

Attachment 1

FDA Approved Provocholine[®] Labeling 100 mg/vial

Exp.

Lot No.

The vial contains 100 mg Methacholine Chloride USP powder for the preparation of stock solution and dilutions.
A sterile bacterial-retentive filter (pore size 0.22µm) should be used when transferring a solution from each vial (at least 2 mL) to a nebulizer.

20 mL size container

For Oral Inhalation Only

NDC 64281-100-00

PROVOCHOLINE®
(Methacholine Chloride USP)
Powder For Inhalation

100 mg

WARNING: Not for Injection.

Manufactured by Parcep for
Purdue Pharma, Inc.
Kalamazoo, Michigan
Manufactured in Canada N3T 2V6
Rx Only

For use as a challenge test under physician supervision only.
Storage: Store powder at 59° to 86°F.
Refrigerate solutions at 36° to 46°F.
IMPORTANT: For directions, warnings and other important use information, read accompanying insert.



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