CAREONE DAYTIME NIGHTTIME SEVERE COLD AND FLU- acetaminophen, dextromethorphan hbr, doxylamine succinate, guaifenesin, phenylephrine hcl American Sales Company

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

American Sales Company Daytime Severe Cold & Flu, Nighttime Severe Cold & Flu Drug Facts

Nighttime Severe Cold & Flu Active ingredients (in each 30 mL)

Acetaminophen 650 mg

Dextromethorphan HBr 20 mg

Doxylamine succinate 12.5 mg

Phenylephrine HCl 10 mg

Purpose

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Nasal decongestant

Uses

temporarily relieves common cold/flu symptoms:

- nasal congestion
- sinus congestion and pressure
- minor aches and pains
- headache
- fever
- sore throat
- runny nose and sneezing
- cough due to minor throat and bronchial irritation
- cough to help you sleep
- reduces swelling of nasal passages
- promotes nasal and/or sinus drainage
- temporarily restores freer breathing through the nose

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.
- if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if you have

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- glaucoma
- cough that occurs with too much phlegm (mucus)
- a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- a sodium-restricted diet

Ask a doctor or pharmacist before use if you are

- taking sedatives or tranquilizers
- taking the blood thinning drug warfarin

When using this product

- do not use more than directed
- excitability may occur, especially in children
- marked drowsiness may occur
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery
- alcohol, sedatives, and tranquilizers may increase drowsiness

Stop use and ask a doctor if

- you get nervous, dizzy or sleepless
- pain, nasal congestion, or cough gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back or occurs with rash or headache that lasts. These could be signs of a serious condition.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

Overdose warning: In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- take only as directed see Overdose warning
- only use the dose cup provided
- do not exceed 4 doses per 24 hrs

adults & children 12 yrs & over	30 mL every 4 hrs
children 4 to under 12 yrs	ask a doctor
children under 4 yrs	do not use

Other information

- each 30 mL contains: sodium 41 mg
- store at 20-25°C (68-77°F)

Inactive ingredients

anhydrous citric acid, edetate disodium, FD&C blue #1, FD&C red #40, flavor, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium chloride, sodium citrate, sorbitol solution, sucralose, xanthan gum

Questions or comments?

1-800-719-9260

Daytime Severe Cold & Flu Active ingredients (in each 15 mL)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Guaifenesin 200 mg

Phenylephrine HCl 5 mg

Purpose

Pain reliever/fever reducer

Cough suppressant

Expectorant

Nasal decongestant

Uses

temporarily relieves common cold/flu symptoms:

- nasal congestion
- sinus congestion and pressure
- cough due to minor throat and bronchial irritation
- minor aches and pains
- headache
- fever
- sore throat
- reduces swelling of nasal passages
- temporarily restores freer breathing through the nose
- promotes nasal and/or sinus drainage
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if

- adult takes more than 4,000 mg of acetaminophen in 24 hours
- child takes more than 5 doses in 24 hours
- taken with other drugs containing acetaminophen
- adult has 3 or more alcoholic drinks every day while using this product

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.
- if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if you have

- liver disease
- heart disease
- thyroid disease
- diabetes
- high blood pressure
- trouble urinating due to an enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema

Ask a doctor or pharmacist before use if you are

taking the blood thinning drug warfarin

When using this product

do not use more than directed

Stop use and ask a doctor if

- you get nervous, dizzy or sleepless
- pain, nasal congestion or cough gets worse or lasts more than 5 days (children) or 7 days (adults)
- fever gets worse or lasts more than 3 days
- redness or swelling is present

- new symptoms occur
- cough comes back or occurs with rash or headache that lasts. These could be signs of a serious condition.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

Overdose warning: In care of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- take only as directed see Overdose warning
- only use the dose cup provided
- do not exceed 4 doses per 24 hrs

adults & children 12 yrs & over	30 mL every 4 hrs
children 6 to under 12 yrs	15 mL every 4 hrs
children 4 to under 6 yrs	ask a doctor
children under 4 yrs	do not use

Other information

- each 15 mL contains: sodium 6 mg
- store at 20-25°C (68-77°F). Do not refrigerate.

Inactive ingredients

butylated hydroxyanisole, edetate disodium, FD&C yellow #6, flavor, glycerin, menthol, monobasic sodium phosphate, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sucrose, xanthan gum

Questions or comments?

1-800-719-9260

Principal Display Panel

COMBINATION PACK

CAREone®

Compare to the active ingredients in Vicks[®] DayQuil[®] Severe Cold & Flu

DAYTIME SEVERE COLD & FLU

Pain Reliever/Fever Reducer-Acetaminophen Cough Suppressant-Dextromethorphan HBr Expectorant-Guaifenesin Nasal Decongestant-Phenylephrine HCl Non-Drowsy/Max Strength Alcohol Free Relieves: Aches, Fever, Sore Throat Nasal/Sinus Congestion & Sinus Pressure Cough **Chest Congestion** OUR PHARMACISTS RECOMMEND Original Flavor 12 FL OZ (355mL) (Day) CAREone® Compare to the active ingredients in Vicks[®] NyQuil[®] Severe Cold & Flu NIGHTTIME SEVERE COLD & FLU Pain Reliever/Fever Reducer-Acetaminophen Cough Suppressant-Dextromethorphan HBr Antihistamine-Doxylamine Succinate Nasal Decongestant-Phenylephrine HCl Max Strength Relieves: Aches, Fever, Sore Throat Nasal/Sinus Congestion & Sinus Pressure **Runny Nose** Sneezing Cough OUR PHARMACISTS RECOMMEND Berry Flavor 12 FL OZ (355mL) (Night)

COMBINATION PACK

CAREONE®

Compare to the active ingredients in Vicks®DayQuil® Severe Cold & Flu*

DAYTIME SEVERE COLD & FLU

Pain Reliever/Fever Reducer-Acetaminophen Cough Suppressant-Dextromethorphan HBr Expectorant-Gualfenesin Nasal Decongestant-Phenylephrine HCI

Non-Drowsy/Max Strength

Alcohol Free

Relieves: Aches, Fever, Sore Throat Nasal/Sinus Congestion & Sinus Pressure Cough Chest Congestion





Original Flavor

12 FL OZ (355mL) (Day)



Compare to the active ingredients in Vicks®NyQuil® Severe Cold & Flu*

NDC 41520-507-02

NIGHTTIME SEVERE COLD & FLU

Pain Reliever/Fever Reducer-Acetaminophen Cough Suppressant-Dextromethorphan HBr Antihistamine-Doxylamine Succinate Nasal Decongestant-Phenylephrine HCI

Max Strength

Relieves: Aches, Fever, Sore Throat Nasal/Sinus Congestion & Sinus Pressure Runny Nose Sneezing Cough





12 FL OZ (355mL) (Night)

DO NOT USE IF PRINTED NECKBAND IS BROKEN OR MISSING

*These products are not manufactured or distributed by Procter & Gamble, distributor of Vicks@ DayQuit@ Severe Cold & Ru and Vicks@ NyQuit@ Severe Cold & Ru.



www.StopMedicineAbuse.org

Gluten Free

DISTRIBUTED BY: ADUSA DISTRIBUTION, LLC SALISBURY, NC 28147 1-833-992-3872 Quality guaranteed or your money back.





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Nighttime Severe Cold & Flu		Daytime Severe Cold & Flu	
Drug Facts		Drug Facts	
Active ingredients (in each 30 mL) Actaminophen 650 mg.	Purpose Pain relever Aever reducer Cough suppressant	Active ingredients (in each 15 Aostani nophen 325 mg Dextromethorphan HEr 10 mg	mL) Purpose Pain relever/lever reducer Cough suppresent
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These could be signs of a serious condition. If pregnant or breast-leveling, ask a health professi Keep out of reach of children. Overdose warning: I	onal before use. In case of overdose, get medical help	If pregnant or breast-feeding, ask a heal Keep out of reach of children. Overdose or contact a Polson Control Center right aw	h professional before use. warning: In case of overdose, get medical help sy (1-800-222-1222). Guick medical attention wen if you do not notice any signs or symptoms.
or contact a Poison Control Center right away (1-500- is critical for adults as well as for children even if you		Directions	and all a subsection of all a subsections.
Directions take only as directed – see Overdose warming		take only as directed – see 0 verdose was only use the dose cup provided in do n	
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Other information each 30 mL contains: sodiun 41 ng store at 20-25°C (68-77°F)		Other information each 15 mL contains: sodium 6 mg store at 20-25°C (68-77°F). Do not refrig	
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Questions or comments?1-800-719-9260

Questions or comments? 1-800-719-9280

CAREONE DAYTIME NIGHTTIME SEVERE COLD AND FLU

acetaminophen, dextromethorphan hbr, doxylamine succinate, guaifenesin, phenylephrine hcl kit

Product Type	Product Information						
	HUMAN	OTC DRUG	Item Co	de (Sour	rce)	NDC:4152	20-597
Packaging							
# Item Code	Рас	kage Descriptio	n		eting Start Date		eting End Date
1 NDC:41520-597- 02	1 in 1 KIT; Ty Product	pe 0: Not a Combinat	ion	10/01/201	8		
Quantity of P	arts						
Part #	Package (Quantity		То	tal Product C	Quantity	
Part 1 1 BOTTLE			355 mL				
Part 2 1 BOTTLE			355 mL				
Part 1 of 2							
		1E SEVERE C			U		
		orphan hbr, doxyla					
acctarinioprici	, uchuomeur			ccinate	nhonvlonhrind	a nci sali i	ition
		· · ·		ccinate,	phenylephrine	e nci solu	ition
		<u> </u>		ccinate,	phenylephrine	e nci solu	ition
Product Infor	rmation		amine su	ccinate,	phenylephrine	e nci solu	ition
Product Infor Item Code (Sou		NDC:41520-561		ccinate,	phenylephrine	e nci solu	ition
	rce)			ccinate,	phenylephrine	e nci solu	ition
ltem Code (Sou	rce)	NDC:41520-561		ccinate,	phenylephrine	e nci solu	ition
ltem Code (Sou	rce)	NDC:41520-561		ccinate,	phenylephrine	e nci solu	ition
ltem Code (Sou	rce) istration	NDC:41520-561 ORAL		ccinate,	phenylephrine	e nci solu	ition
Item Code (Sou Route of Admin	rce) istration ient/Active	NDC:41520-561 ORAL		ccinate,	phenylephrine Basis of St		Strength
Item Code (Sou Route of Admin Active Ingred	rce) istration ient/Active Ingree	NDC:41520-561 ORAL Moiety				trength	
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Item Code (Sou Route of Admin Active Ingred ACETAMINOPHEN DEXTROMETHORF (DEXTROMETHORPH DOXYLAMINE SUC UNII:95QB77JKPL)	rce) istration ient/Active ingred I (UNII: 36209ITE PHAN HYDROB IAN - UNII:7355X CCINATE (UNII: 1	NDC:41520-561 ORAL Moiety Jient Name JO) (ACETAMINOPHEN ROMIDE (UNII: 9D2RT (3ROTS) V9BI9B5YI2) (DOXYLAI	N - UNII:362 19KYH) MINE -	2O9ITL9D)	Basis of St ACETAMINOPHEN DEXTROMETHOR HYDROBROMIDE DOXYLAMINE SU	trength N RPHAN ICCINATE	Strength 650 mg in 30 mL 20 mg in 30 mL 12.5 mg in 30 mL
Item Code (Sou Route of Admin Active Ingred ACETAMINOPHEN DEXTROMETHORF (DEXTROMETHORPH DOXYLAMINE SUC UNII:95QB77JKPL)	rce) istration ient/Active ingred i (UNII: 36209ITL PHAN HYDROB HAN - UNII:7355X CCINATE (UNII: 1 HYDROCHLORI	NDC:41520-561 ORAL Moiety dient Name -9D) (ACETAMINOPHEN ROMIDE (UNII: 9D2RT (3ROTS)	N - UNII:362 19KYH) MINE -	2O9ITL9D)	Basis of St ACETAMINOPHEN DEXTROMETHOR HYDROBROMIDE	trength N RPHAN ICCINATE	Strength 650 mg in 30 mL 20 mg in 30 mL 12.5 mg
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		Ingredient Name		Strength
ANHYDROUS CITR	IC ACID (UNII:	XF417D3PSL)		
EDETATE DISODIU	M (UNII: 7FLD9	1C86K)		
FD&C BLUE NO. 1	(UNII: H3R47K3	3TBD)		
FD&C RED NO. 40	(UNII: WZB912	7XOA)		
GLYCERIN (UNII: PE	DC6A3C0OX)			
PROPYLENE GLYC	OL (UNII: 6DC9	Q167V3)		
WATER (UNII: 059Q	F0KO0R)			
SACCHARIN SODIL	JM (UNII: SB8Z	UX40TY)		
SODIUM BENZOAT	E (UNII: 0J245I	FE5EU)		
SODIUM CHLORID	E (UNII: 451W4)	7IQ8X)		
SODIUM CITRATE,	UNSPECIFIED	FORM (UNII: 1Q73Q2JULR)		
SORBITOL (UNII: 50	06T60A25R)			
SUCRALOSE (UNII:	96K6UQ3ZD4)			
XANTHAN GUM (UN	NII: TTV12P4NEI	E)		
Product Chara	acteristics			
Color	RED (clear, dark)	Score	
Shape			Size	
Flavor	BERRY	(Imprint Code	
Contains			•	
Packaging				
# Item Code	Pa	ckage Description	Marketing Start Date	Marketing End Date
		CKage Description OTTLE; Type 0: Not a Combination	-	-
1 NDC:41520-561-	355 mL in 1 B		-	-
1 NDC:41520-561-	355 mL in 1 B Product	OTTLE; Type 0: Not a Combination	-	-
1 NDC:41520-561- 40 Marketing Marketing	355 mL in 1 B Product	OTTLE; Type 0: Not a Combination	-	-
1 NDC:41520-561- 40 Marketing Category	355 mL in 1 Bo Product	OTTLE; Type 0: Not a Combination	Date Marketing Start Date	Date Marketing End
1 NDC:41520-561- 40 Marketing Marketing	355 mL in 1 Bo Product	OTTLE; Type 0: Not a Combination	Date Marketing Start	Date Marketing End
1 NDC:41520-561- 40 Marketing Marketing Category OTC monograph find	355 mL in 1 Bo Product	OTTLE; Type 0: Not a Combination	Date Marketing Start Date	Date Marketing End
1 NDC:41520-561- 40 Marketing Category OTC monograph fina Part 2 of 2	355 mL in 1 B Product	OTTLE; Type 0: Not a Combination	Date Date Date	Date Marketing End
1 NDC:41520-561- 40 Marketing Category OTC monograph fina Part 2 of 2	355 mL in 1 B Product	OTTLE; Type 0: Not a Combination	Date Date Date	Date Marketing End
1 NDC:41520-561- 40 Marketing Category OTC monograph fina Part 2 of 2 CAREONE D	355 mL in 1 B Product Applica al part341	OTTLE; Type 0: Not a Combination	Date Date Date Date	Date Marketing End Date
1 NDC:41520-561- 40 Marketing Category OTC monograph fina Part 2 of 2 CAREONE D	355 mL in 1 B Product Applica al part341	OTTLE; Type 0: Not a Combination	Date Date Date Date	Date Marketing End Date
1 NDC:41520-561- 40 Marketing Category OTC monograph find Part 2 of 2 CAREONE D acetaminophen,	355 mL in 1 B Product	OTTLE; Type 0: Not a Combination	Date Date Date Date	Date Marketing End Date
1 NDC:41520-561- 40 Marketing Category OTC monograph find Part 2 of 2 CAREONE D acetaminophen, Product Infor	355 mL in 1 Bo Product Applica al part341	OTTLE; Type 0: Not a Combination Citation SEVERE COLD AND I orphan hbr, guaifenesin, phe	Date Date Date Date	Date Marketing End Date
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Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII: 36209ITL9D)	ACETAMINOPHEN	325 mg in 15 mL		
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 15 mL		
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 15 mL		
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 15 mL		

Inactive Ingredients

BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)Image: Rek4960K2U)BETATE DISODIUM (UNII: 7FLD91C86K)Image: Rek4960K2U)BAC YELLOW NO. 6 (UNII: H77VEI93A8)Image: Rek4960K2U)BAC YELLOW NO. 6 (UNII: H77VEI93A8)Image: Rek4960K2U)BACTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)Image: Rek4960K2U)BODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM (UNII: 3980JIH2SW)Image: Rek4960K2U)BOLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)Image: Rek4960K2U)PROPYLENE GLYCOL (UNII: 6DC9Q167V3)Image: Rek4960K2U)BACCHARIN SODIUM (UNII: SB8ZUX40TY)Image: Rek4960K2U)	Strength
D&C YELLOW NO. 6 (UNII: H77VEI93A8) SIYCERIN (UNII: PDC6A3C00X) MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM (UNII: 3980JIH2SW) POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) PROPYLENE GLYCOL (UNII: 6DC9Q167V3) VATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C00X) GLYCERIN (UNII: PDC6A3C00X) MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) GODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM (UNII: 3980JIH2SW) FOLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) GODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED (UNII: 3WJQ0SDW1A) FOOPYLENE GLYCOL (UNII: 6DC9Q167V3) GODIUM PHOSPHATE, UNII: 059QF0K00R)	
AENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM (UNII: 3980JIH2SW) POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A) PROPYLENE GLYCOL (UNII: 6DC9Q167V3) VATER (UNII: 059QF0K00R)	
GODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM (UNII: 3980JIH2SW) POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) PROPYLENE GLYCOL (UNII: 6DC9Q167V3) VATER (UNII: 059QF0K00R)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) PROPYLENE GLYCOL (UNII: 6DC9Q167V3) VATER (UNII: 059QF0K00R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3) VATER (UNII: 059QF0K00R)	
VATER (UNII: 059QF0KO0R)	
ACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SUCROSE (UNII: C151H8M554)	
(ANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	ORANGE (clear)	Score
Shape		Size
Flavor	FRUIT, MENTHOL	Imprint Code
Contains		

Packaging

# Item Code	Package Description	Marketing Start Date	Marketing End Date
	355 mL in 1 BOTTLE; Type 0: Not a Combination Product		
Marketing	Information		
Marketing Marketing Category	I nformation Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Marketing	Application Number or Monograph Citation	-	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	10/01/2018	

Labeler - American Sales Company (809183973)

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American Sales Company