ACETAMINOPHEN, DEXTROMETHORPHAN HYDROBROMIDE, DOXYLAMINE SUCCINATE- acetaminophen, dextromethorphan hydrobromide, doxylamine succinate 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.

NIGHTTIME COLD AND FLU capsule, liquid filled (Acetaminophen 325mg, Dextromethorpha HBr 15mg and Doxylamine Succinate 6.25mg)

Active ingredients (in each capsule)

Acetaminophen 325 mg

Dextromethorphan HBr 15 mg

Doxylamine Succinate 6.25 mg

Purpose:

Pain reliever/ fever reducer

Cough suppressant

Antihistamine

Uses:

temporarily relieves common cold/flu symptoms:
- cough due to minor throat & bronchial irritation
- sore throat
- headache
- minor aches/pains
- fever
- runny nose & sneezing

Warnings:

Liver warning This product contains acetaminophen. Severe liver damage may occur if you take:
- more than 4 doses in 24 hours, which is the maximum daily amount for this product
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks daily while using this product

Sore throat warning If sore throat is severe, lasts more than 2 days, occurs with or is followed by fever, headache, rash, nausea, or vomiting, see 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
- 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

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

- pain 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.

Directions

- take only as directed - see **Overdose warning**
- do not exceed 4 doses per 24 hours

Adults and children 12 years of age and older	2 LiquiCaps with water every 4 hours

Children under 12 years of age	ask doctor

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

Other Information

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

Inactive ingredients

polyethylene glycol 400, propylene glycol, povidone k30, fd&c blue no. 1, d&c yellow no. 10, titanium dioxide, gelatin, glycerin, sorbitol, water

PRINCIPAL DISPLAY PANEL - Shipping Label

Acetaminophen, Dextromethorphan HBr, Doxylamine Succinate capsules

Each Softgel Contains:
(Acetaminophen USP 325 mg, Dextromethorphan Hydrobromide USP 15 mg, Doxylamine Succinate 6.25 mg)

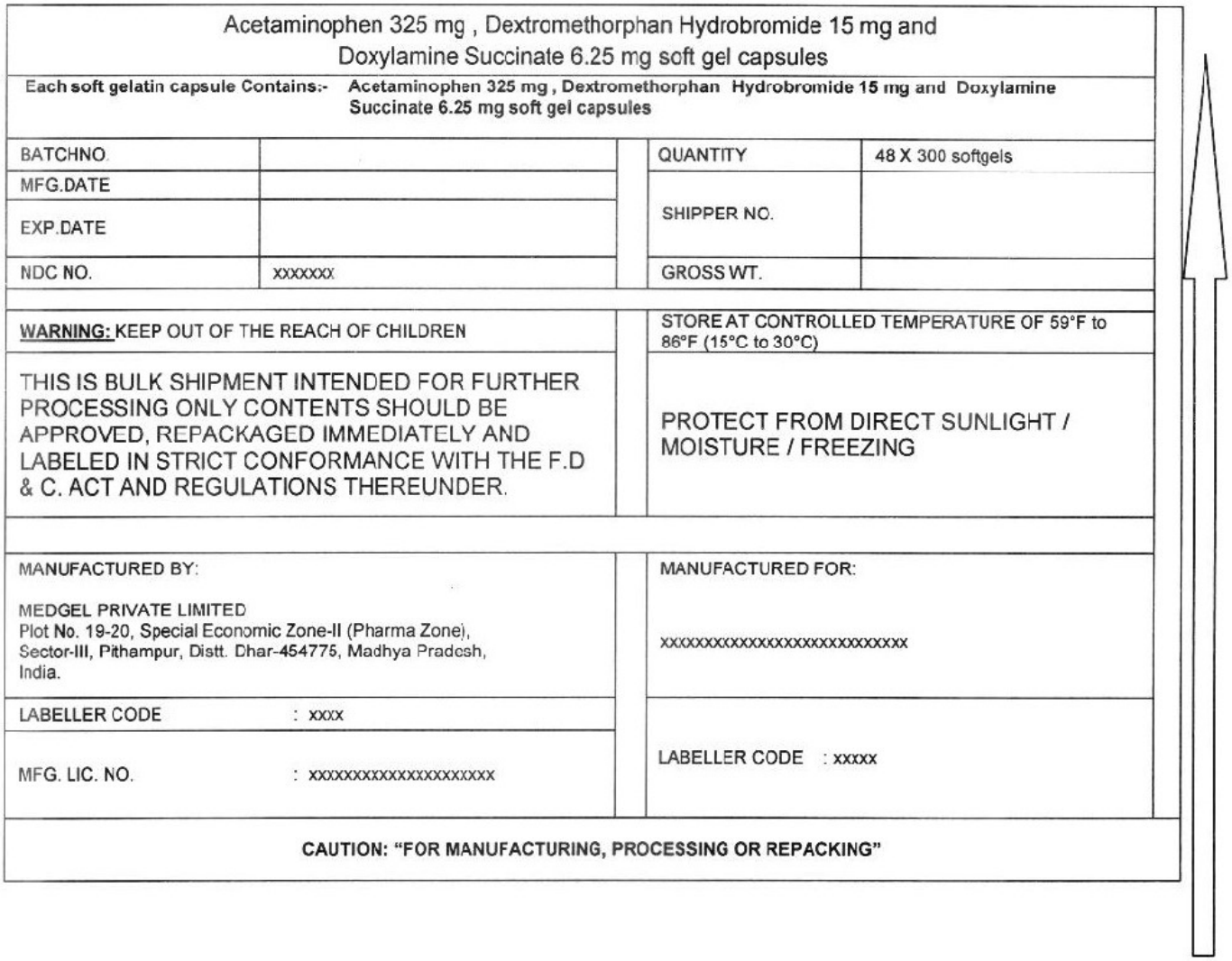
LOT NO:
DRUM NO:
MFG DATE:
QUANTITY:
NDC NO: 55629-014-
EXP DATE:

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.



Acetaminophen 325 mg , Dextromethorphan Hydrobromide 15 mg and Doxylamine Succinate 6.25 mg soft gel capsules

Each soft gelatin capsule Contains:- Acetaminophen 325 mg , Dextromethorphan Hydrobromide 15 mg and Doxylamine Succinate 6.25 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

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.

STORE AT CONTROLLED TEMPERATURE OF 59°F to 86°F (15°C to 30°C)

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.

LABELLER CODE : xxxx

MFG. LIC. NO. : xxxxxxxxxxxxxxxxxxxx

MANUFACTURED FOR:

xxxxxxxxxxxxxxxxxxxxxxxxxxxx

LABELLER CODE : xxxxx

CAUTION: "FOR MANUFACTURING, PROCESSING OR REPACKING"

ACETAMINOPHEN, DEXTROMETHORPHAN HYDROBROMIDE, DOXYLAMINE SUCCINATE

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55629-014
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
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POVIDONE K30 (UNII: U725QWY32X)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	green	**Score**	no score
Shape	capsule	**Size**	21mm
Flavor		**Imprint Code**	IS2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55629-014-01	48 in 1 CARTON	03/01/2021	
1	NDC:55629-014-02	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(55629-014)

Revised: 3/2023 ONE2ZEE LIMITED LIABILITY COMPANY