

**ASPIRE CONGESTION AND COUGH RELIEF DM SOFTGELS- aspire congestion and cough relief dm 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**

Dextromethorphan HBr 10 mg - Cough Suppressant

Guaifenesin 200 mg - Expectorant

**DIRECTIONS**

- Do not take more than 12 liquid gels in any 24-hour period
- Adults and children 12 years of age and over: take 2 liquid gels every 4 hours
- Children under 12 years of age: do not use

**USES**

- Helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
- Temporarily relieves:
- Cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants
- The intensity of coughing
- The impulse to cough to help you get to sleep

**Do not use**

- If you are now taking a prescription monamine 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 and MAOI, ask a doctor or pharmacist before taking this product.

**Ask a doctor before use if you have**

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

**When using this product do not use more than directed**

**Stop use and ask a doctor if**

- Cough lasts more than 7 days, comes back, or occurs with fever, 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.**

D&C yellow no. 10, FD&C blue no. 1, Gelatin, Glycerin, Lecithin, Light mineral oil, Polyethylene glycol, Povidone, Propylene glycol, Purified water, Sorbitol sorbitan solution, Titanium dioxide

**Ask a doctor before use if you have**

- 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 your prescription drug contains and MAOI

**Do not use**

- If you are now taking a prescription monamine 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 and MAOI, ask a doctor or pharmacist before taking this product.

**Keep out of reach of children**

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

**Active Ingredient Purpose**

Guaifenesin 200 mg -Expectorant

Dextromethorphan HBr 10 mg -Cough suppressant

1-732-447-1444

**Stop use and ask a doctor if**

- Cough lasts more than 7 days, comes back, or occurs with fever, rash, or headache that lasts. These could be signs of a serious condition.

**When using this product do not use more than directed**

**Do not use**

- If you are now taking a prescription monamine 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 and MAOI, ask a doctor or pharmacist before taking this product.

**Ask a doctor before use if you have**

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

**When using this product do not use more than directed**

**Stop use and ask a doctor if**

- cough lasts more than 7 days, comes back, or occurs with fever, 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.**

## ASPIRE CONGESTION AND COUGH RELIEF DM SOFTGELS

aspire congestion and cough relief dm softgels capsule, liquid filled

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:81013-104
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>POVIDONE K12</b> (UNII: 333AG72FWJ)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	
<b>LIGHT MINERAL OIL</b> (UNII: N6K5787QVP)	
<b>LECITHIN, SUNFLOWER</b> (UNII: 834K0WOS5G)	
<b>GELATIN, UNSPECIFIED</b> (UNII: 2G86QN327L)	
<b>SORBITOL</b> (UNII: 506T60A25R)	

### Product Characteristics

<b>Color</b>	green	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	15mm
<b>Flavor</b>		<b>Imprint Code</b>	AR08
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81013-104-01	8000 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)