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Ranitidine Oral Solution

Products approved by Health Canada[1]:

Ingredient	Strength	Brand name	DIN	MFR
RANITIDINE	15MG/ML ORAL SOLUTION	NOVO-RANIDINE	02242940	NOP
RANITIDINE	15MG/ML ORAL SOLUTION	APO-RANITIDINE	02280833	APX

Shortage management:

1. **Ensure valid indication for ranitidine solution.**
    - Acid suppressants are not recommended for uncomplicated gastroesophageal reflux in infants in the absence of warning signals such as poor weight gain, poor feeding, or unusual irritability.[2,3]
2. **If dose corresponds to tablet strengths** (75, 150, 300 mg), tablet can be crushed and mixed with soft food such as apple sauce immediately prior to administering.
3. **Prepare extemporaneous ranitidine liquid formulation[4]**
    - Ranitidine 15 mg/ml Simple Syrup Suspension[5]

Ingredients	Quantity
Ranitidine 150 mg	10 tablets
Distilled or Sterile water	50 mL
Simple syrup	qs to 100 mL

Directions:
1. In a mortar, crush tablets and triturate to a smooth powder.
2. Gradually add water. Mix well.
3. Pour into a graduated cylinder.
4. QS to final volume with simple syrup.
5. Transfer to final container and label.

Shake well. Pour immediately after shaking as suspension settles out rapidly.
Stability: 7 days at room temperature in amber plastic bottle.

- More recent investigations of the stability of extemporaneous ranitidine preparations in various strengths and vehicles, including Ora-Plus, report little or no loss of active ingredient for extended periods when stored at room temperature and refrigerated.[6,7] We do not have access to the original research papers and cannot assess the reliability of these results; furthermore, the form of ranitidine used (eg. powder, commercial

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tablet, injectable, other) is unknown as are the specific procedures followed to compound. Therefore, we would recommend following the USP guidelines for a situation where the stability of an extemporaneous product is unknown i.e. **refrigerate and use within 14 days.**[8]

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medSask, March 2015.

References:

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5. Karnes HT, Harris SR, Garnett WR, et al. Concentration uniformity of extemporaneously prepared ranitidine suspension. Am J Hosp Pharm. 1989;46:304-7.
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