Ranitidine Oral Solution

Products approved by Health Canada¹:

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Strength</th>
<th>Brand name</th>
<th>DIN</th>
<th>MFR</th>
</tr>
</thead>
<tbody>
<tr>
<td>RANITIDINE</td>
<td>15MG/ML ORAL SOLUTION</td>
<td>NOVO-RANIDINE</td>
<td>02242940</td>
<td>NOP</td>
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<tr>
<td>RANITIDINE</td>
<td>15MG/ML ORAL SOLUTION</td>
<td>APO-RANITIDINE</td>
<td>02280833</td>
<td>APX</td>
</tr>
</tbody>
</table>

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 formulation⁴
   - Ranitidine 15 mg/ml Simple Syrup Suspension⁵
     
     **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
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.  

Prepared by Karen Jensen, BSP, MSc. Reviewed by Carmen Bell, BSP
medSask, March 2015.

References: