

CMD(h) RECOMMENDATIONS

**OXYCODONE CONTAINING MEDICINAL PRODUCTS
Labelling and Package Leaflet warning – Taking alcohol**

*Doc. Ref.: CMDh/003/2008
November 2008*

The CMD(h) has agreed to request Marketing Authorisation Holders of oxycodone containing medicinal products to include the following labelling warning and a corresponding warning relevant to the individual product in the package leaflet:

Oxycodone labelling

“WARNING – TAKING ALCOHOL

Do not take these tablets/capsules with alcohol”

Oxycodone package leaflet

“These tablets/capsules should not be taken with alcohol. Alcohol use could increase serious side-effects of oxycodone, such as sleepiness and drowsiness and slow and shallow breathing. These tablets/capsules are designed to release a strong painkiller slowly over 12 hours. Alcohol may speed up the release of oxycodone from the tablet/capsule and this might result in increased side-effects.

Tablets/capsules should be avoided in patients with a history of or present alcohol and drug abuse.”