ACETAMINOPHEN, DEXTROMETHORPHAN HYDROBROMIDE, PHENYLEPHRINE HYDROCHLORIDE- acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride 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 Cold and Flu capsule, liquid filled (Acetaminophen 325mg, Dextromethorphan HBr 10mg, Phenylephrine HCl 5mg)

Active ingredients (in each capsule)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Phenylephrine HCl 5 mg

Purose

- Pain reliever/ fever reducer
- Cough suppressant
- Nasal decongestant

Uses

temporarily relieves common cold/flu symptoms:

- cough due to minor throat & bronchial irritation
- nasal congestion
- sore throat
- headache
- minor aches/pains
- fever

Alcohol warning: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take acetaminophen or other pain relievers/fever reducers. Acetaminophen may cause liver damage.

Sore throat warning: If sore throat is severe, persists for more than two days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Do Not Use

- **with other medicines containing acetaminophen**
- 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

- heart disease
- thyroid disease
- diabetes
- high blood pressure
- trouble urinating due to enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough as occurs with smoking, asthma, 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
- symptoms get worse or last more than 5 days (children) or 7 days (adults)
- 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 the recommended dose 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 recommended - see **OVERDOSE** warning
- do not exceed 6 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 DayQuil or NyQuil products, carefully read each label to insure 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 red no. 40, fd&c yellow no. 6, titanium dioxide, gelatin, glycerin, sorbitol, water

PRINCIPAL DISPLAY PANEL - Shipping Label

Acetaminophen, Dextromethorphan HBr Phenylephrine HCL capsules

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

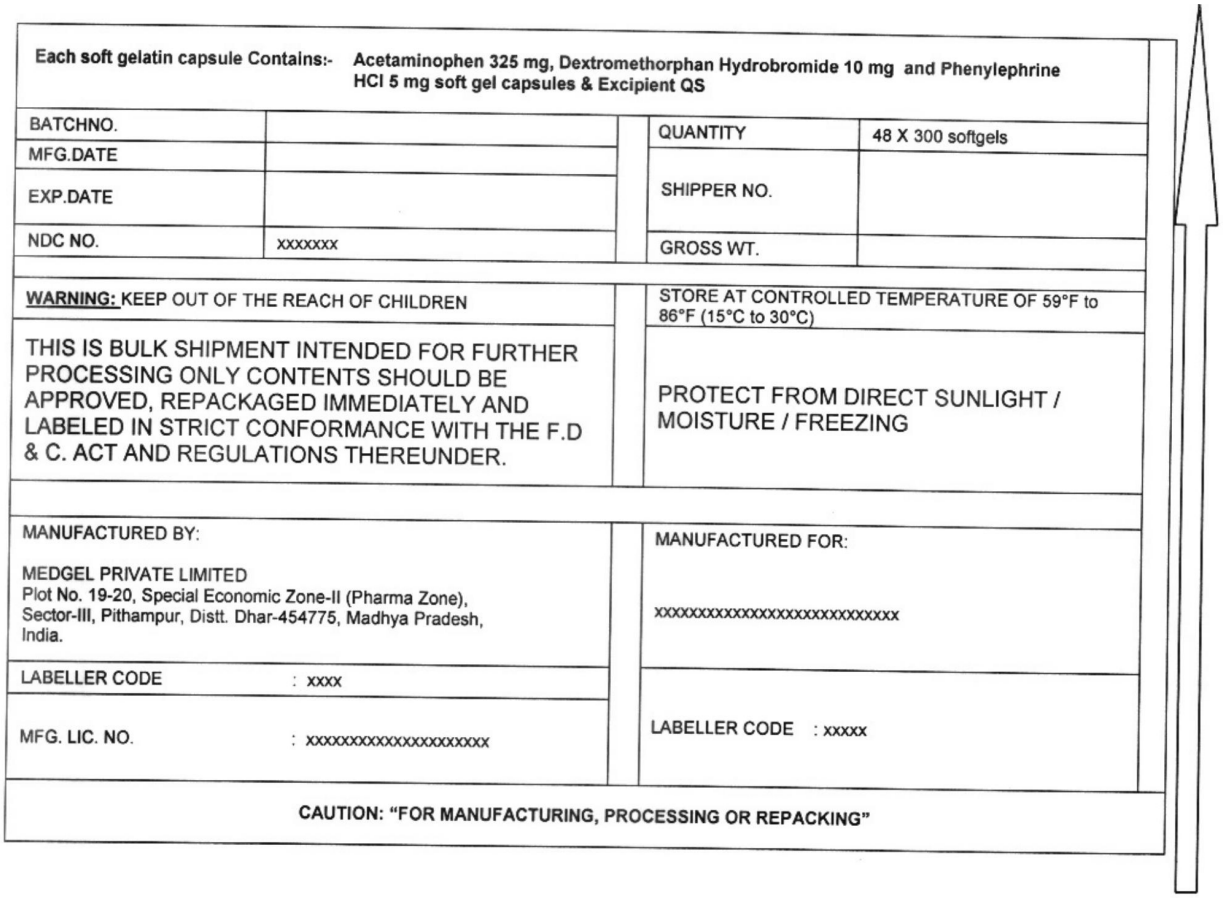
LOT NO:
DRUM NO:
MFG DATE:
QUANTITY:
NDC NO: 55629-012-
EXP DATE:

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 and Phenylephrine HCl 5 mg soft gel capsules & Excipient QS		
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. : xxxxxxxxxxxxxxxxxxxx		LABELLER CODE : xxxxx	
CAUTION: "FOR MANUFACTURING, PROCESSING OR REPACKING"			

ACETAMINOPHEN, DEXTROMETHORPHAN HYDROBROMIDE, PHENYLEPHRINE HYDROCHLORIDE

acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55629-012
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	5 mg

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POVIDONE K30 (UNII: U725QWY32X)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
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**	IS1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55629-012-01	48 in 1 CARTON	03/01/2021	
1	NDC:55629-012-02	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(55629-012)

Revised: 3/2023 ONE2ZEE LIMITED LIABILITY COMPANY