MODEL AA-8565CV-ACT MODEL AA-8565CV- emergency response safety kit
Aerospace Accessory Service, Inc

Model AA-8565CV-ACT
Model AA-8565CV

Aerospace Accessory Service

Aerospace Accessory Service

P/N:

S/N:

EXP:

Prep. By:

AEROSPACE AA ACCESSORY

F.A.A. No XM4R653M **SERVICE** E.A.S.A. No EASA 145.5194

P/N: _____ **EXP:** ____/____/____

S/N: _____ **PREP. BY:** _____

IF SEAL IS BROKEN OR EXPIRATION DATE ARRIVES,
REMOVE IMMEDIATELY FOR RE-CERTIFICATION

Aerospace Accessory Service, Inc.
Ph: 305-594-1955 Fax: 305-470-2026
www.aerospaceaccessory.com

MODEL AA-8565CV-ACT MODEL AA-8565CV

emergency response safety kit kit

Product Information

Product Type	MEDICAL DEVICE	**Item Code (Source)**	NHRIC:27860-013

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:27860-013-16	1 in 1 PACKAGE; Type 1: Convenience Kit of Co-Package		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1		1
Part 2		2
Part 3		3
Part 4		4
Part 5		10
Part 6		11
Part 7		12
Part 8		13
Part 9		14
Part 10		16
Part 11		17
Part 12		18
Part 13		19
Part 14		15
Part 15		9
Part 16		8
Part 17		7
Part 18		6
Part 19		5
Part 20		1
Part 21		20
Part 22		21
Part 23		22
Part 24		23

Part 25		24
Part 26		25
Part 27		26
Part 28		27

Part 1 of 28

SODIUM CHLORIDE

sodium chloride injection, solution

Product Information

Item Code (Source)	NDC:0338-0049
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698, SODIUM CATION - UNII:LYR4M0NH37)	SODIUM CHLORIDE	9 g in 1000 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA016677	12/09/1970	

Part 2 of 28

SODIUM CHLORIDE

sodium chloride injection, solution

Product Information

Item Code (Source)	NDC:0264-7800
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM CHLORIDE (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698, SODIUM CATION - UNII:LYR4M0NH37)	SODIUM CHLORIDE	0.9 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019635	03/09/1988	

Part 3 of 28

ATROPINE SULFATE

atropine sulfate injection, solution

Product Information	
Item Code (Source)	NDC:0409-4910
Route of Administration	INTRAMUSCULAR, INTRAVENOUS, SUBCUTANEOUS, ENDOTRACHEAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ATROPINE SULFATE (UNII: 03J5ZE7KA5) (ATROPINE - UNII:7C0697DR9I)	ATROPINE SULFATE	0.1 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SULFURIC ACID (UNII: O40UQP6WCF)	
WATER (UNII: 059QF0KO0R)	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021146	01/19/2006	

Part 4 of 28

ATROPINE SULFATE

atropine sulfate injection

Product Information	
Item Code (Source)	NDC:76329-3339
Route of Administration	PARENTERAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Atropine Sulfate (UNII: 03J5ZE7KA5) (ATROPINE - UNII:7C0697DR9I)	Atropine Sulfate	0.1 mg in 1 mL

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		06/01/2000	

Part 5 of 28

DEXTROSE MONOHYDRATE

dextrose monohydrate injection

Product Information	
Item Code (Source)	NDC:76329-3301
Route of Administration	PARENTERAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	DEXTROSE MONOHYDRATE	500 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Water (UNII: 059QF0KO0R)	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		06/01/2000	

Part 6 of 28

DEXTROSE

dextrose monohydrate injection, solution

Product Information

Item Code (Source)	NDC:0409-6648
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	DEXTROSE MONOHYDRATE	25 g in 50 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019445	12/02/2005	

Part 7 of 28

NITROGLYCERIN

nitroglycerin tablet

Product Information

Item Code (Source)	NDC:68462-639
Route of Administration	SUBLINGUAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
NITROGLYCERIN (UNII: G59M7S0WS3) (NITROGLYCERIN - UNII:G59M7S0WS3)	NITROGLYCERIN	0.4 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CALCIUM STEARATE (UNII: 776XM7047L)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)	

Product Characteristics			
Color	white (white to off white)	**Score**	no score
Shape	ROUND (Flat faced)	**Size**	4mm
Flavor		**Imprint Code**	2;C
Contains			

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA206391	08/19/2017	

Part 8 of 28

DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride injection

Product Information	
Item Code (Source)	NDC:0641-0376
Route of Administration	INTRAMUSCULAR, INTRAVENOUS

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	50 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
BENZETHONIUM CHLORIDE (UNII: PH41D05744)	
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

HYDROCHLORIC ACID (UNII: QTT17582CB)	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA080817	11/27/1972	

Part 9 of 28

EPINEPHRINE

epinephrine injection, solution, concentrate

Product Information

Item Code (Source)	NDC:54288-103
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Epinephrine (UNII: YKH834O4BH) (EPINEPHRINE - UNII:YKH834O4BH)	Epinephrine	1 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Sodium Chloride (UNII: 451W47IQ8X)	
Hydrochloric Acid (UNII: QTT17582CB)	
Water (UNII: 059QF0KO0R)	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA205029	08/08/2014	

Part 10 of 28

ALCOHOL PREP

isopropyl alcohol swab

Product Information

Item Code (Source)	NDC:67777-121

Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	0.7 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/01/2010	

Part 11 of 28

MOORE MEDICAL NON ASPIRIN

acetaminophen tablet, film coated

Product Information

Item Code (Source)	NDC:55670-467
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg

Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	white (white)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	10mm
Flavor		**Imprint Code**	AZ;234
Contains			

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	12/30/2008	

Part 12 of 28

ASPIRIN

aspirin tablet, film coated

Product Information	
Item Code (Source)	NDC:55670-131
Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	325 mg

Inactive Ingredients	
Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MINERAL OIL (UNII: T5L8T28FGP)	
STARCH, CORN (UNII: O8232NY3SJ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	white (white)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	10mm
Flavor		**Imprint Code**	TCL;011
Contains			

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part343	12/30/2008	08/31/2022

Part 13 of 28

MOOREBRAND ASPIRIN

aspirin tablet, film coated

Product Information

Item Code (Source)	NDC:55670-616(NDC:50844-957)
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	325 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	

Product Characteristics

Color	white	**Score**	no score
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	Aspirin;44;157
Contains			

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	10/05/2020	

Part 14 of 28

VENTOLIN HFA

albuterol sulfate aerosol, metered

Product Information	
Item Code (Source)	NDC:0173-0682
Route of Administration	RESPIRATORY (INHALATION)

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALBUTEROL SULFATE (UNII: 021SEF3731) (ALBUTEROL - UNII:QF8SVZ843E)	ALBUTEROL	90 ug

Inactive Ingredients	
Ingredient Name	**Strength**
NORFLURANE (UNII: DH9E53K1Y8)	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020983	06/09/2006	

Part 15 of 28

ALBUTEROL SULFATE HFA

albuterol sulfate aerosol, metered

Product Information	
Item Code (Source)	NDC:66993-019
Route of Administration	RESPIRATORY (INHALATION)

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALBUTEROL SULFATE (UNII: 021SEF3731) (ALBUTEROL - UNII:QF8SVZ843E)	ALBUTEROL	90 ug

Inactive Ingredients	
Ingredient Name	**Strength**
NORFLURANE (UNII: DH9E53K1Y8)	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA authorized generic	NDA020983	01/15/2019	

Part 16 of 28

ALBUTEROL SULFATE

albuterol sulfate aerosol, metered

Product Information

Item Code (Source)	NDC:45802-088
Route of Administration	RESPIRATORY (INHALATION)

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALBUTEROL SULFATE (UNII: 021SEF3731) (ALBUTEROL - UNII:QF8SVZ843E)	ALBUTEROL	90 ug

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
NORFLURANE (UNII: DH9E53K1Y8)	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA203760	02/26/2020	

Part 17 of 28

ALBUTEROL SULFATE HFA

albuterol sulfate aerosol, metered

Product Information

Item Code (Source)	NDC:0093-3174
Route of Administration	RESPIRATORY (INHALATION)

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALBUTEROL SULFATE (UNII: 021SEF3731) (ALBUTEROL - UNII:QF8SVZ843E)	ALBUTEROL	90 ug

Inactive Ingredients

Ingredient Name	Strength
NORFLURANE (UNII: DH9E53K1Y8)	
ALCOHOL (UNII: 3K9958V90M)	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021457	01/16/2019	

Part 18 of 28

ALBUTEROL SULFATE

albuterol sulfate inhalant

Product Information

Item Code (Source)	NDC:69097-142
Route of Administration	RESPIRATORY (INHALATION)

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALBUTEROL SULFATE (UNII: 021SEF3731) (ALBUTEROL - UNII:QF8SVZ843E)	ALBUTEROL	108 ug

Inactive Ingredients

Ingredient Name	Strength
OLEIC ACID (UNII: 2UMI9U37CP)	
NORFLURANE (UNII: DH9E53K1Y8)	
ALCOHOL (UNII: 3K9958V90M)	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA209959	04/08/2020	

Part 19 of 28

ALBUTEROL SULFATE

albuterol sulfate aerosol, metered

Product Information

Item Code (Source)	NDC:0254-1007
Route of Administration	RESPIRATORY (INHALATION)

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALBUTEROL SULFATE (UNII: 021SEF3731) (ALBUTEROL - UNII:QF8SVZ843E)	ALBUTEROL	108 ug

Inactive Ingredients

Ingredient Name	Strength
OLEIC ACID (UNII: 2UMI9U37CP)	
NORFLURANE (UNII: DH9E53K1Y8)	
ALCOHOL (UNII: 3K9958V90M)	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA authorized generic	NDA020503	04/03/2019	

Part 20 of 28

PROAIR HFA

albuterol sulfate aerosol, metered

Product Information

Item Code (Source)	NDC:59310-579
Route of Administration	RESPIRATORY (INHALATION)

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALBUTEROL SULFATE (UNII: 021SEF3731) (ALBUTEROL - UNII:QF8SVZ843E)	ALBUTEROL	90 ug

Inactive Ingredients

Ingredient Name	Strength
NORFLURANE (UNII: DH9E53K1Y8)	
ALCOHOL (UNII: 3K9958V90M)	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021457	12/03/2012	

Part 21 of 28

POVIDONE-IODINE

povidone-iodine solution

Product Information

Item Code (Source)	NDC:46414-7777
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
NONOXYNOL-9 (UNII: 48Q180SH9T)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	02/14/1976	

Part 22 of 28

BZK PADS

benzalkonium chloride swab

Product Information

Item Code (Source)	NDC:67777-245
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1.3 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/05/2011	

Part 23 of 28

SOLU-CORTEF

hydrocortisone sodium succinate injection, powder, for solution

Product Information	
Item Code (Source)	NDC:0009-0825
Route of Administration	INTRAMUSCULAR, INTRAVENOUS

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HYDROCORTISONE SODIUM SUCCINATE (UNII: 50LQB69S1Z) (HYDROCORTISONE - UNII:WI4X0X7BPJ)	HYDROCORTISONE	100 mg in 2 mL

Inactive Ingredients	
Ingredient Name	**Strength**
SODIUM PHOSPHATE, MONOBASIC, ANHYDROUS (UNII: KH7I04HPUU)	
SODIUM PHOSPHATE, DIBASIC, UNSPECIFIED FORM (UNII: GR686LBA74)	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA009866	04/27/1955	

Part 24 of 28

SOLU-CORTEF

hydrocortisone sodium succinate injection, powder, for solution

Product Information

Item Code (Source)	NDC:0009-0011
Route of Administration	INTRAMUSCULAR, INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE SODIUM SUCCINATE (UNII: 50LQB69S1Z) (HYDROCORTISONE - UNII:WI4X0X7BPJ)	HYDROCORTISONE	100 mg in 2 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM PHOSPHATE, MONOBASIC, ANHYDROUS (UNII: KH7I04HPUU)	
SODIUM PHOSPHATE, DIBASIC, UNSPECIFIED FORM (UNII: GR686LBA74)	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA009866	04/27/1955	

Part 25 of 28

FUROSEMIDE

furosemide injection, solution

Product Information

Item Code (Source)	NDC:23155-473
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FUROSEMIDE (UNII: 7LXU5N7ZO5) (FUROSEMIDE - UNII:7LXU5N7ZO5)	FUROSEMIDE	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength

SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
WATER (UNII: 059QF0KO0R)	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA203428	09/02/2014	

Part 26 of 28

PITOCIN

oxytocin injection

Product Information

Item Code (Source)	NDC:42023-116
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OXYTOCIN (UNII: 1JQS135EYN) (OXYTOCIN - UNII:1JQS135EYN)	OXYTOCIN	10 [iU] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ACETIC ACID (UNII: Q40Q9N063P)	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA018261	02/01/2008	

Part 27 of 28

PROMETHAZINE HYDROCHLORIDE

promethazine hydrochloride injection

Product Information

Item Code (Source)	NDC:0641-1495

Route of Administration	INTRAMUSCULAR, INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PROMETHAZINE HYDROCHLORIDE (UNII: R61ZEH7I1I) (PROMETHAZINE - UNII:FF28EJQ494)	PROMETHAZINE HYDROCHLORIDE	25 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
EDETATE DISODIUM (UNII: 7FLD91C86K)	
CALCIUM CHLORIDE (UNII: M4I0D6VV5M)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
PHENOL (UNII: 339NCG44TV)	
ACETIC ACID (UNII: Q40Q9N063P)	
SODIUM ACETATE (UNII: 4550K0SC9B)	
WATER (UNII: 059QF0KO0R)	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA083312	09/19/1973	

Part 28 of 28

METOPROLOL TARTRATE

metoprolol tartrate tablet, film coated

Product Information

Item Code (Source)	NDC:65862-062
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
METOPROLOL TARTRATE (UNII: W5S57Y3A5L) (METOPROLOL - UNII:GEB06NHM23)	METOPROLOL TARTRATE	25 mg

Inactive Ingredients

Ingredient Name	Strength
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TALC (UNII: 7SEV7J4R1U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	

Product Characteristics

Color	white	**Score**	2 pieces
Shape	ROUND	**Size**	7mm
Flavor		**Imprint Code**	C;73
Contains			

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077739	09/11/2007	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
exempt device	ABC	01/01/2015	

Labeler - Aerospace Accessory Service, Inc (859100547)

Registrant - Aerospace Accessory Service, Inc (859100547)

Establishment

Name	Address	ID/FEI	Business Operations
Aerospace Accessory Service, Inc		859100547	manufacture, repack