855-GOO-BLUE (855-466-2583) Toll Free Phone 855-445-1119 Toll Free Fax info@valiantrx.com www.valiantrx.com



Mouthwash Oral Treatment

Benefits

- Possible uses include treatment of oral mucositis (mouth sores) such as thrush (candidiasis), strep throat, radiation induced mouth sores and oral surgery problems.
 - Doctors may prescribe medications for off-label use, meaning the FDA has not approved the medication to treat that specific condition. Ask your pharmacist or physician if you have any questions regarding the use of your medication.
- The amount of time it takes to see the full effects of the medication varies between each patient. Consult your prescriber for additional information.

Side Effects

- Possible side effects include dry mouth, nausea, dizziness, fatigue, sedation, skin irritation, and nasal/throat dryness.
- There are no reported severe side effects, but it is still possible for severe side effects to occur.
 - If you experience a severe side effect while taking this medication, please call your physician immediately. You may also report the side effects to the FDA Med-Watch Program at 1-800-FDA-1088.

Administration

- Always follow the directions on your prescription label on how to take your medication.
- Use this medication orally:
 - Oral solution: swish and spit or wish and swallow according to the prescription bottle label directions using the measuring device provided.
- Do not eat or drink anything until the feeling has returned to the treated area.
 - Choking may occur as some of the ingredients may cause your mouth and throat to feel numb.

Additional Information/Warnings

Avoid drinking alcohol while taking this medication.

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- If you miss a dose of this medication, take it as soon as possible. If it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take 2 doses at once. If you have any questions, please contact your physician or pharmacist.
- Before taking this medication, tell your healthcare provider about all the medications you are currently taking including prescription medications, herbal supplements, vitamins, and over-the-counter medications.
- Call your doctor immediately if you are pregnant, intend to become pregnant, or intend to breastfeed. Your doctor will need to review each medication used during pregnancy or breastfeeding.
- Continue to have routine appointments with your physician to assess and monitor your response to the medication and condition as recommended.
- Do not share medication with another person, even if they have the same symptoms you are experiencing.
- The information in this patient advisory leaflet is not intended to cover all possible uses, directions, precautions, drug interactions, or adverse effects. If you have questions about the medicines, you are taking or would like more information, check with your doctor or pharmacist.
- This compound medication is customized for the patient and is exclusively available with the prescription from a prescriber.
- Please refer to receipt for a list of ingredients in your medication.

Storage

- Refer to the label on your prescription for refrigeration requirements (do not freeze).
 - If refrigeration is NOT required- store medication at room temperature in a cool, dry place. Do not store it in the bathroom, a vehicle, or any other location with varying temperatures or humidity.
 - If refrigeration is required, store in the refrigerator out of reach of children.
- Compounded medications are not usually prepared in child resistant containers and should be kept away from children and pets. If you would like to have a lockable zip lock bag for your compounded medications, please call the pharmacy and ask the technician to include child resistant packaging with your refills.
- Unused medications left in the medicine cabinet can be a temptation for children and teenagers. Discard unused medications promptly. Do not flush drugs down the toilet or into the sink drain as they could be hazardous to the environment. Contact your local

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disposal company for more details about how to safely discard medications when they are expired or no longer needed. Big Red Barrel and Yellow Jug are national drug disposal programs. Visit www.bigredbarrel.com

• Contamination may be present in the oral solution if a color change occurs, or dark spots appear. If any of which are present, do not use and contact pharmacy at 734-545-1117 extension 0 and ask to speak to a representative.

Prescription Expiration & Medication Beyond Use Date

- Refer to the label for the expiration date of your prescription.
 - Your prescription expires in two ways:
 - You have used all the refills prescribed.
 - The prescription has reached the expiration date of one year (or six months for controlled drugs).
 - When a prescription expires, allow plenty of time to visit your doctor and for the pharmacist to compound your prescription renewal.
- Refer to the discard date or beyond use date on your bottle to learn when your medication should be discarded. Compounded medications have a shorter shelf life than those of manufactured drugs. The beyond use date is the longest date we can guarantee full potency of your medication.

The following medications may be included in your compounded prescription. Please read the prescription ingredient label for a complete list.

Positive Side Effects

- **Diphenhydramine** is an antihistamine used to calm redness and irritation caused by sore throat or oral thrush.
- **Lidocaine**-is a numbing agent that helps soothe the pain of severe mouth sores caused by thrush, cancer treatments or medical procedures.
- Nystatin-antifungal treatment for yeast infections found in the alimentary canal (mouth, gut, intestine)
- **Tetracaine** is a numbing agent that helps soothe the pain of severe mouth sores caused by thrush, cancer treatments or medical procedures.
- Mylanta[®]-is an anti-acid that neutralizes acids.
- Maalox[®]-is an anti-acid that neutralizes acids.

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Negative Side Effects-Report serious side effects

- **Diphenhydramine**-dry mouth, drowsiness, dizziness, nausea, vomiting, constipation, headache
- **Lidocain**e-rash, itching, hives, shallow breathing, difficulty swallowing, drowsiness, blurred vision, or shakiness.
- **Nystatin**-May cause diarrhea, nausea, stomach pain, skin rash
- **Tetracaine** rash, itching, hives, shallow breathing, difficulty swallowing, drowsiness, blurred vision, or shakiness.
- Mylanta®- Tell your doctor about all medications and over-the-counter products you are taking. May cause constipation or diarrhea. Unlikely side effects may include rash, hives, and swelling of the face, lips or tongue, loss of appetite, muscle weakness, nausea, and slow reflexes and/or vomiting. Do not use it if you have kidney disorder.
- Maalox®-Tell your doctor about all medications and over-the-counter products you are taking. May cause constipation or diarrhea. Unlikely side effects may include rash, hives, and swelling of the face, lips or tongue, loss of appetite, muscle weakness, nausea, and slow reflexes and/or vomiting. Do not use it if you have severe kidney disorder.

Please contact Valiant Compounding Pharmacy at 734-545-1117 or toll free at 855-466-2583 with any questions, concerns, or for prescription refills.

