ketoconazole 20 mg/mL Oral Suspension

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Mfr</th>
<th>Lot #</th>
<th>Expiry Date</th>
<th>Quantity</th>
<th>Measured</th>
<th>Checked</th>
</tr>
</thead>
<tbody>
<tr>
<td>ketoconazole</td>
<td>TEVA/APO</td>
<td></td>
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<tr>
<td>200 mg tablets</td>
<td></td>
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<tr>
<td>ORA-Blend</td>
<td>Perrigo</td>
<td></td>
<td></td>
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<tr>
<td>q.s. 30 mL</td>
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</tbody>
</table>

Additional Information:

Equipment:
- mortar and pestle
- glass stirring rod
- graduated measure

Procedure:

Follow your Dept. procedures for risk assessment/training/PPE/equipment/facilities/NAPRA level

1. Crush tablets in the mortar to a fine powder with a pestle, or, soak tablets in a small amount of vehicle for a minimum of 30 minutes.

2. Add a small amount of vehicle to powder and levigate to a smooth paste with a pestle (fan turned on). If soaked tablets, then levigate tablets into a smooth paste with a pestle. Continue to levigate as vehicle is added in small amounts until a liquid is formed.

3. Transfer liquid contents from mortar to graduate.

4. Use a small amount of vehicle to rinse mortar and add it to graduate.

5. Use vehicle to q.s. to the final volume. Stir well.

6. Transfer to amber bottle and label.

Quality Control:

Expected Product Appearance
- White to light pink suspension

Additional Notes

Storage: Room temperature
Packaging: Amber glass/plastic PET bottles
BUD: 60 days

Sample Label:

ketoconazole 20 mg/mL Oral Suspension
Lot: BUD:
Room Temperature Shake Well

Date Made/Prepared By/Checked By: ________________

Reference:


Formulation Reviewed: October, 2020

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