ACETAMINOPHEN, GUAIFENESIN, DEXTROMETHORPHAN HBR, PHENYLEPHRINE HCL- acetaminophen, guaifenesin, dextromethorphan hbr, phenylephrine hcl capsule, liquid filled
ONE2ZEE LIMITED LIABILITY 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.

DayTime Severe Cold and Flu capsule, liquid filled (Acetaminophen 325mg, Guaifenesin 200mg, Dextromethorphan HBr 10mg, Phenylephrine HCl 5mg)

Active ingredients (in each capsule)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Guaifenesin 200 mg

Phenylephrine Hydrochloride 5 mg

Purpose

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 4 softgels in 24 hours, 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

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

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 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:

Taking more than directed can cause serious health problems. 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 - see **Overdose warning**
- do not exceed 4 doses per 24 hours

adults & children 12 years of age and over	2 softgels with water every 4 hours
Children under 12 years of age	ask a doctor

When using other Nighttime or Daytime products, carefully read each label to ensure correct dosing

Inactive ingredients

polyethylene glycol 400, propylene glycol, povidone k30, fd&c yellow no. 6, titanium dioxide, gelatin, glycerin, sorbitol, water

Other Information:

- store at room temperature 59°-86°F (15°-30°C)

PRINCIPAL DISPLAY PANEL - Shipping Label

Acetaminophen, Dextromethorphan HBr, Guifenesin, Phenylephrine HCL capsules

Each Softgel Contains:
(Acetaminophen USP 325 mg, Dextromethorphan Hydrobromide USP 10 mg, Guifenesin 200mg, Phenylephrine Hydrochloride USP 5mg)

LOT NO:
DRUM NO:
MFG DATE:
QUANTITY:
NDC NO: 55629-015-
EXP DATE:

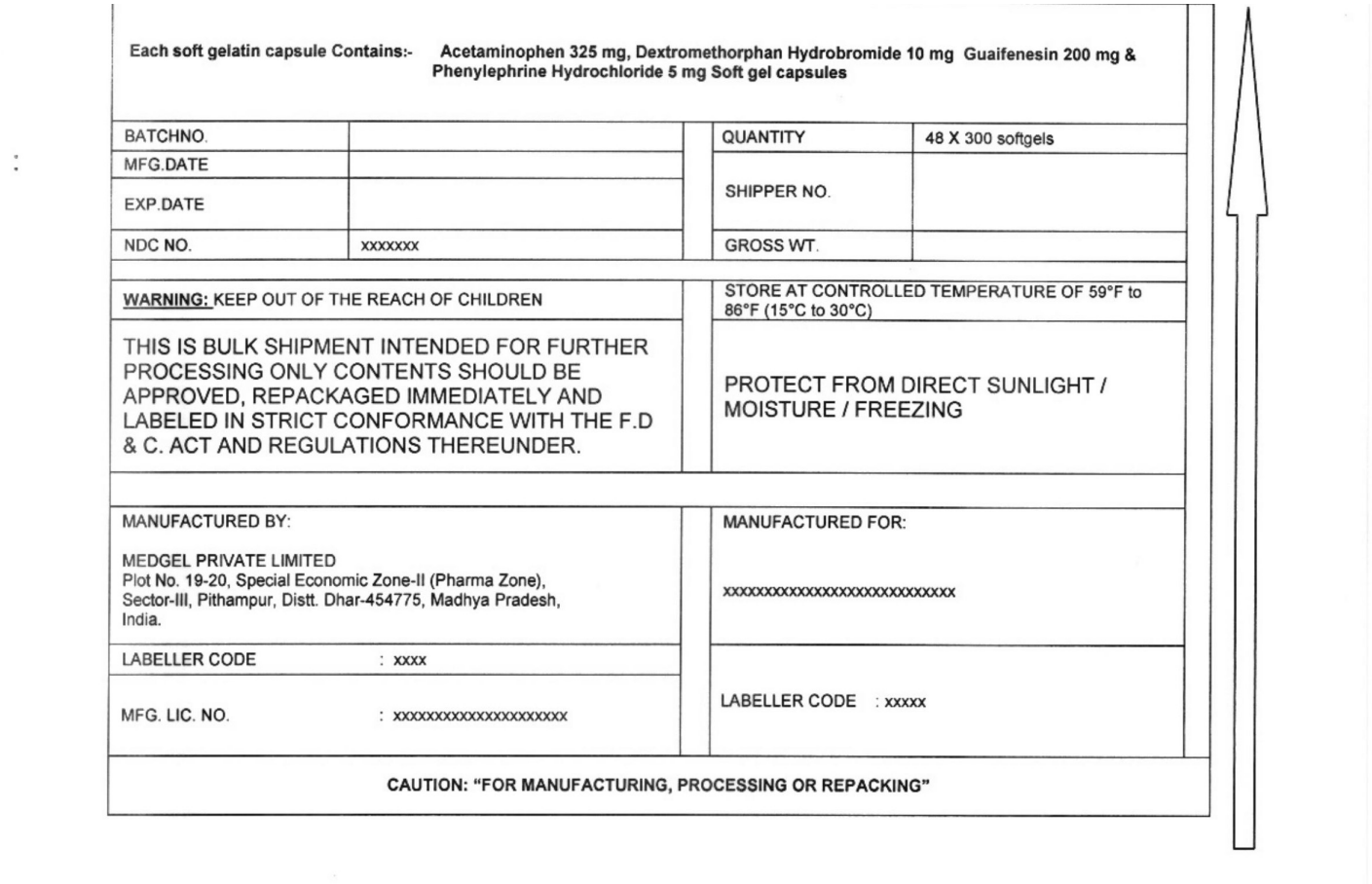
WARNING:
KEEP OUT OF REACH OF CHILDREN

STORE CONTROLLED ROOM TEMPERATURE OF 59° - 86°F (15° - 30°C)
PROTECT FROM LIGHT, MOISTURE AND FREEZING

THIS IS A BULK SHIPMENT INTENDED FOR FURTHER PROCESSING ONLY.

CONTENTS SHOULD BE APPROVED, REPACKAGED IMMEDIATELY AND LABELED IN

STRICT CONFORMANCE WITH
THE F.D & C.ACT AND REGULATIONS THEREUNDER.



Each soft gelatin capsule Contains:-	**Acetaminophen 325 mg, Dextromethorphan Hydrobromide 10 mg Guaifenesin 200 mg & Phenylephrine Hydrochloride 5 mg Soft gel capsules**		
BATCHNO.		QUANTITY	48 X 300 softgels
MFG.DATE		SHIPPER NO.	
EXP.DATE			
NDC NO.	xxxxxxx	GROSS WT.	
WARNING: KEEP OUT OF THE REACH OF CHILDREN		STORE AT CONTROLLED TEMPERATURE OF 59°F to 86°F (15°C to 30°C)	
THIS IS BULK SHIPMENT INTENDED FOR FURTHER PROCESSING ONLY CONTENTS SHOULD BE APPROVED, REPACKAGED IMMEDIATELY AND LABELED IN STRICT CONFORMANCE WITH THE F.D & C. ACT AND REGULATIONS THEREUNDER.		PROTECT FROM DIRECT SUNLIGHT / MOISTURE / FREEZING	
MANUFACTURED BY: MEDGEL PRIVATE LIMITED Plot No. 19-20, Special Economic Zone-II (Pharma Zone), Sector-III, Pithampur, Distt. Dhar-454775, Madhya Pradesh, India.		MANUFACTURED FOR: xxxxxxxxxxxxxxxxxxxxxxxxxxxx	
LABELLER CODE : xxxx			
MFG. LIC. NO. : xxxxxxxxxxxxxxxxxxxxx		LABELLER CODE : xxxxx	
CAUTION: "FOR MANUFACTURING, PROCESSING OR REPACKING"			

ACETAMINOPHEN, GUAIFENESIN, DEXTROMETHORPHAN HBR, PHENYLEPHRINE HCL

acetaminophen, guaifenesin, dextromethorphan hbr, phenylephrine hcl capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55629-015
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
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	5

Inactive Ingredients

Ingredient Name	Strength

POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POVIDONE K30 (UNII: U725QWY32X)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	orange	**Score**	no score
Shape	capsule	**Size**	20mm
Flavor		**Imprint Code**	IS4
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55629-015-01	48 in 1 CARTON	03/01/2021	
1	NDC:55629-015-02	300 in 1 POUCH; 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	03/01/2021	

Labeler - ONE2ZEE LIMITED LIABILITY COMPANY (078656111)

Registrant - ONE2ZEE LIMITED LIABILITY COMPANY (078656111)

Establishment

Name	Address	ID/FEI	Business Operations
Medgel Private Limited		677385498	manufacture(55629-015) , analysis(55629-015)

Revised: 2/2021 ONE2ZEE LIMITED LIABILITY COMPANY