WALGREENS DAYTIME NIGHTTIME WAL-FLU SEVERE COLD AND COUGH KIT-acetaminophen, diphenhydramine hcl, phenylephrine hcl and dextromethorphan hbr Walgreen Co.

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.

Walgreens Daytime Nighttime Wal-Flu Severe Cold & Cough Kit

Active Ingredients for Nighttime

Active ingredients (in each packet) Purpose

Acetaminophen 650 mgPain reliever/Fever reducer

Diphenhydramine hydrochloride 25 mgAnitihistamine/Cough suppressant

Phenylephrine hydrochloride 10 mg......Nasal decongestant.

Active Ingredients for Daytime

Active ingredients (in each packet) Purpose

Acetaminophen 650 mgPain reliever/Fever reducer

Dextromethorphan hydrobromide 20 mgCough suppressant

Phenylephrine hydrochloride 10 mg......Nasal decongestant.

Purpose Nighttime

Uses

- temporarily relieves:
- minor aches and pains headache minor sore throat pain
- nasal and sinus congestion cough due to minor throat and bronchial irritation
- runny nose sneezing itchy, watery eyes due to hay fever
- itchy nose and throat
- temporarily reduces fever.

Purpose Daytime

Uses

- Temporarily relieves:
- minor aches and pains headache minor sore throat pain
- nasal and sinus congestion cough due to minor throat and bronchial irritation
- Temporarily reduces fever.

Nighttime Warnings

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take - more than 6 packets in 24 hours, which is the maximum daily amount - with other drugs containing acetaminophen - 3 or more alcoholic drinks every day while using this product.

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 and nonprescription). Ask a doctor or pharmacist before using with other drugs if you are not sure.
- with any other product containing diphenhydramine, even one used on the skin
- 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 a MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

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

Ask a doctor or pharmacist before use if you are

- taking sedatives or tranquilizers
- taking the blood thinning drug warfarin.

When using this product

- do not exceed recommended dosage
- avoid alcoholic drinks
- marked drowsiness may occur
- alcohol, sedatives and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children.

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occurs
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur

- symptoms do not get better or worsen
- pain, cough or nasal congestion gets worse or lasts more than 7 days
- cough 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 care professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Daytime Warnings

Warnings

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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 and nonprescription). Ask a doctor or pharmacist before using with other drugs if you are not sure.
- 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 a MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

- liver disease - heart disease - high blood pressure - thyroid disease - diabetes - trouble urinating due to an enlarged prostate gland - a breathing problem such as emphysema, asthma, or chronic bronchitis - cough that occurs with too much phlegm (mucus) - cough that lasts or is chronic such 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 dosage.

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occurs
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur

- symptoms do not get better or worsen
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If pregnant or breast-feeding, ask a health care professional before use.

Keep out of reach of children.

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Nighttime Dosage & Administration

Directions

- do not use more than directed
- take every 4 hours; not to exceed 6 packets in 24 hours or as directed by a doctor.
- adults and children 12 years of age and over: dissolve contents of one packet into 8 oz. hot water; sip while hot. Consume entire drink within 10-15 minutes.
- children under 12 years of age: consult a doctor.
- if using a microwave, add contents of one packet to 8 oz. of cool water: stir briskly before and after heating. Do not overheat.

Daytime Dosage & Administration

Directions

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- take every 4 hours; not to exceed 6 packets in 24 hours or as directed by a doctor.
- adults and children 12 years of age and over: dissolve contents of one packet into 8 oz. hot water; sip while hot. Consume entire drink within 10-15 minutes.
- children under 12 years of age: consult a doctor.
- if using a microwave, add contents of one packet to 8 oz. of cool water: stir briskly before and after heating. Do not overheat.

Nighttime Information for Patients

Other information

- each packet contains: potassium 7 mg, sodium 46 mg
- phenylketonurics: contains phenylalanine 13 mg per packet

- store at controlled room temperature 20-25C (68-77F). Protect from excessive heat and moisture.

Daytime Information for Patients

Other information

- each packet contains: potassium 8 mg, sodium 20 mg
- phenylketonurics: contains phenylalanine 14 mg per packet
- store at controlled room temperature 20-25C (68-77F). Protect from excessive heat and moisture.

Nighttime Inactive Ingredient

Acesulfame K, Aspartame, Caramel Color, Citric Acid, D and C Yellow 10, Maltodextrin, Natural Flavors, Sodium Citrate, Starch and Sugar.

Daytime Inactive Ingredient

Acesulfame K, Aspartame, Citric Acid, FD and C Blue No. 1, FD and C Red No. 40, Maltodextrin, Menthol, Natural Flavors, Sodium Citrate, Starch and Sugar.



WALGREENS DAYTIME NIGHTTIME WAL-FLU SEVERE COLD AND COUGH KIT

acetaminophen, diphenhydramine hcl, phenylephrine hcl and dextromethorphan hbr kit

| Product Information | | | |
|---------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0363-1102 |
| | | | |

|] | Packaging | | | |
|---|------------------|---|-----------------------------|--------------------|
| 7 | # Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0363-1102-12 | 1 in 1 BOX; Type 0: Not a Combination Product | | |

| Quant | Quantity of Parts | | |
|--------|-------------------|------------------------|--|
| Part # | Package Quantity | Total Product Quantity | |
| Part 1 | 1 BOX | 6 | |
| Part 2 | 1 BOX | 6 | |

Part 1 of 2

WALGREENS NIGHTTIME WAL-FLU SEVERE COLD AND COUGH HONEY LEMON INFUSED WITH CHAMOMILE AND WHITE TEA FLAVORS

acetaminophen, diphenhydramine hcl and phenylephrine hcl granule, for solution

Product Information

Route of Administration ORAL

| Active Ingredient/Active Moiety | | | |
|---|----------------------------------|----------|--|
| Ingredient Name | Basis of Strength | Strength | |
| ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D) | ACETAMINOPHEN | 650 mg | |
| DIPHENHYDRAMINE HYDRO CHLO RIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M) | DIPHENHYDRAMINE HYDROCHLORIDE | 25 mg | |
| PHENYLEPHRINE HYDRO CHLO RIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV) | PHENYLEPHRINE HYDROCHLORIDE | 10 mg | |

| Inactive Ingredients | |
|--|----------|
| Ingredient Name | Strength |
| ACESULFAME (UNII: MA3UYZ6K1H) | |
| ASPARTAME (UNII: Z0H242BBR1) | |
| CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP) | |
| MALTO DEXTRIN (UNII: 7CVR7L4A2D) | |
| SODIUM CITRATE (UNII: 1Q73Q2JULR) | |
| SUCROSE (UNII: C151H8 M554) | |

| Product Characteristics | | | |
|-------------------------|---|--------------|--|
| Color | yellow (Caramel color), yellow (D and C Yellow 10) | Score | |
| Shape | | Size | |
| Flavor | HONEY (Natural Honey and Lemon flavor) , LEMON (Natural Honey and Lemon flavor) | Imprint Code | |
| Contains | | | |
| | | | |

| P | ackaging | | | |
|---|-----------|---|-----------------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | | 6 in 1 BOX; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|-----------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph final | part341 | 10/08/2013 | |

Part 2 of 2

WALGREENS DAYTIME WAL-FLU SEVERE COLD AND COUGH BERRY INFUSED WITH MENTHOL AND GREEN TEA FLAVORS

acetaminophen, dextromethorphan hbr and phenylephrine hcl granule, for solution

Product Information

Route of Administration ORAL

| Active Ingredient/Active Moiety | | | |
|---|----------------------------------|----------|--|
| Ingredient Name | Basis of Strength | Strength | |
| ACETAMINO PHEN (UNII: 36209 ITL9D) (ACETAMINO PHEN - UNII: 36209 ITL9D) | ACETAMINOPHEN | 650 mg | |
| DEXTRO METHO RPHAN HYDRO BRO MIDE (UNII: 9 D2RTI9 KYH) (DEXTRO METHO RPHAN - UNII: 7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 20 mg | |
| PHENYLEPHRINE HYDRO CHLO RIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV) | PHENYLEPHRINE HYDROCHLORIDE | 10 mg | |

| Inactive Ingredients | |
|--|----------|
| Ingredient Name | Strength |
| ACESULFAME (UNII: MA3UYZ6K1H) | |
| ASPARTAME (UNII: Z0H242BBR1) | |
| CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP) | |
| MALTO DEXTRIN (UNII: 7CVR7L4A2D) | |
| SODIUM CITRATE (UNII: 1Q73Q2JULR) | |
| SUCRO SE (UNII: C151H8 M554) | |

| Product Characteristics | | |
|-------------------------|--|--------------|
| Color | red (FD and C Red No 40), blue (FD and C Blue No 1) | Score |
| Shape | | Size |
| Flavor | BERRY (Berry infused with menthol and green tea flavors) , MENTHOL (Menthol) | Imprint Code |
| Contains | | |

| Packaging | | | | |
|-------------------|---|-----|----------------------|--------------------|
| # Item Code | Package Description | Mai | rketing Start Date | Marketing End Date |
| 1 6 | in 1 BOX; Type 0: Not a Combination Product | | | |
| | | | | |
| | | | | |
| Marketing I | nformation | | | |
| Marketing Categ | ory Application Number or Monograph Citat | ion | Marketing Start Date | Marketing End Date |
| OTC monograph fin | al part341 | | 05/15/2013 | |
| | | | | |
| | | | | |
| Marketing I | nformation | | | |
| Marketing Categ | ory Application Number or Monograph Citat | ion | Marketing Start Date | Marketing End Date |
| OTC monograph fin | al part341 | | 06/18/2014 | |
| | | | | |

Labeler - Walgreen Co. (008965063)

Revised: 12/2015 Walgreen Co.