AXIV DAYTIME - NIGHTTIME 48 SOFTGELS- acetaminophen, dextromethorphan hydrobromide, doxylamine succinate
AXIV DAYTIME - NIGHTTIME 72 SOFTGELS- acetaminophen, dextromethorphan hydrobromide, doxylamine succinate
VIVUNT PHARMA LLC

AXIV DayTime & NightTime

Day Time

Drug Facts

Active ingredients (in each softgel)	***Purpose***
Acetaminophen 325 mg	Pain Reliever-fever reducer
Dextrometrophan HBr 10 mg	Cough Suppressant

Uses

Temporarily relieves common cold/flu symptoms:

- cough due to minor throat and bronchial irritation
- sore throat
- headache
- minor aches and pains
- fever

Warnings

Liver warning

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

- more than 8 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

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

Sore throat warning: If sore throat is severe, lasts 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.
- if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if you have

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

Ask a doctor or pharmacist before use if you are

taking the blood thinning drug warfarin.

When using this product

do not exceed recommended dose

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

Keep out of reach of children

Keep out of reach of children.

If pregnant or breast-feeding

ask a health professional before use.

Overdose warning

In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately.

Directions

- Take only as directed (see overdose warning):
- Do not take more than 8 softgels in 24 hours.

adults and children 12 years and over	2 softgels with water every 4 hours
children 4 to under 12 years	consult a doctor
children under 4 years	do not use

Other information

- Store at 20° - 25 °C (68 °- 77 °F)
- Read all product information before using
- Tamper evident: Do not use if the foil printed on the blister is torn or ripped

Inactive ingredients

FD&C Red No. 40, FD&C Yellow No. 6, Gelatin, Glycerin, Methylparaben, Polyethylene Glycol 400, Povidone K30, Propylene Glycol, Propylparaben, Purified Water, Sorbitol, Titanium Dioxide

Night Time

Drug Facts

Active ingredients (in each softgel)	***Purpose***
Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 15 mg	Cough suppressant
Doxylamine succinate 6.25 mg	Antihistamine

Uses

Temporarily relieves common cold/flu symptoms:

- cough due to minor throat & bronchial irritation
- sore throat
- headache
- minor aches & pains
- fever
- runny nose & sneezing

Warnings

Liver warning

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

- more than 8 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

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, lasts 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.
- if you have ever had an allergic reaction to this product or any of its ingredients
- to make a child sleep

Ask a doctor before use if you have

- liver disease
- glaucoma
- cough that occurs with too much phlegm (mucus)
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema
- trouble urinating due to enlarged prostate gland

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
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery
- alcohol, sedatives, and tranquilizers may increase drowsiness

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.

Keep out of reach of children

Keep out of reach of children.

If pregnant or breast-feeding

ask a health professional before use.

Overdose warning

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.

Directions

- Take only as directed (see overdose warning):
- Do not take more than 8 softgels in 24 hours.

adults and children 12 years and over	2 softgels with water every 6 hours
children 4 to under 12 years	consult a doctor
children under 4 years	do not use

Other information

- Store at 20° - 25 °C (68 °- 77 °F)
- Read all product information before using
- Tamper evident: Do not use if carton is open or blister unit is broken.

Inactive ingredients

D&C Yellow No. 10, FD&C Blue No. 1, Gelatin, Glycerin, Methylparaben, Polyethylene Glycol 400, Povidone K30, Propylene Glycol, Propylparaben, Purified Water, Sorbitol, Titanium Dioxide

Distributed by:

VIVUNT PHARMA LLC
8950 SW 74th. Court. Suite 1901

Miami, Florida, 33156-3178

Made in India

www.vivunt.live

PRINCIPAL DISPLAY PANEL - 48 Caps Day&Night

Compare to Vicks® DayQuil ® & NyQuil ®

Cold&Flu LiquiCaps®

active ingredients*
NDC 82706-017-01
AXIV

DayTime

- Pain Reliever
- Fever Reducer
- Cough Suppressant

Acetaminophen, Dextromethorphan HBr

32 SOFTGELS** **Liquid-filled capsules

NightTime

- Pain Reliever
- Fever Reducer
- Cough Suppressant
- Antihistamine

Acetaminophen, Dextromethorphan HBr, Doxylamine Succinate

16 SOFTGELS** **Liquid-filled capsules

*This product is not manufactured or distributed by The Procter & Gamble Company, owner of the registered trademarks Vicks® DayQuil ® & NyQuil ® Cold&Flu LiquiCaps®.

PRINCIPAL DISPLAY PANEL - 72 Caps Day&Night

Compare to Vicks® DayQuil ® & NyQuil ®

Cold&Flu LiquiCaps®

active ingredients*

NDC 82706-018-01

AXIV

DayTime

- Pain Reliever
- Fever Reducer
- Cough Suppressant

Acetaminophen, Dextromethorphan HBr

48 SOFTGELS** **Liquid-filled capsules

NightTime

- Pain Reliever
- Fever Reducer
- Cough Suppressant
- Antihistamine

Acetaminophen, Dextromethorphan HBr, Doxylamine Succinate

24 SOFTGELS** **Liquid-filled capsules

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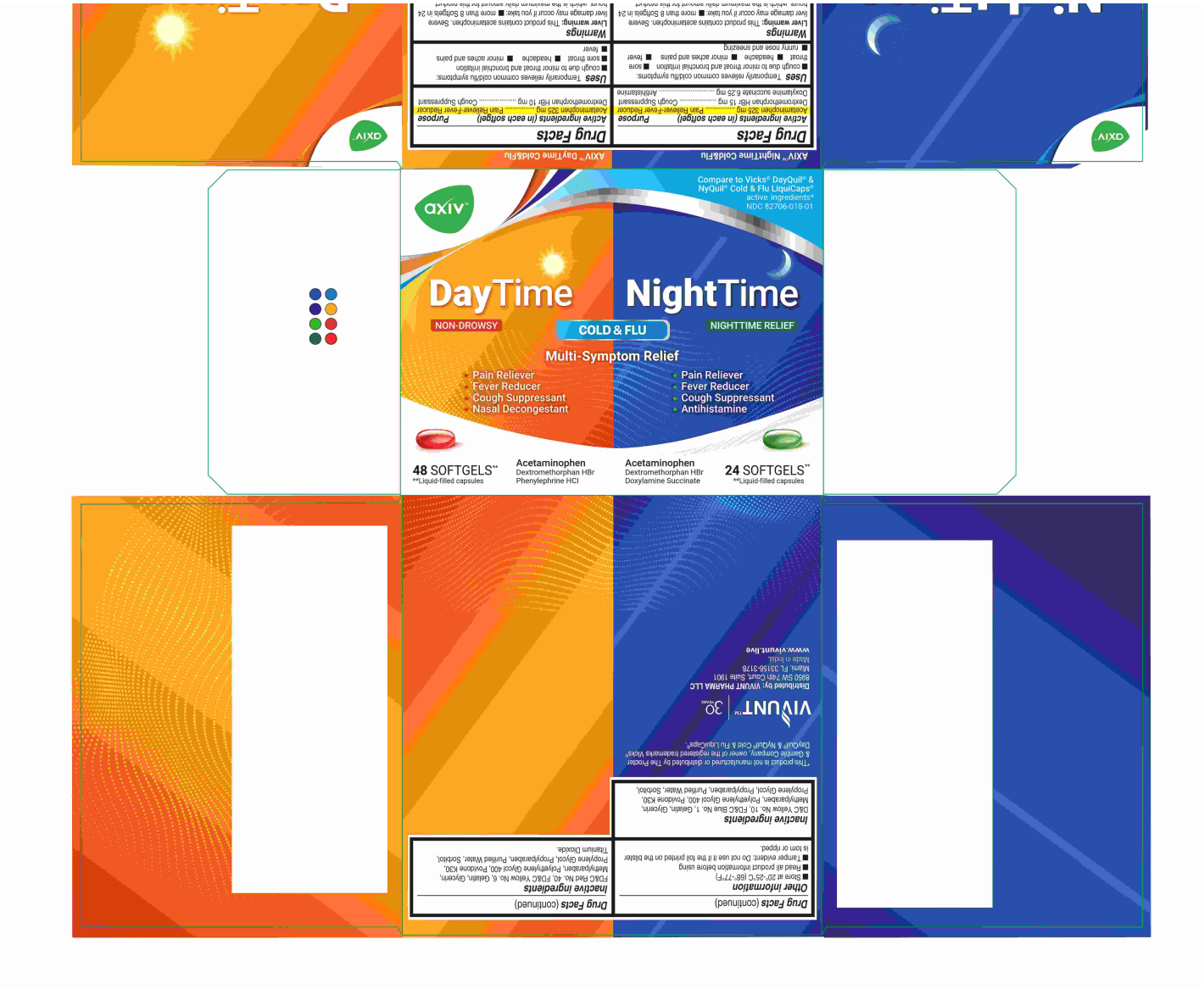

AXIV DAYTIME - NIGHTTIME 48 SOFTGELS

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82706-017

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82706-017-01	1 in 1 PACKAGE; Type 1: Convenience Kit of Co-Package	03/08/2024	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	4 BLISTER PACK	32
Part 2	2 BLISTER PACK	16

Part 1 of 2

AXIV DAYTIME

acetaminophen, dextromethorphan hydrobromide capsule, liquid filled

Product Information	
Item Code (Source)	NDC:82706-015
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

Inactive Ingredients	
Ingredient Name	**Strength**
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
WATER (UNII: 059QF0KO0R)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POVIDONE K30 (UNII: U725QWY32X)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics			
Color	orange	**Score**	no score
Shape	OVAL	**Size**	22mm
Flavor		**Imprint Code**	AXIV
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		8 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	03/08/2024	

Part 2 of 2

AXIV NIGHTTIME

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate capsule, liquid filled

Product Information

Item Code (Source)	NDC:82706-016
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg

Inactive Ingredients

Ingredient Name	Strength
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GELATIN (UNII: 2G86QN327L)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
POVIDONE K30 (UNII: U725QWY32X)	
WATER (UNII: 059QF0KO0R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
GLYCERIN (UNII: PDC6A3C0OX)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	green	**Score**	no score
Shape	OVAL	**Size**	22mm

Flavor		**Imprint Code**	AXIV
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		8 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	03/08/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	03/08/2024	

AXIV DAYTIME - NIGHTTIME 72 SOFTGELS

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate kit

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:82706-018

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82706-018-01	1 in 1 PACKAGE; Type 1: Convenience Kit of Co-Package	03/08/2024	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	6 BLISTER PACK	48
Part 2	3 BLISTER PACK	24

Part 1 of 2

AXIV DAYTIME

acetaminophen, dextromethorphan hydrobromide capsule, liquid filled

Product Information

Item Code (Source)	NDC:82706-015
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

Inactive Ingredients

Ingredient Name	Strength
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
WATER (UNII: 059QF0KO0R)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POVIDONE K30 (UNII: U725QWY32X)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	orange	**Score**	no score
Shape	OVAL	**Size**	22mm
Flavor		**Imprint Code**	AXIV
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		8 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	03/08/2024	

Part 2 of 2

AXIV NIGHTTIME

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate capsule, liquid filled

Product Information

Item Code (Source)	NDC:82706-016
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg

Inactive Ingredients

Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GELATIN (UNII: 2G86QN327L)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
POVIDONE K30 (UNII: U725QWY32X)	
WATER (UNII: 059QF0KO0R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
GLYCERIN (UNII: PDC6A3C0OX)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	

Product Characteristics

Color	green	**Score**	no score
Shape	OVAL	**Size**	22mm
Flavor		**Imprint Code**	AXIV
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1		8 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	03/08/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	03/08/2024	

Labeler - VIVUNT PHARMA LLC (045829437)

Revised: 3/2024 VIVUNT PHARMA LLC