VICKS ZZZQUIL NIGHT PAIN- diphenhydramine hydrochloride and acetaminophen tablet, coated
The Procter & Gamble Manufacturing Company

Vicks ZzzQuil Night Pain GelTabs

Drug Facts

Active ingredients (in each geltab)

Acetaminophen 500 mg

Diphenhydramine HCl 25 mg

Purpose

Pain reliever

Nighttime sleep-aid

Uses

- for the temporary relief of occasional minor aches and pains with accompanying sleeplessness.

Warnings

Liver warning:

This product contains acetaminophen. Severe liver damage may occur if

• adult takes more than 4 doses (2 geltabs each) in 24 hrs, which is the maximum daily amount for this product

• taken 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

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.
- for children under 12 years of age
- with any other product containing diphenhydramine, even one used on skin.

Ask a doctor before use if you have
- liver disease
- a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- difficulty in urination due to enlargement of the prostate gland

Ask a doctor or pharmacist before use if you are
- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

When using this product
- avoid alcoholic beverages
- drowsiness will occur
- do not drive a motor vehicle or operate machinery

Stop use and ask a doctor if
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- new symptoms occur
- sleeplessness persists continuously for more than 2 weeks. Insomnia may be a symptom of serious underlying medical illness.

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.

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 2 geltabs per day (24 hours)

adults & children 12 yrs & over	2 geltabs at bedtime
children under 12 yrs	do not use

Other information
- store at no greater than 25° C

Inactive ingredients

corn starch, croscarmellose sodium, D&C Red No. 27 Aluminum Lake, FD&C Blue No. 1, FD&C Blue No. 1 Aluminum Lake, gelatin, glycerin, hypromellose, iron oxide black,

maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl acetate phthalate, povidone, propylene glycol, purified water, silicon dioxide, stearic acid, titanium dioxide

Questions?

1-877-881-5813

TAMPER EVIDENT: Do not use if printed safety seal under cap is broken or missing.

DIST. BY PROCTER & GAMBLE,

CINCINNATI, OH 45202

PRINCIPAL DISPLAY PANEL - 60 GelTab Carton

VICKS ®

ZzzQuil™
NIGHT PAIN
NIGHTTIME SLEEP-AID

PAIN RELIEVER
Diphenhydramine HCl

Acetaminophen

- Fall Asleep Fast
- Max Strength Pain Reliever
- Non-Habit Forming

Not for colds.

60 GelTabs

VICKS ZZZQUIL NIGHT PAIN

diphenhydramine hydrochloride and acetaminophen tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:37000-974
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)	
POLYVINYL ACETATE PHTHALATE (UNII: 58QVG85GW3)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
WATER (UNII: 059QF0KO0R)	
D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX)	
STARCH, CORN (UNII: O8232NY3SJ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	purple (and white)	**Score**	no score
Shape	ROUND	**Size**	8mm
Flavor		**Imprint Code**	Zzz
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37000-974-60	1 in 1 CARTON	06/01/2020	
1		60 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M010	06/01/2020	

Labeler - The Procter & Gamble Manufacturing Company (004238200)

Establishment

Name	Address	ID/FEI	Business Operations
Supriya Lifesciences, Ltd.		650542744	api manufacture(37000-974)

Establishment

Name	Address	ID/FEI	Business Operations
Granules India Limited		918610754	api manufacture(37000-974)