

Ranitidine out of stock – guidance on alternatives

Ranitidine oral preparations as tablets, effervescent tablets and oral solution are expected to be out of stock until further notice.

This is due to global regulatory investigations into possible contamination of the active substance with N-nitrosodimethylamine (NDMA), a probable carcinogen.

Please refer to the THREE Central Alerting System (CAS) alerts issued:

- <https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=102934> (November 2019)
- <https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=102952> (December 2019)
- [May 2020 Medicines Supply notification update](#)

This is likely to be a long-term supply issue as at present, in Europe, all suppliers of ranitidine's active ingredient have had their Certificate of Suitability (CEP) suspended. Therefore, until regulatory investigations are complete, and an uncontaminated supplier of ranitidine active ingredient has been found, no further supplies of ranitidine will be manufactured.

There is no current advice for patients to stop taking ranitidine that is already dispensed to them, as there have been NO patient level recalls. If you receive queries about this issue from patients, advise them not to stop taking their medication as the health risk of discontinuing the medicine is higher than the potential risk presented by the contaminant. The following NHS webpage has a message to support patients:

<https://www.nhs.uk/medicines/ranitidine/>

Recommendations for adults

- No new prescribing of ranitidine.
- Review repeat prescriptions at the point of being requested if still clinically required.
- Stop if no longer clinically indicated.
- If ongoing treatment is required, switch to clinical alternatives:
 - 1st line choice omeprazole. Omeprazole is the first-choice proton pump inhibitor (PPI) as there are currently sufficient supplies to manage an increase in demand
 - 2nd line choice lansoprazole.
- *For adult patients with swallowing difficulties on ranitidine liquid:*
 - 1st line choice – Omeprazole MUPs
 - 2nd line choice – Lansoprazole orodispersible tablets
 - 3rd line choice – omeprazole oral suspension – reserved only for patients on enteral feeding tubes if previously tried orodispersible tablets.

There are currently short-term supply issues affecting the alternative H2 antagonists. These should only be used as an alternative to ranitidine in patients in whom PPIs are unsuitable. Please request advice from the Medicines Optimisation team by emailing MECCG.PIMMS@nhs.net

Guidance for babies and children

The guidance aims to suggest possible alternatives to ranitidine liquid for GORD in babies and children. If the indication for the ranitidine liquid is not GORD (e.g. gastric/duodenal ulceration), then this lies outside the scope of this guidance and specialist advice should be sought.

NICE guidance (NG1) suggests PPIs as an alternative option to ranitidine in the pharmacological management of GORD. It should be noted that treatment of GORD in babies and children with ranitidine/PPIs should be reassessed after a 4 week trial and referral to a specialist (for possible endoscopy) should be considered if symptoms have not resolved or recur after stopping treatment. Treatment with ranitidine/PPIs should only continue beyond the initial 4 week trial in endoscopy proven reflux oesophagitis. For further information on diagnosis and management consult the full NICE guidance a

<https://www.nice.org.uk/guidance/ng1/chapter/1-Recommendations#initial-management-of-gor-and-gord>

Recommended preparations to prescribe:

	Dose and further information - always check BNF for children or SPC	Rationale
<p>1st choice - Omeprazole gastro resistant dispersible tablets 10mg and 20mg (omeprazole MUPs)</p>	<p>700 micrograms/kg once daily, increased if necessary to 3 mg/kg once daily (max. per dose 20 mg). For Child 2–17 years (body-weight 10–19 kg) 10 mg once daily – (max dose 20mg). For Child 2–17 years (body-weight 20 kg and above) 20 mg once daily. (max dose 40mg)</p> <p>Disperses easily in water and can be administered much in the same way as the omeprazole suspension</p> <p>The dispersible tablets (MUPS) can be cut in half using a tablet cutter if the dose is half of the full tablet e.g. 5mg, before dispersing in water.</p> <p>Instructions for use: <i>For patients with swallowing difficulties and for children who can drink or swallow semi-solid food</i></p> <p>Tablet can be broken up and disperse it in a spoonful of non-carbonated water and if required, mix with some fruit juices or applesauce.</p> <p>The dispersion should be taken immediately (or within 30 minutes) and always be stirred just before drinking and rinsed down with half a glass of water. DO NOT USE milk or carbonated water. The enteric-coated pellets must not be chewed.</p>	<p>Most cost-effective choice</p> <p>Licensed in <u>Children over 1 year of age and ≥ 10 kg</u></p> <p>Off label for <1 year old and <10kg</p>
<p>2nd choice Omeprazole suspension</p>	<p>See dosing above</p> <p>Reserved for patients with enteral feeding tubes that have tried omeprazole MUPS or where omeprazole dosing is not a half or whole of a tablet.</p> <p>There is now a licensed formulation of omeprazole suspension produced by Rosemont. Available as 2mg/ml and 4mg/ml strength.</p> <p>Listed in the drug tariff as Omeprazole 10mg/5ml oral suspension sugar free and Omeprazole 20mg/5ml oral suspension sugar free</p>	<p>Licensed in Children over 1 month of age</p> <p>2mg/ml x 75ml = £92.17</p> <p>4mg/ml x 75ml = £178.35</p>
<p>3rd choice Lansoprazole Fastabs 15mg and 10mg (off license)</p>	<p>For Child (body-weight up to 30 kg) 0.5–1 mg/kg once daily (max. per dose 15 mg once daily), doses to be taken in the morning. For Child (body-weight 30 kg and above) 15–30 mg once daily, doses to be taken in the morning.</p> <p>Orodispersible tablets should be placed on the tongue, allowed to disperse and swallowed, or may be swallowed whole with a glass of water. Alternatively, tablets can be dispersed in a small amount of water and administered by an oral syringe. Some guidance advises that for doses less than 15mg, the dose can be rounded to the nearest quarter/half tablet (a tablet cutter should be used).</p>	<p>Not licensed in children</p>

Reference: Barnsley Guidance on Alternatives to Ranitidine Liquid for Gastro-Oesophageal Reflux Disease in Babies and Children