NHS
Sheffield
Clinical Commissioning Group

Ranitidine Liquid formulations: ethanol (alcohol) content
Recommendations for primary care prescribers

Background

Ranitidine liquid preparations (oral solution and syrup) contain approximately 800mg ethanol per 10ml. They are licensed for children from 3 years with a caution regarding the ethanol content, which for a 5ml dose is equivalent to 8 to 11ml of beer or 3 to 5ml of wine. There has been no recent change in the ethanol content, but, due to a change in the EU labelling requirements, the ethanol content must be stated on the packaging of the product when it exceeds certain limits. The amount is a labelling requirement and not a safety limit (see further information for more details).

This has, however, led to a re-appraisal of the use of ranitidine liquid preparations at Sheffield Children's Hospital. The pharmacy has issued advice to prescribers where ranitidine effervescent tablets may be a more appropriate formulation.

Advice for primary care prescribers

- If a child is discharged on ranitidine effervescent tablets for on-going therapy, continue this formulation in primary care and do not switch to the liquid product. The parent/carer will have been counselled on administration where a dose less than 150mg is prescribed.

- When initiating prescribing ranitidine to a child, consider the ethanol content and whether this poses a risk to the individual. You may wish to avoid ethanol in the following groups of patients:

  - premature neonates
  - patients with severe liver disease
  - patients who are taking other medicines containing ethanol e.g. Oramorph®, furosemide oral solution (discuss this with a pharmacist)
  - patients who may be more susceptible to the central effects of small amounts of ethanol e.g. patients with ADHD, autism

  If the child has not received the effervescent tablets previously, counsel the parent/carer on administration.

Administration of ranitidine effervescent 150mg tablets

Either:

Disperse one 150mg tablet in 10mls of water and give a proportion corresponding to the correct dose.

Or:

If a patient is on a 37.5mg dose (quarter of a tablet), 75mg dose (half a tablet) or 112.5mg (3/4 of a tablet), the tablet can be split and dispersed in a small amount of water.

Note: there may be inaccuracies in dosing when administration small doses in this way; in addition, each effervescent tablet contains 5mmol sodium.

Ranitidine effervescent tablets are licensed for children from 3 years, which is the same as for the liquid formulations. Use in children under 3 years is therefore 'off-label' but doses are given in the BNFC.

Further Information

Q. Why is ethanol included in children's medicines?

A. Ethanol is used as an additive to many oral solutions to help dissolve the drug and to increase stability. It is generally accepted that medicines for children should be free from ethanol but this is not always possible.

Q. What is a safe limit?

There are FDA safety limits which state that a medicine should not cause a blood alcohol concentration (BAC) of > 25mg/100ml.

Q. What does this mean for my patients on ranitidine liquid preparations?

A. Using these at the BNFC dose will lead to a BAC of 1-3mg/100ml in children. These are very low levels and will not be problematic for the majority of patients.

Q. What are the EU labelling and package information requirements for ethanol?

A. Background Information from the EMA is available here:
http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2014/02/WC500162033.pdf

Prepared by:

Hilde Storkes
Medicines Governance Pharmacist

Heidi Taylor
Clinical Effectiveness Pharmacist

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Acknowledgement: Gillian Hinson Clinical Pharmacy Services Manager –SCH NHSFT