

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 19834/S009

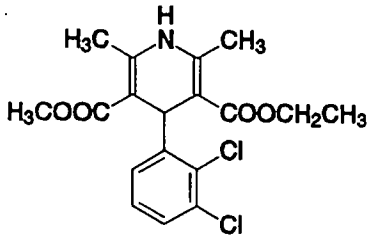

CHEMISTRY REVIEW(S)

NDA 19-834

PLENDIL

ASTRA-MERCK

OCT - 9 1997

CHEMIST'S REVIEW		1. ORGANIZATION HFD - 110	2. NDA Number 19-834
3. Name and Address of Applicant (City & State) Astra Merck 725 Chesterbrook Blvd. Wayne, Pa 19087-5677		4. Supplement(s) Number/Date 009 SLR-013 (AF) 10-02-97	
5. Drug Name PLENDIL	6. Nonproprietary Name Felodipine		8. Amendments & Other (reports, etc) - Dates
7. Supplement Provides For: Final Printed Labeling			
9. Pharmacological Category Hypertension	10. How Dispensed <input checked="" type="checkbox"/> / RX <input type="checkbox"/> / OTC		11. Related IND(s) / NDA(s) / DMF(s)
12. Dosage Form(s) Tablets	13. Potency(ies) 2.5 mg, 5 mg and 10 mg		
14. Chemical Name and Structure (±) Ethylmethyl 4-(2,3-dichlorophenyl)-1,4-dihydro-2,6-dimethyl-3,5-pyridine-dicarboxylate. 			15. Records/Reports Current <input checked="" type="checkbox"/> / Yes <input type="checkbox"/> / No Reviewed <input checked="" type="checkbox"/> / Yes <input type="checkbox"/> / No
16. Comments: The applicant provided Final Printed Labeling as per Agency's letter of May 13, 1997 and subsequent response submitted on June 20, 1997 and telephone conversation with Mr. David Roeder of Agency. The labeling revisions did not effect "DESCRIPTION" AND " HOW SUPPLIED" sections.			
17. Conclusions and Recommendations: The "DESCRIPTION" AND " HOW SUPPLIED" sections remain satisfactory.			
18. REVIEWER			
Name Ramsharan D. Mittal	Signature 		Date Completed 10-08-97
19. Distribution: <input type="checkbox"/> / Original Jacket <input type="checkbox"/> / Reviewer <input type="checkbox"/> / Division File <input type="checkbox"/> / CSO			

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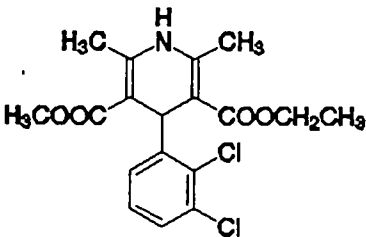
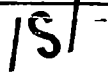
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JUL 7 1997

NDA 19-834

PLENDIL

ASTRA-MERCK

CHEMIST'S REVIEW		1. ORGANIZATION HFD - 110	2. NDA Number 19-834
3. Name and Address of Applicant (City & State) Astra Merck 725 Chesterbrook Blvd. Wayne, Pa 19087-5677		4. Supplement(s) Number/Date SLR-009 (BL) 06-20-97	
5. Drug Name PLENDIL	6. Nonproprietary Name Felodipine		8. Amendments & Other (reports, etc) - Dates
7. Supplement Provides For: Revised labeling as par Agency's letter of May 13, 1997.			
9. Pharmacological Category Hypertension	10. How Dispensed <input checked="" type="checkbox"/> / RX <input type="checkbox"/> / OTC		11. Related IND(s)/ NDA(s)/DMF(s)
12. Dosage Form(s) Tablets	13. Potency(ies) 2.5 mg, 5 mg and 10 mg		
14. Chemical Name and Structure (±) Ethylmethyl 4-(2,3-dichlorophenyl)-1,4-dihydro-2,6-dimethyl-3,5-pyridine-dicarboxylate. 			15. Records/Reports Current <input checked="" type="checkbox"/> / Yes <input type="checkbox"/> / No Reviewed <input checked="" type="checkbox"/> / Yes <input type="checkbox"/> / No
16. Comments: The circular for Plendil has been revised under CLINICAL PHARMACOLOGY, Pharmacokinetics and Metabolism subsection and DOSAGE AND ADMINISTRATION The labeling revisions did not effect "DESCRIPTION" AND " HOW SUPPLIED" sections.			
17. Conclusions and Recommendations: The "DESCRIPTION" AND " HOW SUPPLIED" sections remain satisfactory.			
18. REVIEWER			
Name Ramsharan D. Mittal	Signature 		Date Completed 07-07-97
19. Distribution: <input checked="" type="checkbox"/> / Original Jacket <input type="checkbox"/> / Reviewer <input type="checkbox"/> / Division File <input type="checkbox"/> / CSO			

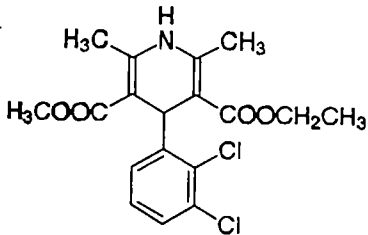
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NDA 19-834

PLENDIL

ASTRA-MERCK

CHEMIST'S REVIEW		1. ORGANIZATION HFD - 110	2. NDA Number 19-834
3. Name and Address of Applicant (City & State) Astra Merck 725 Chesterbrook Blvd. Wayne, Pa 19087-5677		4. Supplement(s) Number/Date SLR-009 09-19-96	
5. Drug Name PLENDIL	6. Nonproprietary Name Felodipine		8. Amendments & Other (reports, etc) - Dates
7. Supplement Provides For: Revised labeling.			
9. Pharmacological Category Hypertension	10. How Dispensed <u>/x/</u> RX <u>/</u> OTC		11. Related IND(s) / NDA(s) / DMF(s)
12. Dosage Form(s) Tablets	13. Potency(ies) 2.5 mg, 5 mg and 10 mg		
14. Chemical Name and Structure (±) Ethylmethyl 4-(2,3-dichlorophenyl)-1,4-dihydro-2,6-dimethyl-3,5-pyridine-dicarboxylate. 			15. Records/Reports Current <u>/x/</u> Yes <u>/</u> No Reviewed <u>/x/</u> Yes <u>/</u> No
16. Comments: The circular for Plendil has been revised under CLINICAL PHARMACOLOGY, Pharmacokinetics and Metabolism and DOSAGE AND ADMINISTRATION to update the information on the effect of food on the metabolism of felodipine. The labeling revisions did not effect "DESCRIPTION" AND "HOW SUPPLIED" sections.			
17. Conclusions and Recommendations: The "DESCRIPTION" AND "HOW SUPPLIED" sections remain satisfactory.			
18. REVIEWER			
Name Ramsharan D. Mittal	Signature <u>/S/</u>		Date Completed 09-24-96
19. Distribution: <u>/</u> Original Jacket <u>/</u> Reviewer <u>/</u> Division File <u>/</u> CSO			

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9/26/96