

CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER

20-364/SE8-016

Final Printed Labeling

Labeling: WORKING COPY
NDA No. 20-9661 Rcd. 53
Reviewed by: CU 6/13/02

Exp.
Lot
85043502
Novartis Pharmaceuticals Corp.
East Hanover, NJ 07936
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NDC 0078-9364-01
LOTREL[®] 10/20
amlodipine besylate
(equivalent to amlodipine 10 mg)
benazepril HCl 20 mg
4 capsules
Physician
Sample—
Not for Sale
Rx only
NOVARTIS

Store at 25°C (77°F);
excursions permitted to
15°C-30°C (59°F-86°F).
[See USP controlled room
temperature.]
Protect from moisture.
Dispense in light container
(USP).
Keep this and all drugs out
of the reach of children.

85043702 ©2002 Novartis
Store at 25°C (77°F); excursions
permitted to 15°C-30°C (59°F-86°F).
[See USP controlled room
temperature.]
Protect from moisture.
Dispense in tight container (USP).
Keep this and all drugs out of the
reach of children.
Novartis Pharmaceuticals Corp.
East Hanover, New Jersey 07936

NDC 0078-0364-05
Lotrel[®] 10/20
amlodipine besylate
(equivalent to amlodipine 10 mg)
benazepril HCl 20 mg
100 capsules
Rx only
NOVARTIS



EXP.
LOT

NDC 0078-9364-01
LOTREL[®]
amlodipine besylate
(equivalent to amlodipine 10 mg)
benazepril HCl 20 mg
10/20 mg per capsule
Physician Sample—
Not for Sale
Rx only
4 capsules
Novartis Pharmaceuticals Corp.
East Hanover, NJ 07936
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