NIAFLU- dextromethorphan hbr, guaifenesin capsule, liquid filled
Pharmadel LLC

Niaflu (HHH)

Drug Facts

Active Ingredients and Purposes

.

Active ingredients (in each softgel)	***Purposes***
Dextromethorphan HBr 20 mg	Cough suppressant
Guaifenesin 400 mg	Expectorant

Uses

Temporarily alleviates common cold/flu symptoms:
- cough due to minor throat and bronchial irritation
- helps loosen phlegm (mucus) and thin bronchial secretions to
- drain bronchial tubes
- make coughs more productive

Warnings

Do not use
- 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
- a cough that is accompanied by excessive phlegm (mucus)
- a persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis or emphysema

Stop use and ask a doctor if
- cough persists for more than 7 days, tends to recur, or is accompanied by fever, rash, or persistent headache. 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.

Directions

- do not take more than 6 softgels in a 24 hour period

Age	**Dose**
adults and children 12 years and older	1 softgel, every 4 hours
children under 12 years	do not use

Other information

- store between 68-77°F (20-25°C)
- do not use if blister pack is torn or punctured

Inactive ingredients

gelatin, glycerin, polyethylene glycol 400, propylene glycol, povidone k30, sodium hydroxide, sorbitol sorbitan solution, titanium dioxide, water

Questions or comments?

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

Dist. by/ por:

PHARMADEL LLC

New Castle, DE, 19720

+1-866-359-3478

NIAFLU

dextromethorphan hbr, guaifenesin capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55758-507
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg

Inactive Ingredients	
Ingredient Name	**Strength**
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	

POVIDONE K30 (UNII: U725QWY32X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
1,4-SORBITAN (UNII: AV0YTZ4E6J)	

Product Characteristics

Color	yellow	**Score**	no score
Shape	CAPSULE	**Size**	21mm
Flavor		**Imprint Code**	AC3
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55758-507-01	1 in 1 CARTON	07/10/2025	
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 Drug	M012	07/10/2025	

Labeler - Pharmadel LLC (030129680)

Revised: 7/2025 Pharmadel LLC