

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
DISCN	BUDESONIDE	RHINOCORT	N020233	001	AEROSOL, METERED	NASAL	0.032MG/INH				ASTRAZENECA LP	Feb 14, 1994
OTC	BUDESONIDE	RHINOCORT ALLERGY	N020746	003	SPRAY, METERED	NASAL	0.032MG/SPRAY		RLD	RS	ASTRAZENECA PHARMACEUTICALS I	Mar 23, 2015
OTC	BUDESONIDE	BUDESONIDE	A078949	002	SPRAY, METERED	NASAL	0.032MG/SPRAY				APOTEX INC RICHMOND HILL	Nov 20, 2015
RX	BUDESONIDE	UCERIS	N205613	001	AEROSOL, FOAM	RECTAL	2MG/ACTUATION		RLD	RS	VALEANT PHARMACEUTICALS INTEF	Oct 7, 2014
RX	BUDESONIDE	BUDESONIDE	A206724	001	CAPSULE	ORAL	3MG	AB			ALVOGEN MALTA OPERATIONS LTD	Nov 23, 2016
RX	BUDESONIDE	BUDESONIDE	A206200	001	CAPSULE	ORAL	3MG	AB			AMNEAL PHARMACEUTICALS OF NE	Jul 31, 2017
RX	BUDESONIDE	BUDESONIDE	A207367	001	CAPSULE	ORAL	3MG	AB			APPCO PHARMA LLC	Apr 7, 2017
RX	BUDESONIDE	BUDESONIDE	A090379	001	CAPSULE	ORAL	3MG	AB			BARR LABORATORIES INC SUB TEVA	Apr 2, 2014
RX	BUDESONIDE	BUDESONIDE	A206623	001	CAPSULE	ORAL	3MG	AB			MAYNE PHARMA LLC	Apr 8, 2016
RX	BUDESONIDE	BUDESONIDE	A090410	001	CAPSULE	ORAL	3MG	AB			MYLAN PHARMACEUTICALS INC	May 16, 2011
RX	BUDESONIDE	BUDESONIDE	A209041	001	CAPSULE	ORAL	3MG	AB			SCIECURE PHARMA INC	Sep 28, 2017
RX	BUDESONIDE	BUDESONIDE	A206134	001	CAPSULE	ORAL	3MG	AB			ZYDUS PHARMACEUTICALS USA INC	May 4, 2017
RX	BUDESONIDE	ENTOCORT EC	N021324	001	CAPSULE	ORAL	3MG	AB	RLD	RS	PERRIGO PHARMA INTERNATIONAL	Oct 2, 2001
RX	BUDESONIDE	PULMICORT FLEXHALER	N021949	001	POWDER, METERED	INHALATION	0.08MG/INH		RLD		ASTRAZENECA LP	Jul 12, 2006
RX	BUDESONIDE	PULMICORT FLEXHALER	N021949	002	POWDER, METERED	INHALATION	0.16MG/INH		RLD	RS	ASTRAZENECA LP	Jul 12, 2006
RX	BUDESONIDE	BUDESONIDE	A078202	001	SUSPENSION	INHALATION	0.25MG/2ML	AN			APOTEX INC	Mar 30, 2009
RX	BUDESONIDE	BUDESONIDE	A205710	001	SUSPENSION	INHALATION	0.25MG/2ML	AN			CIPLA LTD	Nov 16, 2017
RX	BUDESONIDE	BUDESONIDE	A078404	001	SUSPENSION	INHALATION	0.25MG/2ML	AN			IMPAX LABORATORIES INC	Jul 31, 2012
RX	BUDESONIDE	BUDESONIDE	A201966	003	SUSPENSION	INHALATION	0.25MG/2ML	AN			SANDOZ INC	Sep 27, 2013
RX	BUDESONIDE	BUDESONIDE	A077519	001	SUSPENSION	INHALATION	0.25MG/2ML	AN			TEVA PHARMACEUTICALS USA	Nov 18, 2008
RX	BUDESONIDE	BUDESONIDE	A078202	002	SUSPENSION	INHALATION	0.5MG/2ML	AN			APOTEX INC	Mar 30, 2009
RX	BUDESONIDE	BUDESONIDE	A205710	002	SUSPENSION	INHALATION	0.5MG/2ML	AN			CIPLA LTD	Nov 16, 2017
RX	BUDESONIDE	BUDESONIDE	A078404	002	SUSPENSION	INHALATION	0.5MG/2ML	AN			IMPAX LABORATORIES INC	Jul 31, 2012
RX	BUDESONIDE	BUDESONIDE	A201966	002	SUSPENSION	INHALATION	0.5MG/2ML	AN			SANDOZ INC	Sep 27, 2013
RX	BUDESONIDE	BUDESONIDE	A077519	002	SUSPENSION	INHALATION	0.5MG/2ML	AN			TEVA PHARMACEUTICALS USA	Nov 18, 2008
RX	BUDESONIDE	BUDESONIDE	A205710	003	SUSPENSION	INHALATION	1MG/2ML	AN			CIPLA LTD	Nov 16, 2017
RX	BUDESONIDE	BUDESONIDE	A201966	001	SUSPENSION	INHALATION	1MG/2ML	AN			SANDOZ INC	Sep 27, 2013
RX	BUDESONIDE	BUDESONIDE	A204548	001	SUSPENSION	INHALATION	1MG/2ML	AN			TEVA PHARMACEUTICALS USA	Mar 8, 2016
RX	BUDESONIDE	PULMICORT RESPULES	N020929	001	SUSPENSION	INHALATION	0.25MG/2ML	AN	RLD		ASTRAZENECA PHARMACEUTICALS I	Aug 8, 2000
RX	BUDESONIDE	PULMICORT RESPULES	N020929	002	SUSPENSION	INHALATION	0.5MG/2ML	AN	RLD		ASTRAZENECA PHARMACEUTICALS I	Aug 8, 2000
RX	BUDESONIDE	PULMICORT RESPULES	N020929	003	SUSPENSION	INHALATION	1MG/2ML	AN	RLD	RS	ASTRAZENECA PHARMACEUTICALS I	Aug 8, 2000
RX	BUDESONIDE	UCERIS	N203634	001	TABLET, EXTENDED RELEASE	ORAL	9MG	RLD	RS		VALEANT PHARMACEUTICALS INTEF	Jan 14, 2013
RX	BUDESONIDE; FORMOTEROL FUMARATE DIHYDRATE	SYMBICORT	N021929	001	AEROSOL, METERED	INHALATION	0.08MG/INH; 0.0045MG/INH	RLD	RS		ASTRAZENECA LP	Jul 21, 2006
RX	BUDESONIDE; FORMOTEROL FUMARATE DIHYDRATE	SYMBICORT	N021929	002	AEROSOL, METERED	INHALATION	0.16MG/INH; 0.0045MG/INH	RLD	RS		ASTRAZENECA LP	Jul 21, 2006
DISCN	BUDESONIDE	PULMICORT	N020441	002	POWDER, METERED	INHALATION	0.16MG/INH				ASTRAZENECA PHARMACEUTICALS I	Jun 24, 1997
DISCN	BUDESONIDE	PULMICORT	N020441	003	POWDER, METERED	INHALATION	0.32MG/INH				ASTRAZENECA PHARMACEUTICALS I	Jun 24, 1997

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