ASPIRE MUCUS AND PAIN RELIEF SOFTGELS- aspire mucus and pain relief softgels capsule, liquid filled
Aspire Pharmaceuticals Inc.

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.

Active ingredients (in each liquid gel) Purposes
Acetaminophen 325 mg - Pain reliever/fever reducer
Guaifenesin 200 mg - Expectorant

DIRECTIONS

- **Do not take more than directed (see OVERDOSE WARNING)**
- Do not take more than 12 liquid gels in any 24-hour period
- Adults and children 12 years of age and older: take 2 liquid gels every 4 hours
- Children under 12 years of age: do not use

WARNINGS

Liver warning

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

- more than 12 liquid gels in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks daily 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, 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.

Ask a doctor before use if you have

- liver disease
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- cough that occurs with too much phlegm (mucus)

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

When using this product do not use more than directed

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.

Overdose warning

Taking more than the recommended dose (overdose) may cause liver damage. 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.

USES

- Temporarily relieves these common cold and flu symptoms:
  - Headache
  - Minor aches and pains
  - Sore throat
- Helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
- Temporarily reduces fever

FD&C blue no. 1, Gelatin, Glycerin, Hypromellose, Lecithin, Light mineral oil, Polyethylene glycol, Povidone, Propylene glycol, Purified water, Sorbitol sorbitan solution, Titanium dioxide

Ask a doctor before use if you have

- Liver disease
- Persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- Cough that occurs with too much phlegm (mucus)

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

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.

Keep out of reach of children

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

Active Ingredient Purpose

Acetaminophen 325 mg - Pain reliever/fever reduce

Guaifenesin 200 mg -Expectorant

1-732-447-1444

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.

When using this product do not use more than directed

ASPIRE MUCUS AND PAIN RELIEF SOFTGELS

aspire mucus and pain relief softgels capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:81013-105
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg

Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POVIDONE K30 (UNII: U725QWY32X)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
WATER (UNII: 059QF0KO0R)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
SORBITOL (UNII: 506T60A25R)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
GLYCERIN (UNII: PDC6A3C0OX)	
LECITHIN, SUNFLOWER (UNII: 834K0WOS5G)	

Product Characteristics

Color	blue (Opaque Navy Blue)	**Score**	no score
Shape	OVAL (Oblong Shape)	**Size**	22mm
Flavor		**Imprint Code**	AR09
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81013-105-01	6000 in 1 BAG; Type 0: Not a Combination Product	04/14/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

OTC monograph final	part341	04/14/2022	

Labeler - Aspire Pharmaceuticals Inc. (078797046)

Registrant - Dr Madhav Pai (078797046)

Revised: 2/2023 Aspire Pharmaceuticals Inc.