Drugs@FDA: FDA-Approved Drugs

New Drug Application (NDA): 022200
Company: ASTRAZENECA AB

EMAIL (MAILTO:?SUBJECT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&BODY=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS%26VARAPPLNO=022200)

- Medication Guide (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/022200s034lbl.pdf#page=37)
- Summary Review (http://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/022200Orig1s000SumRedt.pdf)

Products on NDA 022200

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Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
BYDUREON	EXENATIDE SYNTHETIC	2MG/VIAL	FOR SUSPENSION, EXTENDED RELEASE;SUBCUTANEOUS	Discontinued	None	Yes	No
BYDUREON PEN	EXENATIDE SYNTHETIC	2MG	FOR SUSPENSION, EXTENDED RELEASE;SUBCUTANEOUS	Discontinued	None	Yes	No

Showing 1 to 2 of 2 entries

Approval Date(s) and History, Letters, Labels, Reviews for NDA 022200

Original Approvals or Tentative Approvals

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Action Date	Submission	Action Type	Submission Classification	Review Priority; Orphan Status	Letters, Reviews, Labels, Patient Package Insert	Notes
01/27/2012	ORIG-1	Approval	Type 3 - New Dosage Form	STANDARD	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/022200Orig1s000lbledt.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2012/022200Orig1s000_corrected_ltr.pdf) Review (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/022200Orig1s000TOC.cfm) Summary Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/022200Orig1s000SumRedt.pdf)	test

Showing 1 to 1 of 1 entries

Supplements

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Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
12/21/2022	SUPPL-34	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/022200s034lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/022200Orig1s034ltr.pdf)	
07/26/2022	SUPPL-32	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/022200s032lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/022200Orig1s032ltr.pdf)	
06/10/2022	SUPPL-33	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/022200s033lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/022200Orig1s033ltr.pdf)	
07/22/2021	SUPPL-31	Efficacy-New Indication	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/022200s031lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2021/022200Orig1s031ltr.pdf)	
02/28/2020	SUPPL-30	Labeling-Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/022200s030lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/022200Orig1s030ltr.pdf)	
02/15/2019	SUPPL-28	Efficacy-Labeling Change With Clinical Data	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/022200s028lbl.pdf) Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/022200Orig1s028ltr.pdf)	

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
04/02/2018	SUPPL-26	Efficacy-Labeling Change With Clinical Data	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/022200s026lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2018/022200s026ltr.pdf)**	
10/20/2017	SUPPL-25	Efficacy-Labeling Change With Clinical Data	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/022200s025lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/022200Orig1s025ltr.pdf)**	
06/10/2016	SUPPL-24	Manufacturing (CMC)		Label is not available on this site.
01/11/2016	SUPPL-23	Manufacturing (CMC)		Label is not available on this site.
12/31/2015	SUPPL-21	Manufacturing (CMC)		Label is not available on this site.
12/23/2015	SUPPL-22	Manufacturing (CMC)		Label is not available on this site.
09/24/2015	SUPPL-18	Efficacy-Labeling Change With Clinical Data	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/022200s015s016s017s018lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/022200Orig1s015,s016,s017,s018ltr.pdf)**	
09/24/2015	SUPPL-17	Efficacy-Labeling Change With Clinical Data	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/022200s015s016s017s018lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/022200Orig1s015,s016,s017,s018ltr.pdf)**	
09/24/2015	SUPPL-16	Efficacy-Labeling Change With Clinical Data	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/022200s015s016s017s018lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/022200Orig1s015,s016,s017,s018ltr.pdf)**	
09/24/2015	SUPPL-15	Efficacy-Labeling Change With Clinical Data	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/022200s015s016s017s018lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/022200Orig1s015,s016,s017,s018ltr.pdf)**	
09/18/2015	SUPPL-20	Labeling-Container/Carton Labels	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/022200s020lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/022200Orig1s020ltr.pdf)**	
08/14/2015	SUPPL-11	Manufacturing (CMC)		Label is not available on this site.
04/29/2015	SUPPL-10	REMS-Assessment, REMS-Modified	**Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/022200Orig1s010ltr.pdf)**	Label is not available on this site.
03/09/2015	SUPPL-19	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/022200s019lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/022200Orig1s019ltr.pdf)**	
03/05/2015	SUPPL-14	Manufacturing (CMC)	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/022200s014lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/022200Orig1s014ltr.pdf)**	
05/22/2014	SUPPL-13	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/022200s012s013lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2014/022200Orig1s012,s013ltr.pdf)**	
05/22/2014	SUPPL-12	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/022200s012s013lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2014/022200Orig1s012,s013ltr.pdf)**	
03/24/2014	SUPPL-9	Manufacturing (CMC)		Label is not available on this site.
02/28/2014	SUPPL-8	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/022200s008lbl.pdf)** **Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2014/022200Orig1s008ltr.pdf)** **Review (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/022200Orig1s008.pdf)**	
02/28/2014	SUPPL-7	Labeling-Proprietary Name Change		Label is not available on this site.

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
06/12/2013	SUPPL-4	Manufacturing (CMC)		Label is not available on this site.
02/27/2013	SUPPL-5	Manufacturing (CMC)		Label is not available on this site.

Showing 1 to 28 of 28 entries

Labels for NDA 022200

Drugs@FDA: FDA-Approved Drugs

New Drug Application (NDA): 022200
Company: ASTRAZENECA AB

EMAIL (MAILTO:?SUBJECT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&BODY=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS%26VARAPPLNO=022200)

- Medication Guide (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/022200s034lbl.pdf#page=37)
- Summary Review (http://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/022200Orig1s000SumRedt.pdf)

Products on NDA 022200

Approval Date(s) and History, Letters, Labels, Reviews for NDA 022200

Labels for NDA 022200

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Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
12/21/2022	SUPPL-34	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/022200s034lbl.pdf)**	
07/26/2022	SUPPL-32	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/022200s032lbl.pdf)**	
06/10/2022	SUPPL-33	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/022200s033lbl.pdf)**	
07/22/2021	SUPPL-31	Efficacy-New Indication	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/022200s031lbl.pdf)**	
02/28/2020	SUPPL-30	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/022200s030lbl.pdf)**	
02/15/2019	SUPPL-28	Efficacy-Labeling Change With Clinical Data	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/022200s028lbl.pdf)**	
04/02/2018	SUPPL-26	Efficacy-Labeling Change With Clinical Data	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/022200s026lbl.pdf)**	
10/20/2017	SUPPL-25	Efficacy-Labeling Change With Clinical Data	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/022200s025lbl.pdf)**	
09/24/2015	SUPPL-18	Efficacy-Labeling Change With Clinical Data	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/022200s015s016s017s018lbl.pdf)**	
09/24/2015	SUPPL-17	Efficacy-Labeling Change With Clinical Data	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/022200s015s016s017s018lbl.pdf)**	
09/24/2015	SUPPL-16	Efficacy-Labeling Change With Clinical Data	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/022200s015s016s017s018lbl.pdf)**	
09/24/2015	SUPPL-15	Efficacy-Labeling Change With Clinical Data	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/022200s015s016s017s018lbl.pdf)**	
09/18/2015	SUPPL-20	Labeling-Container/Carton Labels	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/022200s020lbl.pdf)**	

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
03/09/2015	SUPPL-19	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/022200s019lbl.pdf)**	
03/05/2015	SUPPL-14	Manufacturing (CMC)	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/022200s014lbl.pdf)**	This supplement type does not usually require new labeling.
05/22/2014	SUPPL-13	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/022200s012s013lbl.pdf)**	
05/22/2014	SUPPL-12	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/022200s012s013lbl.pdf)**	
02/28/2014	SUPPL-8	Labeling-Package Insert	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/022200s008lbl.pdf)**	
01/27/2012	ORIG-1	Approval	**Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/022200Orig1s000lbledt.pdf)**	test

Showing 1 to 19 of 19 entries