

ANDA Suitability Petition

Benazepril Hydrochloride and Hydrochlorothiazide Oral Liquid

**APPENDIX 2: FDA ORANGE BOOK – LOTENSIN HCT (ACCESSED
16 SEPTEMBER 2024)**

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

Mkt. Status	Active Ingredient	Proprietary Name	Appl. No.	Product Number	Dosage Form	Route	Strength	TE Code	RLD	RS	Applicant Holder	Approval Date
RX	BENAZEPRIL HYDROCHLORIDE; HYDROXYLOTENSIN HCT		N020033	003	TABLET	ORAL	20MG; 25MG	AB	RLD	RS	VALIDUS PHARMACEUTICALS LLC	May 19, 1992
RX	BENAZEPRIL HYDROCHLORIDE; HYDROXYLOTENSIN HCT		N020033	002	TABLET	ORAL	10MG; 12.5MG	AB	RLD		VALIDUS PHARMACEUTICALS LLC	May 19, 1992
RX	BENAZEPRIL HYDROCHLORIDE; HYDROXYLOTENSIN HCT		N020033	004	TABLET	ORAL	20MG; 12.5MG	AB	RLD		VALIDUS PHARMACEUTICALS LLC	May 19, 1992
DISCN	BENAZEPRIL HYDROCHLORIDE; HYDROXYLOTENSIN HCT		N020033	001	TABLET	ORAL	5MG; 6.25MG **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**		RLD		VALIDUS PHARMACEUTICALS LLC	May 19, 1992
RX	BENAZEPRIL HYDROCHLORIDE; HYDROXYBENAZEPRIL HYDROCHLORIDE AND HY	A076342		001	TABLET	ORAL	5MG; 6.25MG	AB			ANI PHARMACEUTICALS INC	Feb 11, 2004
RX	BENAZEPRIL HYDROCHLORIDE; HYDROXYBENAZEPRIL HYDROCHLORIDE AND HY	A078794		001	TABLET	ORAL	5MG; 6.25MG	AB			APOTEX INC	Aug 21, 2014
RX	BENAZEPRIL HYDROCHLORIDE; HYDROXYBENAZEPRIL HYDROCHLORIDE AND HY	A076631		001	TABLET	ORAL	5MG; 6.25MG	AB			SANDOZ INC	Feb 11, 2004
RX	BENAZEPRIL HYDROCHLORIDE; HYDROXYBENAZEPRIL HYDROCHLORIDE AND HY	A076342		002	TABLET	ORAL	10MG; 12.5MG	AB			ANI PHARMACEUTICALS INC	Feb 11, 2004
RX	BENAZEPRIL HYDROCHLORIDE; HYDROXYBENAZEPRIL HYDROCHLORIDE AND HY	A078794		002	TABLET	ORAL	10MG; 12.5MG	AB			APOTEX INC	Aug 21, 2014
RX	BENAZEPRIL HYDROCHLORIDE; HYDROXYBENAZEPRIL HYDROCHLORIDE AND HY	A076631		002	TABLET	ORAL	10MG; 12.5MG	AB			SANDOZ INC	Feb 11, 2004
RX	BENAZEPRIL HYDROCHLORIDE; HYDROXYBENAZEPRIL HYDROCHLORIDE AND HY	A076342		003	TABLET	ORAL	20MG; 12.5MG	AB			ANI PHARMACEUTICALS INC	Feb 11, 2004
RX	BENAZEPRIL HYDROCHLORIDE; HYDROXYBENAZEPRIL HYDROCHLORIDE AND HY	A078794		003	TABLET	ORAL	20MG; 12.5MG	AB			APOTEX INC	Aug 21, 2014
RX	BENAZEPRIL HYDROCHLORIDE; HYDROXYBENAZEPRIL HYDROCHLORIDE AND HY	A076631		003	TABLET	ORAL	20MG; 12.5MG	AB			SANDOZ INC	Feb 11, 2004
RX	BENAZEPRIL HYDROCHLORIDE; HYDROXYBENAZEPRIL HYDROCHLORIDE AND HY	A076342		004	TABLET	ORAL	20MG; 25MG	AB			ANI PHARMACEUTICALS INC	Feb 11, 2004
RX	BENAZEPRIL HYDROCHLORIDE; HYDROXYBENAZEPRIL HYDROCHLORIDE AND HY	A078794		004	TABLET	ORAL	20MG; 25MG	AB			APOTEX INC	Aug 21, 2014
RX	BENAZEPRIL HYDROCHLORIDE; HYDROXYBENAZEPRIL HYDROCHLORIDE AND HY	A076631		004	TABLET	ORAL	20MG; 25MG	AB			SANDOZ INC	Feb 11, 2004
DISCN	BENAZEPRIL HYDROCHLORIDE; HYDROXYBENAZEPRIL HYDROCHLORIDE AND HY	A076348		001	TABLET	ORAL	5MG; 6.25MG				ANI PHARMACEUTICALS INC	Feb 11, 2004
DISCN	BENAZEPRIL HYDROCHLORIDE; HYDROXYBENAZEPRIL HYDROCHLORIDE AND HY	A076688		001	TABLET	ORAL	5MG; 6.25MG				AUROBINDO PHARMA USA INC	Feb 11, 2004
DISCN	BENAZEPRIL HYDROCHLORIDE; HYDROXYBENAZEPRIL HYDROCHLORIDE AND HY	A076612		001	TABLET	ORAL	5MG; 6.25MG				MYLAN PHARMACEUTICALS INC	Feb 11, 2004
DISCN	BENAZEPRIL HYDROCHLORIDE; HYDROXYBENAZEPRIL HYDROCHLORIDE AND HY	A077483		001	TABLET	ORAL	5MG; 6.25MG				SUN PHARMACEUTICAL INDUSTRIES LTD	Sep 8, 2005
DISCN	BENAZEPRIL HYDROCHLORIDE; HYDROXYBENAZEPRIL HYDROCHLORIDE AND HY	A076348		002	TABLET	ORAL	10MG; 12.5MG				ANI PHARMACEUTICALS INC	Feb 11, 2004
DISCN	BENAZEPRIL HYDROCHLORIDE; HYDROXYBENAZEPRIL HYDROCHLORIDE AND HY	A076688		002	TABLET	ORAL	10MG; 12.5MG				AUROBINDO PHARMA USA INC	Feb 11, 2004
DISCN	BENAZEPRIL HYDROCHLORIDE; HYDROXYBENAZEPRIL HYDROCHLORIDE AND HY	A076612		002	TABLET	ORAL	10MG; 12.5MG				MYLAN PHARMACEUTICALS INC	Feb 11, 2004
DISCN	BENAZEPRIL HYDROCHLORIDE; HYDROXYBENAZEPRIL HYDROCHLORIDE AND HY	A077483		002	TABLET	ORAL	10MG; 12.5MG				SUN PHARMACEUTICAL INDUSTRIES LTD	Sep 8, 2005
DISCN	BENAZEPRIL HYDROCHLORIDE; HYDROXYBENAZEPRIL HYDROCHLORIDE AND HY	A076348		003	TABLET	ORAL	20MG; 12.5MG				ANI PHARMACEUTICALS INC	Feb 11, 2004
DISCN	BENAZEPRIL HYDROCHLORIDE; HYDROXYBENAZEPRIL HYDROCHLORIDE AND HY	A076688		003	TABLET	ORAL	20MG; 12.5MG				AUROBINDO PHARMA USA INC	Feb 11, 2004
DISCN	BENAZEPRIL HYDROCHLORIDE; HYDROXYBENAZEPRIL HYDROCHLORIDE AND HY	A076612		003	TABLET	ORAL	20MG; 12.5MG				MYLAN PHARMACEUTICALS INC	Feb 11, 2004
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