

**AXIM DAYTIME- acetaminophen, dextromethorphan hydrobromide,
phenylephrine hydrochloride capsule, liquid filled
VIVUNT PHARMA LLC**

AXIM - DayTime Cold & Flu

Drug Facts

| <i>Active ingredients (in each softgel)</i> | <i>Purpose</i> |
|----------------------------------------------------|-----------------------------|
| Acetaminophen 325 mg | Pain reliever/fever reducer |
| Dextromethorphan HBr 10 mg | Cough suppressant |
| Phenylephrine HCl 5 mg | Nasal decongestant |

Uses

Temporarily relieves common cold/flu symptoms:

- nasal Congestion
- 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 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day 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, 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
- heart disease
- high blood pressure
- diabetes
- thyroid disease
- trouble urinating due to an enlarged prostate gland
- 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

- you get nervous, dizzy or sleepless
- 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.**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 carton is open or blister unit is broken.

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

Product of India

Distributed by:

VIVUNT PHARMA LLC
8950 SW 74th. Court. Suite 1901
Miami, Florida. Z,C. 33156-3178

PRINCIPAL DISPLAY PANEL - Axim DayTime Carton 24

Compare to

VICKS ® DayQuil®

Cold&Flu LiquiCaps®

active ingredients*

NDC 82706-001-01

AXIM - DayTime

COLD&FLU

Multi-Symptom Relief

- Pain Reliever
- Fever Reducer
- Cough Suppressant
- Nasal Decongestant

Non-Drowsy

Acetaminophen , Phenylephrine HCl,

Dextromethorphan HBr

24 SOFTGELS** **Liquid-filled capsules

*This product is not manufactured or distributed by

The Procter &Gamble Company, owner of the registered trademarks Vicks® DayQuil® and LiquiCaps®.



AXIM DAYTIME

acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride capsule, liquid filled

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:82706-001 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|----------------------------------------------------------------------------------------------|-------------------------------|----------|
| ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | ACETAMINOPHEN | 325 mg |
| DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 10 mg |
| PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1VS297W6MV) | PHENYLEPHRINE HYDROCHLORIDE | 5 mg |

Inactive Ingredients

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

Product Characteristics

| | | | |
|-----------------|--------|---------------------|----------|
| Color | orange | Score | no score |
| Shape | OVAL | Size | 22mm |
| Flavor | | Imprint Code | axim |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--------------------------------------------------------|----------------------|--------------------|
| 1 | NDC:82706-001-01 | 3 in 1 CARTON | 05/09/2022 | |
| 1 | | 8 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 2 | NDC:82706-001-02 | 3 in 1 CARTON | 09/20/2023 | 09/20/2023 |
| 2 | | 2 in 1 POUCH; 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 | 05/09/2022 | |

