Diazepam suspension 1 mg/mL

There is no standardised oral formulation for this medicine

The New Zealand Compounding Working Group has decided not to develop a standardised oral formulation batch sheet for diazepam suspension 1 mg/mL at this time. This is due to safety concerns over the quantity of ethanol and propylene glycol used in extemporaneously compounded diazepam formulations.

Are there any other options?

Diazepam tablets disperse easily and rapidly in water. However, as diazepam is practically insoluble in water, tablet dispersion is only suitable if the dose required corresponds to a whole tablet or easily prepared fraction (eg, half or even a quarter tablet if this can be done accurately). As diazepam does not dissolve in water it is not possible to accurately measure out an aliquot from a known volume of water as the drug is in suspension. Dose rounding should also be considered to reduce variability and facilitate dosing.

Examples using a 2.5 mg dose of diazepam:

1. Accurately half a 5 mg tablet and disperse this in water immediately prior to administration

Or

2. Suggest rounding the dose down to 2 mg and disperse a 2 mg tablet in water.

There is also a Section 29 commercial diazepam 10 mg/10 mL oral liquid available (Diazepam Onelink),[1] which is on the Hospital Medicines List but unfunded in the community. This preparation contains ethanol and propylene glycol, so caution is required in children.

Further details

Published data on the stability of extemporaneously compounded diazepam oral liquids are based on formulations that contain ethanol and propylene glycol.[2, 3] Neonates and young children are unable to fully metabolise ethanol and propylene glycol, which can lead to accumulation and toxic effects. If ethanol was used as a solvent in extemporaneously compounded oral diazepam liquid, then a child under 6 years receiving the recommended dose of oral diazepam[4] would ingest a higher daily level of ethanol than recommended. The European Medicines Agency (EMA) have proposed daily safety limits for ethanol of 6 mg/kg for children younger than 6 years and 75 mg/kg for children between 6 and 12 years old.[5]

References

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