

**DEFENSOLITO- acetaminophen, phenylephrine hydrochloride tablet,
chewable**

Menper Distributors, Inc.

Defensol-ito

Active ingredients (in each tablet)

Acetaminophen 80 mg

Phenylephrine Hydrochloride 2.5 mg

Purpose

Pain reliever/ Fever Reducer

Nasal Decongestant

Uses

Temporarily relieves

- nasal decongestion due to a common cold, hay fever or other upper respiratory allergies, nasal stuffiness, sinus congestion and pressure
- minor aches and pains associated with the common cold, sore throat, headache, toothache and flu

Warnings

Do not exceed recommended dosage. Do not give to children under 6 years of age.

Liver toxicity may occur if

- recommended dosage is exceeded
- used with other products containing acetaminophen
- used with moderate amounts of alcohol

Drug Interaction Precaution: Do not use in a child who is taking prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, or Parkinson's Disease), or for two weeks after stopping the MAOI drug. If you do not know if your child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.

Do not give this product to a child unless directed by a doctor:

- with any other products containing acetaminophen (prescription or non-prescription)
- if you are not sure whether a drug contains acetaminophen
- if your child is allergic to acetaminophen or any other ingredients in the product
- for more than 5 days for pain
- for more than 3 days for fever
- who has heart disease, high blood pressure, thyroid disease, or diabetes

- who is taking blood thinning drug warfarin
- if your child has liver disease

Stop use and ask doctor promptly if

- pain persists and gets worse, if new symptoms occur or if redness or swelling is present because these could be signs of a serious condition
- symptoms do not improve or are accompanied by a fever
- if sore throat is severe, persists for more than 2 days, is accompanied or followed by a fever, headache, rash, nausea or vomiting
- nervousness, dizziness, or sleeplessness occur

If pregnant or breast feeding,ask a health care professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

Prompt medical attention is critical for adults as well as children even if you do not notice any signs or symptoms

Directions

- **Do not take more than 6 doses (12 chewable tablets) in a 24 hour period**

Children 6 to under 12 years of age	take 2 chewable tablets every 4 hours
Children under 6 years of age	consult a doctor

Inactive IngredientsAspartame, Carboxymethylcellulose Sodium, FD&C #40 aluminum lake, Flavor, Lactose, Magnesium Stearate, Polyvinyl Pirrolidone, Silicon Dioxide, Starch, Sugar and Talc.

Questions?Call 1-800-560-5223 weekdays 9 AM-4 PM EST

CHERRY FLAVOR

ASPIRIN FREE

FOR YOUR LITTLE CHILDREN

DEFENSOL-ITO

ACETAMINOPHEN, Pain Reliever/Fever Reducer
PHENYLEPHRINE HCL, Nasal Decongestant



Relieves:

- Headache
- Minor aches and pains
- Sinus congestion and pressure
- Nasal congestion

30 Chewable Tablets

Drug Facts

Active ingredients (in each tablet)
Acetaminophen 80 mg.....Pain Reliever/Fever Reducer
Phenylephrine Hydrochloride 2.5 mg.....Nasal Decongestant

Purpose
Pain Reliever/Fever Reducer

Uses Temporarily relieves ■ nasal congestion due to a common cold, hay fever or other upper respiratory allergies, nasal stuffiness, sinus congestion and pressure ■ minor aches and pains associated with the common cold, sore throat, headache, toothache and flu

Warnings
Do not exceed recommended dosage. Do not give to children under 6 years of age. Liver toxicity may occur if ■ recommended dosage is exceeded ■ used with other products containing acetaminophen ■ used with moderate amounts of alcohol

Drug Interaction Precaution: Do not use in a child who is taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, Parkinson's disease, or for 2 weeks after stopping the MAOI drug). If you do not know what your prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.

Unless directed by a doctor, do not give this product to a child
■ with any other medicine containing acetaminophen or non-steroidal anti-inflammatory drugs (NSAIDs) such as aspirin, ibuprofen, naproxen or other NSAIDs
■ if your child is allergic to acetaminophen or any other ingredients in the product
■ if your child is taking aspirin within a 6-week period before or after surgery
■ if your child is taking acetaminophen for more than 3 days for fever
■ if your child is taking acetaminophen for more than 10 days for pain
■ if your child has heart disease, high blood pressure, thyroid disease, or diabetes
■ if your child has a seizure disorder

Stop use and ask a doctor promptly if
■ symptoms do not improve or get worse, if new symptoms occur or if redness or swelling is present because these could be signs of a serious condition
■ symptoms do not improve or are accompanied by a fever ■ if sore throat is severe, persists for more than 2 days, is accompanied by difficulty swallowing, headache, rash, nausea or vomiting ■ if you experience dizziness, lightheadedness or faintness occur

If pregnant or trying to get pregnant, ask a health professional before use.
In case of accidental overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions: Do not take more than 6 doses (12 chewable tablets) in a 24 hour period.
Children 6 to under 12 years of age.....Take 2 chewable tablets every 4 hours
Children under 6 years of age.....consult a doctor

Other information: ■ phenylephrine: Contains 6 mg of phenylephrine mg per tablet Store at controlled room temperature: 15°-30°C (59°-86°F).
Tamper Evident Feature: Do not use if imprint seal around neck is torn, broken or missing

Inactive ingredients: aspartame, carboxymethylcellulose sodium, FD&C red #40 aluminum lake, flavor, lactose, magnesium stearate, polyvinyl pyrrolidone, silicon dioxide, starch, sugar, talc

Questions? www.menperdistributors.com or 1-800-566-3223 weekdays 9 am-4 pm EST

Distributed by: **Menper Distributors, Inc.** Rev: 11/11
6500 NW 35th Ave., Miami, FL 33147
www.menperdistributors.com
Lot# / Exp:

DEFENSOLITO

acetaminophen, phenylephrine hydrochloride tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53145-006
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	80 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg

Inactive Ingredients

Ingredient Name	Strength
ASPARTAME (UNII: Z0H242BBR1)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
LACTOSE (UNII: J2B2A4N98G)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYVINYL ACETATE PHTHALATE (UNII: 58QVG85GW3)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
SUGARCANE (UNII: 81H2R5AOH3)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	pink	Score	2 pieces
Shape	ROUND	Size	10mm
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53145-006-02	50 in 1 CARTON	02/21/2012	
1		2 in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:53145-006-30	1 in 1 BOX	02/21/2012	
2		30 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	M012	02/21/2012	

Labeler - Menper Distributors, Inc. (101947166)

Establishment

Name	Address	ID/FEI	Business Operations
Lex Pharma		046172888	manufacture(53145-006)

Revised: 7/2025

Menper Distributors, Inc.