Response to ARM 14 (Request to reclassify Anbesol Adult Strength Gel from P to GSL) from the NPA.

Response of the National Pharmaceutical Association to ARM 14

Thank you for giving the National Pharmaceutical Association (NPA) the opportunity to comment on consultation letter ARM 14, on proposals to reclassify Anbesol Adult Strength Gel from P to GSL.

Rationale for the reclassification

The application states that lidocaine is already available in GSL products for external use at strengths of 2%. In our view this is misleading as at present lidocaine is only available in a maximum strength of 0.7% for GSL internal preparations such as teething gel. Lidocaine is poorly absorbed through intact skin, however it is readily absorbed through mucous membranes. The availability of higher strengths of lidocaine for internal use on mucous membranes would increase the risk of adverse effects. Although the bioavailability of lidocaine is low it can result in significant toxicity when swallowed and there have been reports of CNS toxicity, seizures and death in children and adults after ingestion of topical solutions and after the use of viscous preparations in the mouth.[1] In addition the BNF warns against the risk of anaesthesia of the pharynx which can result in choking.[2]

Mouth ulcers are an early symptom of oral cancer. A recent campaign in Scotland (launched by the West of Scotland Cancer Awareness Project) encouraged people to visit a health professional, such as a pharmacist, to report any of the signs or symptoms of oral cancer especially mouth ulcers. The organisers of the campaign stated that only 50% of mouth cancer patients survive five years after diagnosis as many patients presented late to the NHS due to lack of awareness of oral cancer. If the product were available GSL patients would be more likely to self treat their mouth ulcers and the opportunity for referral by the pharmacist for earlier diagnosis of oral cancer would be missed.

Mouth ulcers can be due to many other causes including herpes zoster, syphilis, fungal infections and GI disorders such as coeliac disease. Ulcers can also be a symptom of dietary deficiency such as Vitamin B12, folate and iron deficiency. These possibilities should be excluded before treatment of the ulcer. It is important that ulcers of over 3 weeks duration should be referred to a practitioner to exclude malignancy or other serious conditions. Pharmacists and their staff are able to advise patients and establish whether the mouth ulcers

[1] Martindale – The Complete Drug Reference
[2] BNF 46

could be due to a more serious cause. Patients can then be referred to their practitioner when necessary. If the product were available GSL this important safety check would be lost.

Indications

The BNF states that local analgesics, such as lidocaine, have only a limited role in the management of oral ulceration. The action is of short duration so analgesia cannot be maintained throughout the day. In addition, Prodigy guidelines for the treatment of aphthous ulcers recommend that local anaesthetic preparations such as lidocaine gel should be reserved for intractable pain due to major aphthae and should not be used for prolonged periods due to the risk of hypersensitization. The product would not therefore be appropriate first line therapy for mouth ulcers and dental trauma.

In our view there is potential for confusion with teething products for infants if the product is available GSL without the advice of pharmacists and their staff, particularly as the Anbesol brand name is also used for the teething gel. In a pharmacy, staff will check whom the product is intended for.

Risk of Misuse

Although the packaging will state that medical advice should be sought if symptoms persist for more than 7 days, patients may persist in using the product for longer periods as an alternative to seeking advice for symptoms that may have a serious cause. Repeat purchase in a pharmacy would be identified and the patient advised accordingly.

Convenience

Due to the wide distribution of pharmacies throughout the country, many of which have extended opening hours, we believe that convenience is not a relevant consideration for reclassification.

Advertising and product information

If, despite our concerns, the application is approved packaging and advertisements should clearly state that the products are not to be used for children under 12 years. We recommend that the product advertisements for Anbesol Adult Strength Gel state that further advice is available from the pharmacist. Advertisements should contain a clear recommendation to read the product literature before use. These points should also be prominent on the label and in the PIL.

We hope you take our comments on board.