



Response to [ARM19](#) (Request to reclassify Zovirax Cold Sore Cream from P to GSL) from the NPA.

Response of the National Pharmaceutical Association to ARM 19

Thank you for giving the National Pharmaceutical Association (NPA) the opportunity to comment on consultation letter ARM 19 on proposals to reclassify Zovirax cold sore cream as a GSL product.

The NPA does not support this proposal, as the organisation is not convinced that it can be used safely and effectively without the supervision of a healthcare professional.

Indications

Zovirax cold sore cream will only be marketed for the treatment of Herpes Simplex virus infections of the lips and face. However, patients may purchase the cream for the treatment of other infections such as genital herpes simplex or other STD's, particularly with the embarrassment factor associated with such conditions. It is also particularly important that the cream is not used in the eyes and again patients may purchase the product inappropriately for this purpose. 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.

Initially, the symptoms of a cold sore are difficult to identify if a patient has not suffered from cold sores before. In our opinion the GSL product should be restricted for use by patients who have previously been diagnosed as suffering from cold sores.

Age limit

The application states that there will be no minimum age limit for the GSL product. However the cream must be applied five times a day, users must not rub the cold sore or touch it and must particularly avoid touching the eyes due to the risk of cross infection. This will be difficult to achieve with a young child. In addition children may suffer from many other skin complaints with a similar appearance to cold sores for example impetigo, chicken pox, hand, foot and mouth disease and other rashes. Without the advice of the pharmacist or their staff, customers may purchase Zovirax for inappropriate use on a child. In our opinion the GSL product should only be marketed for adults and children aged over 12 years. The P product will still be available for the treatment of younger children but this would be with the support

and advice of the pharmacy staff to ensure appropriate treatment or referral to the general practitioner when necessary.

Dosage and administration

Prodigy guidance states that treatment must be started at an early stage of an attack for any benefit. There is little evidence that the cream is effective in the later stages of the cold sore. The pharmacist can explain that for effective treatment Zovirax cream must be used at the earliest sign of attack in the prodromal phase. The pharmacist can advise patients on the correct treatment and the importance of applying the cream five times a day, washing hands before and after application. Particularly important is the advice on prevention of transmission of the virus such as avoiding kissing, close contact or sharing towels and utensils. The pharmacist and their staff are available to provide this information to customers requesting the cream. This advice and support will not be available to patients purchasing the GSL pack and many patients will not read the leaflet enclosed with the GSL product.

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.

Specific GSL requirements

The CSM has requested that the PIL be amended to emphasise the need for the patient to consult a doctor or pharmacist if there is any doubt about the diagnosis, if the cold sore is severe, or if the cold sore is not fully healed after a course of treatment or gets worse at any time. If despite our concerns, 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.