

VICKS DAYQUIL SEVERE AND VICKS NYQUIL SEVERE COLD AND FLU- acetaminophen, phenylephrine hydrochloride, dextromethorphan hydrobromide, guaifenesin and doxylamine succinate

VICKS DAYQUIL AND VICKS NYQUIL COLD AND FLU MULTI-SYMPTOM RELIEF/COLD AND FLU NIGHTTIME RELIEF- acetaminophen, phenylephrine hydrochloride, dextromethorphan hydrobromide, acetaminophen, doxylamine succinate, and dextromethorphan hydrobromide

The Procter & Gamble Manufacturing 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.

Vicks[®] DayQuil[®] Severe and Vicks[®] NyQuil[®] Severe Cold & Flu LiquiCaps

DayQuil[™] SEVERE Cold & Flu

Drug Facts

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Guaifenesin 200 mg

Phenylephrine HCl 5 mg

Pain reliever/Fever reducer

Cough suppressant

Expectorant

Nasal decongestant

Uses

temporarily relieves common cold/flu symptoms:

- nasal congestion
- sinus congestion & pressure
- cough due to minor throat & bronchial irritation
- minor aches & 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 you take

- more than 8 LiquiCaps in 24 hrs, which is the maximum daily amount for this product
- 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.

Ask a doctor before use if you have

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to 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 get worse or last 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. 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
- do not exceed 8 LiquiCaps per 24 hrs

adults & children 12 yrs & over 2 LiquiCaps with water every 4 hrs

children 4 to under 12 yrs ask a doctor

children under 4 yrs do not use

Other information

- do not exceed 25°C

Inactive ingredients

FD&C Red No. 40, FD&C Yellow No. 6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution, titanium dioxide

Questions?

1-800-362-1683

NyQuil™ SEVERE Cold & Flu

Drug Facts**Active ingredients (in each LiquiCap)**

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Doxylamine succinate 6.25 mg

Phenylephrine HCl 5 mg

Purpose

Pain reliever/Fever reducer

Cough suppressant

Antihistamine

Nasal decongestant

Uses

temporarily relieves common cold/flu symptoms:

- nasal congestion
- sinus congestion & pressure
- cough due to minor throat & bronchial irritation
- cough to help you sleep
- minor aches & pains
- headache
- fever
- sore throat
- runny nose & sneezing
- reduces swelling of nasal passages

- temporarily restores freer breathing through the nose
- promotes nasal and/or sinus drainage

Warnings

Liver warning

This product contains acetaminophen.

Severe liver damage may occur if you take

- more than 8 LiquiCaps in 24 hrs, which is the maximum daily amount for this product
- 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.
- to make a child sleep

Ask a doctor before use if you have

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

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, & 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. 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
- do not exceed 8 LiquiCaps per 24 hours

adults & children 12 yrs & over 2 LiquiCaps with water every 6 hrs

children 4 to under 12 yrs ask a doctor

children under 4 yrs do not use

Other information

- do not exceed 25°C

Inactive ingredients

FD&C Blue No. 1, gelatin, glycerin, pharmaceutical ink*, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution *May contain this ingredient

Questions?

1-800-362-1683

Made in Canada

DIST. BY PROCTER & GAMBLE, CINCINNATI OH 45202

PRINCIPAL DISPLAY PANEL - 24 Capsule Kit Carton

NEW

MAX

STRENGTH

LIQUICAPS™

VICKS®

DayQuil™

SEVERE

COLD & FLU

*Acetaminophen, Phenylephrine HCl,
Dextromethorphan HBr, Guaifenesin*

- **Minor Aches & Pains, Fever**
- **Nasal Congestion & Sinus Pressure**
- **Cough**
- **Chest Congestion**

Non-Drowsy

16 DayQuil LiquiCaps

NyQuil™

SEVERE

COLD & FLU

Acetaminophen, PhenylephrineHCl,

Doxylamine Succinate, Dextromethorphan HBr

- **Minor Aches & Pains, Fever**
- **Nasal Congestion & Sinus Pressure**
- **Sneezing, Runny Nose**
- **Cough**

Nighttime Relief

8 NyQuil LiquiCaps: TOTAL 24 LIQUICAPS

Drug Facts (on the top)

Warnings

- Do not take if you are allergic to any of the ingredients.
- Do not take if you are taking other prescription or over-the-counter drugs that contain acetaminophen.
- Do not take if you are taking other prescription or over-the-counter drugs that contain phenylephrine.
- Do not take if you are taking other prescription or over-the-counter drugs that contain dextromethorphan.
- Do not take if you are taking other prescription or over-the-counter drugs that contain doxylamine.
- Do not take if you are taking other prescription or over-the-counter drugs that contain guaifenesin.
- Do not take if you are taking other prescription or over-the-counter drugs that contain pseudoephedrine.
- Do not take if you are taking other prescription or over-the-counter drugs that contain triprolidine.
- Do not take if you are taking other prescription or over-the-counter drugs that contain chlorpheniramine.
- Do not take if you are taking other prescription or over-the-counter drugs that contain diphenhydramine.
- Do not take if you are taking other prescription or over-the-counter drugs that contain promethazine.
- Do not take if you are taking other prescription or over-the-counter drugs that contain hydroxyzine.
- Do not take if you are taking other prescription or over-the-counter drugs that contain lorazepam.
- Do not take if you are taking other prescription or over-the-counter drugs that contain alprazolam.
- Do not take if you are taking other prescription or over-the-counter drugs that contain clonazepam.
- Do not take if you are taking other prescription or over-the-counter drugs that contain diazepam.
- Do not take if you are taking other prescription or over-the-counter drugs that contain lorazepam.
- Do not take if you are taking other prescription or over-the-counter drugs that contain alprazolam.
- Do not take if you are taking other prescription or over-the-counter drugs that contain clonazepam.
- Do not take if you are taking other prescription or over-the-counter drugs that contain diazepam.
- Do not take if you are taking other prescription or over-the-counter drugs that contain lorazepam.
- Do not take if you are taking other prescription or over-the-counter drugs that contain alprazolam.
- Do not take if you are taking other prescription or over-the-counter drugs that contain clonazepam.
- Do not take if you are taking other prescription or over-the-counter drugs that contain diazepam.

Directions

• Adults and children 12 years of age and older: Take 2 capsules 4 times a day.

• Children 6 to 11 years of age: Take 1 capsule 4 times a day.

• Children 2 to 5 years of age: Take 1/2 capsule 4 times a day.

• Children 1 to 2 years of age: Take 1/4 capsule 4 times a day.

• Children under 1 year of age: Do not use.

Other information

• Contains 48 capsules.

• Contains 24 capsules.

• Contains 12 capsules.

• Contains 6 capsules.

• Contains 3 capsules.

• Contains 1 capsule.

Contains 48 capsules.

Contains 24 capsules.

Contains 12 capsules.

Contains 6 capsules.

Contains 3 capsules.

Contains 1 capsule.

NEW MAX STRENGTH LIQUICAPS

VICKS

DayQuil SEVERE

COLD & FLU

Acetaminophen, Phenylephrine HCl, Dextromethorphan HBr, Guaifenesin

- Minor Aches & Pains, Fever
- Nasal Congestion & Sinus Pressure
- Cough
- Chest Congestion

Non-Drowsy

16 DAYQUIL LIQUICAPS

NyQuil SEVERE

COLD & FLU

Acetaminophen, Phenylephrine HCl, Doxylamine Succinate, Dextromethorphan HBr

- Minor Aches & Pains, Fever
- Nasal Congestion & Sinus Pressure
- Sneezing, Runny Nose
- Cough

Nighttime Relief

TOTAL 24 NYQUIL LIQUICAPS

Parents: This product is not recommended for children under 6 years of age. Use only if advised by a doctor. Use only if advised by a doctor. Use only if advised by a doctor.

Drug Facts (continued)

Other information

• Contains 48 capsules.

• Contains 24 capsules.

• Contains 12 capsules.

• Contains 6 capsules.

• Contains 3 capsules.

• Contains 1 capsule.

Contains 48 capsules.

Contains 24 capsules.

Contains 12 capsules.

Contains 6 capsules.

Contains 3 capsules.

Contains 1 capsule.

PRINCIPAL DISPLAY PANEL - 48 Capsule Kit Carton

NEW
MAX

STRENGTH

LIQUICAPS™

VICKS®

DayQuil™

SEVERE

COLD & FLU

*Acetaminophen, Phenylephrine HCl,
Dextromethorphan HBr, Guaifenesin*

- Minor Aches & Pains, Fever
- Nasal Congestion & Sinus Pressure
- Cough
- Chest Congestion

Non-Drowsy

16 DayQuil LiquiCaps

NyQuil™

SEVERE

COLD & FLU

*Acetaminophen, PhenylephrineHCl,
Doxylamine Succinate, Dextromethorphan HBr*

- **Minor Aches & Pains, Fever**
- **Nasal Congestion & Sinus Pressure**
- **Sneezing, Runny Nose**
- **Cough**
-

Nighttime Relief

8 NyQuil LiquiCaps: TOTAL 24 LIQUICAPS

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37000-516
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37000-516-48	1 in 1 PACKAGE	07/10/2018	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	2 BLISTER PACK	16
Part 2	1 BLISTER PACK	8

Part 1 of 2**VICKS DAYQUIL SEVERE COLD AND FLU**

acetaminophen, phenylephine hcl, dextromethorphan hydrobromide, and guaifenesin capsule, liquid filled

Product Information

Item Code (Source)	NDC:37000-517
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
AMMONIA (UNII: 5138Q19F1X)	
SHELLAC (UNII: 46N107B71O)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SORBITOL (UNII: 506T60A25R)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	orange	Score	no score
Shape	BULLET	Size	16mm
Flavor		Imprint Code	DS
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		2 in 1 CARTON		
1		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/10/2018	

Part 2 of 2

VICKS NYQUIL SEVERE COLD AND FLU

acetaminophen, phenylephrine hydrochloride, dextromethorphan hydrobromide, and doxylamine succinate capsule, liquid filled

Product Information

Item Code (Source)	NDC:37000-518
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg

Inactive Ingredients

Ingredient Name	Strength

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	green	Score	no score
Shape	BULLET	Size	16mm
Flavor		Imprint Code	NS
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 CARTON		
1		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/10/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/10/2018	

VICKS DAYQUIL AND VICKS NYQUIL COLD AND FLU MULTI-SYMP TOM RELIEF/COLD AND FLU NIGHTTIME RELIEF

acetaminophen, phenylephrine hydrochloride, dextromethorphan hydrobromide, acetaminophen, doxylamine succinate, and dextromethorphan hydrobromide kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37000-514
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:37000-514-48	1 in 1 PACKAGE	03/21/2014
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Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	16 BLISTER PACK	32
Part 2	8 BLISTER PACK	16

Part 1 of 2

VICKS DAYQUIL COLD AND FLU MULTI-SYMPTOM RELIEF

acetaminophen, dextromethorphan hydrobromide, and phenylephrine hydrochloride capsule, liquid filled

Product Information

Route of Administration	ORAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	

Product Characteristics

Color	orange	Score	no score
Shape	OVAL	Size	21mm
Flavor		Imprint Code	DQuil
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		16 in 1 CARTON		
1		2 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	03/21/2014	

Part 2 of 2

VICKS NYQUIL COLD AND FLU NIGHTTIME RELIEF

acetaminophen, dextromethorphan hydrobromide, and doxylamine succinate capsule, liquid filled

Product Information

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg

Inactive Ingredients

Ingredient Name	Strength
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	green	Score	no score
Shape	OVAL	Size	21mm
Flavor		Imprint Code	NQUIL
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		8 in 1 CARTON		
1		2 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	03/21/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	03/21/2014	

Labeler - The Procter & Gamble Manufacturing Company (004238200)

Revised: 1/2020

The Procter & Gamble Manufacturing Company