

ASPIRE DAY CONGESTION AND HEADACHE SOFTGEL- aspire day congestion and headache softgel capsule, liquid filled
ASPIRE NIGHT COLD AND FLU SOFTGEL- aspire night cold and flu softgel capsule, liquid filled
ASPIRE DAYTIME MUCUS AND SINUS SOFTGEL- aspire daytime mucus and sinus softgel 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
Dextromethorphan HBr 10 mg - Cough suppressant
Guaifenesin 200 mg - Expectorant
Phenylephrine HCl 5 mg - Nasal Decongestant

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

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.

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.
- 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
- diabetes
- high blood pressure
- thyroid disease
- trouble urinating due to an enlarged prostate gland
- 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

- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion, 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:

Nasal congestion

Headache

Cough

Minor aches and pains

Sore throat

- Temporarily reduces fever
- Helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

INACTIVE INGREDIENTS

Polyethylene Glycol, Unspecified

Propylene Glycol

Povidone, Unspecified

Gelatin, Unspecified

Glycerin

Sorbitol

Purified Water

Lecithin, Sunflower

Light Mineral oil

FD&C Colors

Ask a doctor before use if you have

- Liver disease
- Heart disease
- Diabetes
- High blood pressure
- Thyroid disease
- Trouble urinating due to an enlarged prostate gland
- 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.
- 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.

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 reducer
Dextromethorphan HBr 10 mg -Cough suppressant
Guaifenesin 200 mg -Expectorant
Phenylephrine HCl 5 mg -Nasal Decongestant

1-732-447-1444

Stop use and ask a doctor if

- Nervousness, dizziness, or sleeplessness occur
- Pain, nasal congestion, 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

Active ingredients in each liquid gel -Purposes

Acetaminophen 325 mg-Pain reliever/fever reducer
Dextromethorphan HBr 10 mg -Cough suppressant
Doxylamine Succinate 6.25 mg - Antihistamine
Phenylephrine HCl 5 mg-Nasal Decongestant

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

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.

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.
- 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
- diabetes
- high blood pressure
- thyroid disease
- glaucoma
- trouble urinating due to an enlarged prostate gland
- breathing problems such as emphysema or chronic bronchitis
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema

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 use more than directed**
- excitability may occur, especially in children
- marked drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion, 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:
 - cough
 - nasal congestion
 - minor aches and pains
 - sore throat
 - headache
 - runny nose
 - sneezing
- temporarily reduces fever
- controls cough to help you get to sleep

INACTIVE INGREDIENTS

Polyethylene Glycol, Unspecified

Propylene Glycol

Povidone, Unspecified

Gelatin, Unspecified

Glycerin

Sorbitol

Purified Water

Lecithin, Sunflower

Light Mineral oil

FD&C Colors

Ask a doctor before use if you have

- Liver disease
- Heart disease
- Diabetes

- High blood pressure
- Thyroid disease
- Glaucoma
- Trouble urinating due to an enlarged prostate gland
- Breathing problems such as emphysema or chronic bronchitis
- Cough that occurs with too much phlegm (mucus)
- Persistent or chronic cough such as occurs with smoking, asthma, or emphysema

Ask a doctor or pharmacist before use if you are

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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.

Keep out of reach of children.

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

Active ingredients Purposes

Acetaminophen 325 mg -Pain reliever/fever reducer
 Dextromethorphan HBr 10 mg -Cough suppressant
 Doxylamine succinate 6.25 mg -Antihistamine
 Phenylephrine HCl 5 mg -Nasal decongestant

1-732-447-1444

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- 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
- Excitability may occur, especially in children
- Marked drowsiness may occur
- Alcohol, sedatives, and tranquilizers may increase drowsiness
- Avoid alcoholic drinks
- Be careful when driving a motor vehicle or operating machinery

Active ingredients (in each liquid gel) Purposes

Acetaminophen 325 mg -Pain reliever/fever reducer

Dextromethorphan HBr 10 mg -Cough suppressant

Phenylephrine HCl 5 mg -Nasal decongestant

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- heart disease
- diabetes

- high blood pressure
- thyroid disease
- trouble urinating due to an enlarged prostate gland
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USES

- temporarily relieves these common cold and flu symptoms:
 - nasal congestion
 - cough
 - headache
 - minor aches and pains
 - sinus congestion and pressure
- temporarily reduces fever
- temporarily promotes nasal and/or sinus drainage

INACTIVE INGREDIENTS

Polyethylene Glycol, Unspecified

Propylene Glycol

Povidone, Unspecified

Gelatin, Unspecified

Glycerin

Sorbitol

Purified Water

Lecithin, Sunflower

Light Mineral oil

FD&C Colors

Ask a doctor before use if you have

- Liver disease
- Heart disease
- Diabetes
- High blood pressure
- Thyroid disease
- Trouble urinating due to an enlarged prostate gland
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Phenylephrine HCl 5 mg -Nasal decongestant

1-732-447-1444

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- 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 Pharmaceuticals Inc
37 Veronica Avenue, Somerset, New Jersey, 08873 USA

NDC No.: 81013-101-01

Product: Aspire Daytime Mucus and Sinus Softgels

Code: 3154698

Each Softgel contains Acetaminophen 325 mg/ Guaifenesin 200 mg/ Dextromethorphan Hydrobromide 10 mg/ Phenylephrine Hydrochloride 5 mg
Caution: FOR FURTHER MANUFACTURING, PROCESSING OR REPACKAGING

Product Code: A30001

Quantity: 4000 Capsules

Lot Number: OTCXXXX

Manufacturing Date: MMM YYYY



OTCXXXX



MMM YYYY

Box No: 1

IMPORTANT

- Inspect immediately upon receipt.
- This is a bulk shipment intended for further processing only
- Protect from heat, humidity and heat. Do not refrigerate.
- Store 15-30°C (59-86°F).

MADE IN USA

A30001

REV-02/ 2021

Aspire Pharmaceuticals Inc
37 Veronica Avenue, Somerset, New Jersey, 08873 USA

NDC No.: 81013-102-01

Product: Aspire Night Cold and Flu Softgels

Code: 3154697

Each Softgel contains Acetaminophen 325 mg/ Dextromethorphan Hydrobromide USP 10 mg/ Doxylamine Succinate 6.25 mg/ Phenylephrine Hydrochloride 5 mg
Caution: FOR FURTHER MANUFACTURING, PROCESSING OR REPACKAGING

Product Code: A30003

Quantity: 5000 Capsules

Lot Number: OTCXXXX

Manufacturing Date: MMM YYYY



OTCXXXX



MMM YYYY

Box No: 1

IMPORTANT

- Inspect immediately upon receipt.
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MADE IN USA

A30003

REV-02/ 2021

Aspire Pharmaceuticals Inc
37 Veronica Avenue, Somerset, New Jersey, 08873 USA

NDC No.: 81013-103-01

Product: Aspire Day Congestion & Headache Softgel

Code: 3154690

Each Softgel contains Acetaminophen 325 mg/ Dextromethorphan Hydrobromide USP 10 mg/ Phenylephrine Hydrochloride 5 mg
Caution: FOR FURTHER MANUFACTURING, PROCESSING OR REPACKAGING

Product Code: A30004

Quantity: 5000 Capsules

Lot Number: OTCXXXX

Manufacturing Date: MMM YYYY



OTCXXXX



MMM YYYY

Box No:

MADE IN USA

A30004

IMPORTANT

- Inspect immediately upon receipt.
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- Store 15-30°C (59-86°F).

REV-02/ 2021

ASPIRE DAY CONGESTION AND HEADACHE SOFTGEL

aspire day congestion and headache softgel capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81013-103
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C RED NO. 40 (UNII: WZB9127XOA)	
LECITHIN, SUNFLOWER (UNII: 834K0WOS5G)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
GLYCERIN (UNII: PDC6A3C0OX)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0K00R)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)

Product Characteristics

Color	red	Score	no score
Shape	OVAL (OBLONG SHAPE)	Size	21mm
Flavor		Imprint Code	AR04
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81013-103-01	5000 in 1 BAG; Type 0: Not a Combination Product	03/17/2021	

Aspire Pharmaceuticals Inc
37 Veronica Avenue, Somerset, New Jersey, 08873 USA

NDC No.: 81013-103-01
Product: Aspire Day Congestion & Headache Softgel

Code: 3154690

Each Softgel contains Acetaminophen 325 mg/ Dextromethorphan Hydrobromide USP 10 mg/ Phenylephrine Hydrochloride 5 mg
Caution: FOR FURTHER MANUFACTURING, PROCESSING OR REPACKAGING

Product Code: A30004

Quantity: 5000 Capsules

Lot Number: OTCXXXX

Manufacturing Date: MMM YYYY



Box No:

MADE IN USA

A30004

IMPORTANT

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- This is a bulk shipment intended for further processing only.
- Protect from heat, humidity and heat. Do not refrigerate.
- Store 15-30°C (59-86°F).

REV-02/2021

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	03/17/2021	

ASPIRE NIGHT COLD AND FLU SOFTGEL

aspire night cold and flu softgel capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81013-102
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
LECITHIN, SUNFLOWER (UNII: 834K0WOS5G)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
GLYCERIN (UNII: PDC6A3C0OX)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	

Product Characteristics

Color	green	Score	no score
Shape	OVAL (OBLONG SHAPE)	Size	21mm
Flavor		Imprint Code	AR03
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81013-102-01	5000 in 1 BAG; Type 0: Not a Combination Product	03/17/2021	

Aspire Pharmaceuticals Inc
37 Veronica Avenue, Somerset, New Jersey, 08873 USA

NDC No.: 81013-102-01
Product: Aspire Night Cold and Flu Softgels

Code: 3154697

Each Softgel contains Acetaminophen 325 mg/ Dextromethorphan Hydrobromide USP 10 mg/ Doxylamine Succinate 6.25 mg/ Phenylephrine Hydrochloride 5 mg
Caution: FOR FURTHER MANUFACTURING, PROCESSING OR REPACKAGING

Product Code: A30003

Quantity: 5000 Capsules

Lot Number: OTCXXXX

Manufacturing Date: MMM YYYY



OTCXXXX



MMM YYYY

Box No: 1

IMPORTANT

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MADE IN USA

A30003

REV-02/ 2021

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	03/17/2021	

ASPIRE DAYTIME MUCUS AND SINUS SOFTGEL

aspire daytime mucus and sinus softgel capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81013-101
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
LECITHIN, SUNFLOWER (UNII: 834K0WOS5G)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	orange	Score	no score
Shape	OVAL (OBLONG SHAPE)	Size	25mm
Flavor		Imprint Code	AR01
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81013-101-01	4000 in 1 BAG; Type 0: Not a Combination Product	03/17/2021	

Aspire Pharmaceuticals Inc
37 Veronica Avenue, Somerset, New Jersey, 08873 USA

NDC No.: 81013-101-01
Product: Aspire Daytime Mucus and Sinus Softgels

Code: 3154698

Each Softgel contains Acetaminophen 325 mg/ Guaifenesin 200 mg/ Dextromethorphan Hydrobromide 10 mg/ Phenylephrine Hydrochloride 5 mg
Caution: FOR FURTHER MANUFACTURING, PROCESSING OR REPACKAGING

Product Code: A30001

Quantity: 4000 Capsules

Lot Number: OTCXXXX

Manufacturing Date: MMM YYYY



OTCXXXX



MMM YYYY

Box No: 1

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- Store 15-30°C (59-86°F).

MADE IN USA

A30001

REV-02/ 2021

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	03/17/2021	

Labeler - Aspire Pharmaceuticals Inc. (078797046)

Registrant - Dr Madhav Pai (078797046)

Establishment

Name	Address	ID/FEI	Business Operations
Aspire Pharmaceuticals Inc.		078797046	manufacture(81013-101, 81013-102, 81013-103)

Revised: 1/2023

Aspire Pharmaceuticals Inc.