ACETAMINOPHEN, DEXTROMETHORPHAN HYDROBROMIDE, DOXYLAMINE SUCCINATE AND PHENYLEPHRINE HYDROCHLORIDE- acetaminophen, dextromethorphan hydrobromide, doxylamine succinate and phenylephrine hydrochloride capsule, liquid filled
Softgel Healthcare Pvt Ltd

Acetaminophen 325 mg , Dextromethorphan Hydrobromide 10 mg, Doxylamine Succinate 6.25 mg and Phenylephrine Hydrochloride 5 mg (Night Time Severe)

Active ingredients (in each Softgel)

Acetaminophen USP 325 mg

Dextromethorphan Hydrobromide USP 10 mg

Doxylamine succinate USP 6.25 mg

Phenylephrine Hydrochloride USP 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 free 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 Softgels 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
- 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.

Keep out of reach of children.

Overdosage

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 Softgels per 24 hrs

Adults & children 12 years & over	2 softgels with water every 4 hours
Children 4 to under 12 years	Ask a doctor
Children under 4 years	Do not use

Other information

Store at no greater than 25ºC

Inactive ingredients

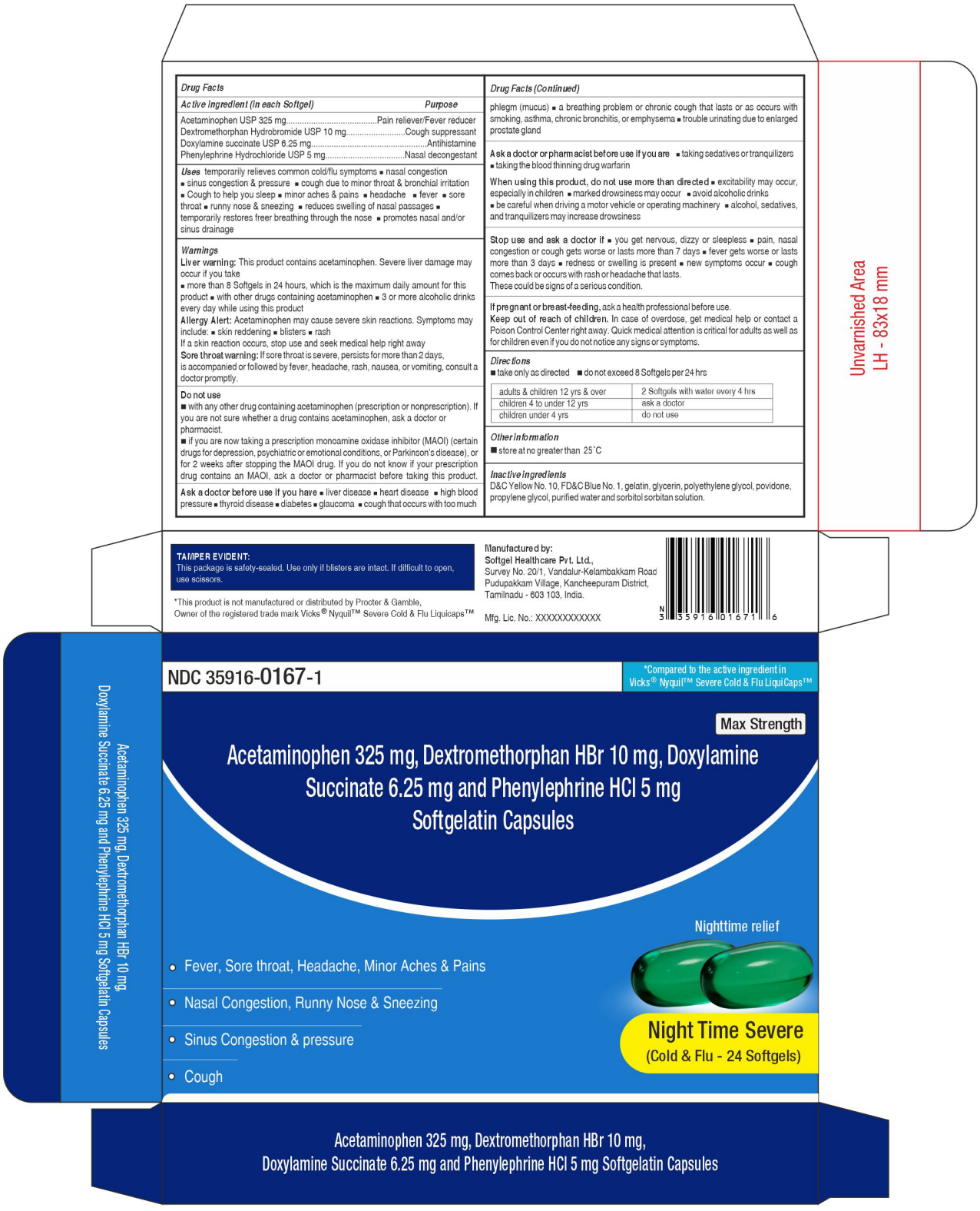
FD&C Blue No.1, D&C Yellow No.10, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water and sorbitol sorbitan solution.

TAMPER EVIDENT

This package is safety-sealed. Use only if blisters are intact. If difficult to open, use scissors.

Manufactured by

Softgel Healthcare Pvt. Ltd.,
Survey No. 20/1, Vandalur-Kelambakkam Road,
Pudupakkam Village, Kancheepuram District,
Tamilnadu - 603 103, India.
Mfg. Lic. No.: XXXXXXXXXXXX



ACETAMINOPHEN, DEXTROMETHORPHAN HYDROBROMIDE, DOXYLAMINE SUCCINATE AND PHENYLEPHRINE HYDROCHLORIDE

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate and phenylephrine

hydrochloride capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:35916-0167
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	10 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 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)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GELATIN (UNII: 2G86QN327L)	
WATER (UNII: 059QF0KO0R)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	green (Transparent)	**Score**	no score
Shape	CAPSULE (Oblong square)	**Size**	21mm
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35916-0167-1	2 in 1 CARTON	08/22/2024	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date
OTC Monograph Drug	M012	08/22/2024	

Labeler - Softgel Healthcare Pvt Ltd (675584180)

Revised: 8/2024 Softgel Healthcare Pvt Ltd