



KEYSTONE FOLDING BOX CO.  
367 VERONA AVENUE  
NEWARK, NJ 07104  
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P02826 Granules Pharma Valganciclovir  
Prog# GRAN007A  
12/13/21 MS



Red dielines do not print

CUSTOMER APPROVAL

**ATTENTION: Please proofread carefully.** Keystone cannot be held responsible for any typographical errors or omissions either in format or content. By signing this proof you are agreeing to these terms, and authorizing its release into production under these conditions.

**THIS PROOF MUST BE SIGNED AND RETURNED**

Signature: \_\_\_\_\_  
Date: \_\_\_\_\_ As is  With Corrections

Each mL of constituted oral solution contains 50 mg valganciclovir free base.

50 mg/1 mL

Valganciclovir Hydrochloride for Oral Solution

NDC 70069-810-01

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Valganciclovir Hydrochloride for Oral Solution

50 mg/1 mL

Each mL of constituted oral solution contains 50 mg valganciclovir free base.

Rx only

100 mL (3.4 fl oz)



Manufactured for: Somerset Therapeutics, LLC  
Hollywood, FL 33024

Manufactured by: Granules Pharmaceuticals Inc.,  
Chantilly, VA 20151

Rev. 11/21  
DC0017-00

Net contents after constitution: 100 mL, containing 5 grams valganciclovir free base. Deliverable volume after constitution: 88 mL.

**Usual Dosage:** For dosage recommendations, handling and other important prescribing information, read accompanying insert.

**Store dry powder at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].**

**Store constituted solution under refrigeration at 2° to 8°C (36° to 46°F). Do not freeze.**

Store in the original bottle. Keep the bottle tightly closed. Avoid direct contact with powder and constituted solution. Discard any unused portion 49 days after constitution.

NDC 70069-810-01

Valganciclovir Hydrochloride for Oral Solution

50 mg/1 mL

Each mL of constituted oral solution contains 50 mg valganciclovir free base.

Rx only

100 mL (3.4 fl oz)



**To the pharmacist:** Measure 91 mL of purified water in a graduated cylinder. Shake closed bottle to loosen the powder. Remove the child resistant cap and add approximately half the total amount of water for constitution to the bottle and shake the closed bottle well for about 1 minute. Add the remainder of water and shake the closed bottle well for about 1 minute.

This solution contains 50 mg of valganciclovir free base per 1 mL.

Remove the child resistant cap and push the bottle adapter into the neck of the bottle.

Close bottle with child resistant cap tightly. This will assure the proper seating of the bottle adapter in the bottle and child resistant status of the cap. The constituted oral solution should be used within 49 days of preparation; write the date of expiration of the constituted oral solution on the bottle label.

Dispense with patient instructions and 2 oral dispensers. Contains 1 bottle of 12 g oral solution, 1 bottle adapter and 2 oral dispensers.

See enclosed patient instructions for use of oral dispenser.



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