TABCIN EXTRA STRENGTH- acetaminophen, chlorpheniramine maleate, dextromethorphan hbr, phenylephrine hcl, capsule, liquid filled
Pharmadel LLC

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.

Tabcin Antigrip Softgel (HL)

Drug Facts

Active Ingredients & Purposes

Acetaminophen 250mg

Chlorpheniramine maleate 2 mg

Dextromethorphan hydrobromide 10 mg

Phenylephrine hydrochloride 5 mg

Active Ingredients	***Purposes***
Acetaminophen 250mg.....	Pain reliever/ fever reducer
Chlorpheniramine maleate 2 mg.....	Antihistamine
Dextromethorphan hydrobromide 10 mg.....	Cough suppressant
Phenylephrine hydrochloride 5 mg.....	Nasal decongestant

Uses

For the temporary relief of symptoms due to the common cold/ flu:

- runny nose
- sneezing
- cough due to minor bronchial irritation
- nasal congestion
- minor aches and pain
- headache
- sore throat
- and to reduce fever

Warnings

Liver warning

This product contains **acetaminophen**. Severe liver damage may occur if you take

- more than **10 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

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, and 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
- a breathing problem such as emphysema or chronic bronchitis
- difficulty in urination due to enlargement of the prostate gland
- a persistent or chronic cough such as occurs with smoking, asthma, or emphysema, or if cough is accompanied by excessive phlegm (mucus) unless directed by a doctor

Ask a doctor or pharmacist before use if you are
- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

When using this product
- **do not exceed the recommended dosage**
- may cause excitability, especially in children
- may cause drowsiness; alcohol, sedatives, and tranquilizers may increase the drowsiness effect avoid alcoholic beverages while taking this product
- use caution when driving a motor vehicle or operating machinery

Stop use and ask a doctor if
- nervousness, dizziness, or sleeplessness occurs

- the 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 a 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.

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 for children even if you do not notice any signs or symptoms.

Directions

- **adults and children 12 years and over:** take 2 softgels with water every 4 hours. Do not exceed 10 softgels in 24 hours or as directed by a doctor.
- **children under 12 years:** do not use

Other information

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

Inactive ingredients

FD&C blue no.1, gelatin, glycerin, polyethylene glycol 400, povidone k30, propylene glycol, propylparaben, methylparaben, sodium hydroxide, sorbitol, titanium dioxide, water

Questions or comments

1-866-359-3478 (M-F) 9 AM to 5 PM EST or www.pharmadel.com

Principal Display Panel

TABCIN EXTRA STRENGTH

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Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55758-407
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	250 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	2 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONE K30 (UNII: U725QWY32X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Product Characteristics

Color	blue	**Score**	score with uneven pieces
Shape	CAPSULE (Oblong)	**Size**	21mm
Flavor		**Imprint Code**	SN5
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55758-407-12	1 in 1 CARTON	10/02/2023	
1		12 in 1 BLISTER PACK; 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	10/02/2023	

Labeler - Pharmadel LLC (030129680)

Revised: 9/2023 Pharmadel LLC