain specify a stepwise approach to pain management, with medicines with a combination of paracetamol and ibuprofen a suitable third line choice for people who can take it. It is highlighted on the box that Nuromol is for use only after trying ibuprofen or paracetamol individually first. We believe that people should consult a healthcare professional when initial GSL products have failed, this should be part of identifying any concerns and red flags. Therefore, placing this into a GSL category is not a valid position in the care pathway of any of the conditions listed.

2. Do you have any specific comments on the leaflet or label provided at Annexes, 2 & 3?

The outer packaging and patient information leaflet for a GSL product consistently advises patients to seek advice from their doctor or pharmacist. In non-pharmacy outlets where GSL medicines are sold, professional advice is not available. The request for all GSL and P medicine in a Pharmacy setting will be handled by trained health care advisors, with pharmacists on hand to offer further professional advice where needed in order to ensure the safe and appropriate use of medicines.

3. Do you have any other comments on the reclassification?

We are supportive of wider access to medicines however this access must be carefully managed balancing the convenience of self-selection with the risk of losing the opportunity for a health intervention or health advice.

Pharmacy sale of medicines offer added safety for patients, as pharmacists and trained healthcare advisors are on hand to counsel the patients on their medicines and we would advocate this added safety measure is needed for a combination medicine.

Our aim as the Royal Pharmaceutical Society is to ensure patients get the most from their medicines. To facilitate this we advocate that patients must be able to self-care with the support of the professional expertise and judgment of a pharmacist, and the P category of medicines help facilitate this interaction. This is especially important when a product contains more than one medicine.

[1] https://www.medicines.org.uk/emc/product/7020/smpc#gref
[2] https://www.medicines.org.uk/emc/product/7020/smpc#gref

4. The MHRA may publish consultation responses. Do you want your response to remain confidential?

No

*If partially, please indicate which parts you wish to remain confidential. In line with the Freedom of Information Act 2000, if we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. Responses to consultation will not normally be released under FOI until the regulatory process is complete.

Responses can be continued onto a separate page if required. This form should be returned by email (reclassification@mhra.gov.uk) to arrive by **3 June 2021.** Contributions received after that date cannot be included in the exercise.

The National Institute for Health and Care Excellence (NICE) clinical guidelines in the UK for the treatment of mild-moderate pain specify a stepwise approach to pain management, with medicines with a combination of paracetamol and ibuprofen a suitable third line choice for people who can take it. It is highlighted on the box that nuromol is for use only after trying ibuprofen or paracetamol individually first. We believe that this would be the time to consult a healthcare professional when initial GSL products have failed and should be part of identifying any red flags or potential for misdiagnosing. Therefore placing this into a GSL category is not a valid position in the care pathway of any of the conditions.