



Response to ARM21 ([Request to reclassify Voltarol Pain-Eze Emulgel from P to GSL](#)) from the NPA.

Response of the National Pharmaceutical Association to ARM 21

Thank you for giving the National Pharmaceutical Association (NPA) the opportunity to comment on consultation letter ARM 21 on proposals to reclassify Voltarol Pain-Eze Emulgel as a GSL product.

The NPA has concerns regarding this proposal, as the organisation is not convinced that it can be used safely and effectively without the supervision of a healthcare professional for the indications proposed.

Indications

The application states that the product will be indicated for the local symptomatic relief of trauma of the tendons, ligaments, muscles and joints and for localised forms of soft tissue rheumatism. The term “rheumatism” is misleading in this context. Customers will interpret the term rheumatism to mean a range of joint problems including rheumatoid and osteoarthritis. The product may be purchased inappropriately for these conditions. Many patients with rheumatoid and osteoarthritis are already receiving prescription medicines for such disorders, including systemic non steroidal anti-inflammatory drugs, thus increasing the risk of interactions and adverse effects with the product. In addition, many of these customers will be elderly and therefore already at increased risk of adverse effects. In our opinion the term “rheumatism” should not be used in association with this product.

In the pharmacy the pharmacist and their staff can ensure that the product is not being purchased inappropriately and will refer to a medical practitioner when necessary. This safeguard will be lost if the product is available as GSL. Therefore the pack and patient leaflet must carry clear warnings to consult the pharmacist for further advice.

Safety profile

Patients with a history of asthma are at risk of wheezing or asthma attack with topical NSAIDs. A recent study of cross sensitivity to NSAIDs showed that 93% of people with aspirin induced asthma have cross sensitivity to oral diclofenac¹. In a pharmacy the pharmacist and their staff can ensure that the product is not supplied to asthma sufferers. The pack and product literature must carry clear warnings that it must not be used by patients with a history of asthma.

Dosage and administration

The pack will advise that 2 – 4g should be applied 3 – 4 times a day for a maximum of 7 days. The risk of systemic side effects increases if large amounts are applied. In a pharmacy the pharmacist and their staff can ensure that frequent purchasers of the product are counselled accordingly. Patients will be advised on a suitable quantity of product to use. This safeguard will be lost if the product is available as GSL.

Specific GSL requirements

If the application is approved we recommend further information should be included on the pack and patient information leaflet. All the advice that is available from the pharmacist, as listed above, should be included. Product information and advertisements must state that further advice is available from the pharmacist. Also, because of the issues outlined above, advertisements should contain a clear recommendation to read the product literature before use.

We hope you take our comments on board.

ⁱ Systematic review of prevalence of aspirin induced asthma and its implications for clinical practice
BMJ 2004; 328: 434