

MALLINCKRODT

LABEL NO. 3080-11

Size \_\_\_\_\_

DATE 01/11/07

Prepared by v12

- Colors:
- A) YELLOW
  - B) BLACK
  - C) BLUE 2945
  - D) BLUE 306

**SPECIMEN**



PMS Yellow

PMS 2945

PMS 306

**MALLINCKRODT**

LABEL NO. blisterback

Size 2 5/8" x 1 1/4"

DATE 01/11/07

Prepared by vl2

- Colors: A) BLACK
- B) \_\_\_\_\_
- C) \_\_\_\_\_
- D) \_\_\_\_\_

## SPECIMEN

<p><b>TussiCaps™</b> (III)</p> <p>(Hydrocodone Polistirex and Chlorpheniramine Polistirex) Extended-Release Capsule</p> <p><b>5 mg/4 mg</b></p> <p>Each capsule contains: Hydrocodone Polistirex equivalent to 5 mg hydrocodone bitartrate Chlorpheniramine Polistirex equivalent to 4 mg chlorpheniramine maleate</p> <p><b>USUAL DOSAGE: Children 6-12:</b> 1 half-strength capsule every 12 hours; do not exceed 2 capsules in 24 hours. <b>Not recommended for children under 6 years of age.</b></p> <p>Mallinckrodt Inc. St. Louis, MO 63134</p> <p>LOT XX000000X EXP. 00/0000</p>	<p><b>TussiCaps™</b> (III)</p> <p>(Hydrocodone Polistirex and Chlorpheniramine Polistirex) Extended-Release Capsule</p> <p><b>5 mg/4 mg</b></p> <p>Each capsule contains: Hydrocodone Polistirex equivalent to 5 mg hydrocodone bitartrate Chlorpheniramine Polistirex equivalent to 4 mg chlorpheniramine maleate</p> <p><b>USUAL DOSAGE: Children 6-12:</b> 1 half-strength capsule every 12 hours; do not exceed 2 capsules in 24 hours. <b>Not recommended for children under 6 years of age.</b></p> <p>Mallinckrodt Inc. St. Louis, MO 63134</p> <p>LOT XX000000X EXP. 00/0000</p>
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MALLINCKRODT

LABEL NO. 6159-11

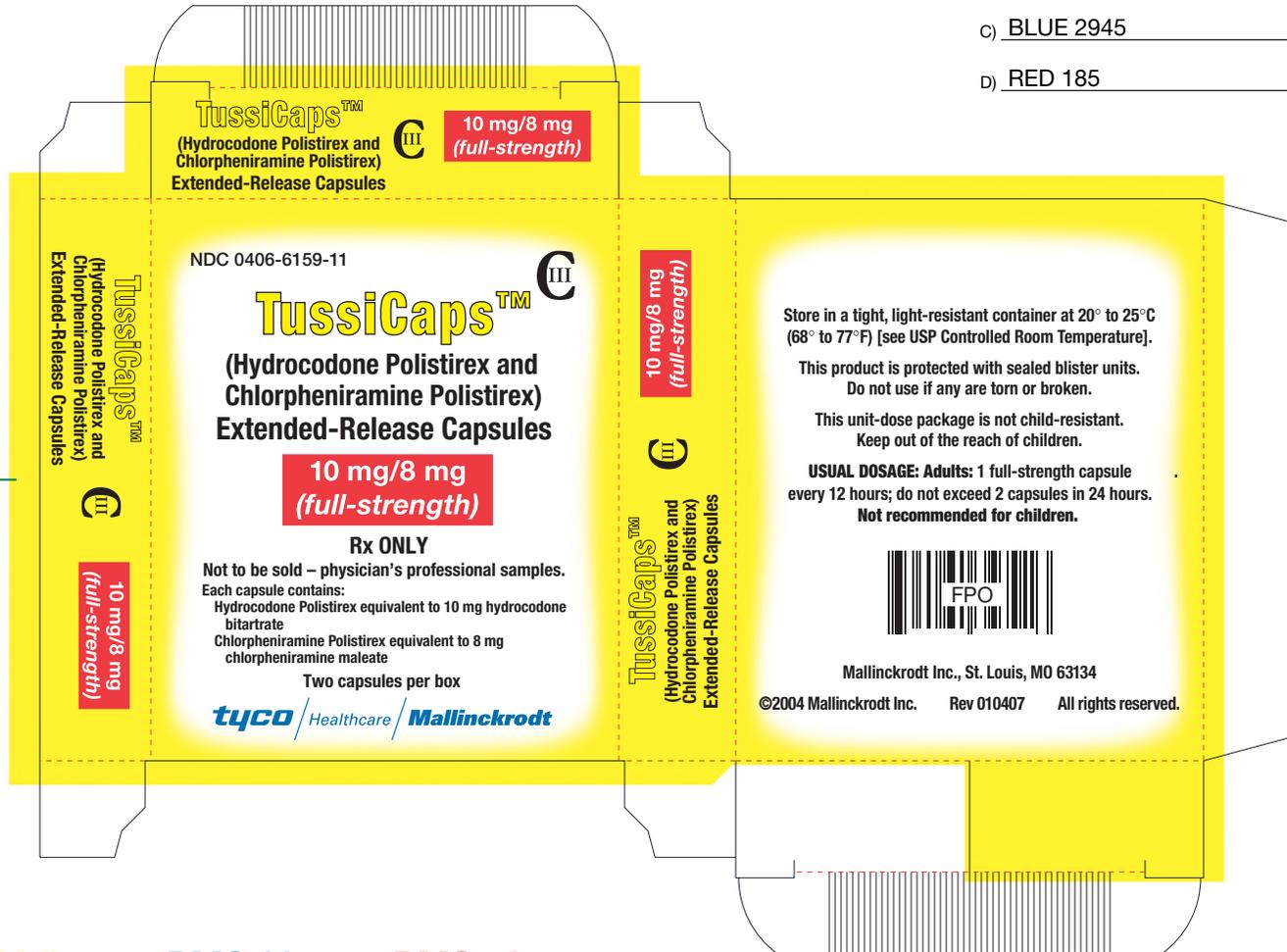
Size \_\_\_\_\_

DATE 01/11/07

Prepared by v12

- Colors: A) YELLOW 
- B) BLACK 
- C) BLUE 2945 
- D) RED 185 

SPECIMEN



PMS Yellow

PMS 2945

PMS 185

CL

**MALLINCKRODT**

LABEL NO. blisterback

Size 2 5/8" x 1 1/4"

DATE 01/11/07

Prepared by vl2

- Colors: A) BLACK
- B) \_\_\_\_\_
- C) \_\_\_\_\_
- D) \_\_\_\_\_

## SPECIMEN

<p><b>TussiCaps™</b> </p> <p>(Hydrocodone Polistirex and Chlorpheniramine Polistirex) Extended-Release Capsule</p> <p><b>10 mg/8 mg</b></p> <p>Each capsule contains: Hydrocodone Polistirex equivalent to 10 mg hydrocodone bitartrate Chlorpheniramine Polistirex equivalent to 8 mg chlorpheniramine maleate</p> <p><b>USUAL DOSAGE: Adults:</b> 1 full-strength capsule every 12 hours; do not exceed 2 capsules in 24 hours. <b>Not recommended for children.</b></p> <p>Mallinckrodt Inc. St. Louis, MO 63134</p> <p>LOT XX000000X EXP. 00/0000</p>	<p><b>TussiCaps™</b> </p> <p>(Hydrocodone Polistirex and Chlorpheniramine Polistirex) Extended-Release Capsule</p> <p><b>10 mg/8 mg</b></p> <p>Each capsule contains: Hydrocodone Polistirex equivalent to 10 mg hydrocodone bitartrate Chlorpheniramine Polistirex equivalent to 8 mg chlorpheniramine maleate</p> <p><b>USUAL DOSAGE: Adults:</b> 1 full-strength capsule every 12 hours; do not exceed 2 capsules in 24 hours. <b>Not recommended for children.</b></p> <p>Mallinckrodt Inc. St. Louis, MO 63134</p> <p>LOT XX000000X EXP. 00/0000</p>
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**Rx ONLY**  
Not to be sold – physician's professional samples.

Each capsule contains:  
Hydrocodone Polistirex equivalent to 5 mg hydrocodone bitartrate  
Chlorpheniramine Polistirex equivalent to 4 mg chlorpheniramine  
maleate

**5 mg/4 mg  
(half-strength)**

**Extended-Release Capsules  
(Hydrocodone Polistirex and  
Chlorpheniramine Polistirex)**



**TussiCaps™**

Not to be sold – physician's professional samples.  
CONTAINS FIVE PATIENT SAMPLE BOXES  
Each box contains two capsules

**Rx ONLY**  
**5 mg/4 mg  
(half-strength)**



**Extended-Release Capsules  
(Hydrocodone Polistirex and  
Chlorpheniramine Polistirex)**

**TussiCaps™**

**TussiCaps™**  
**(Hydrocodone Polistirex and  
Chlorpheniramine Polistirex)**  
**Extended-Release Capsules**



**5 mg/4 mg  
(half-strength)**

**Rx ONLY**

Store in a tight, light-resistant container at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

This product is protected with sealed blister units. Do not use if any are torn or broken.

This unit-dose package is not child-resistant. Keep out of the reach of children.

**USUAL DOSAGE: Children 6-12:** 1 half-strength capsule every 12 hours; do not exceed 2 capsules in 24 hours. **Not recommended for children under 6 years of age.**

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Rev 010407

lot & exp(n)area



FOR POSITION ONLY

**CONTAINS  
FIVE PATIENT  
SAMPLE BOXES**

Each box contains two capsules

Store in a tight, light-resistant container at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

This product is protected with sealed blister units. Do not use if any are torn or broken.

This unit-dose package is not child-resistant. Keep out of the reach of children.

tyco Healthcare Mallinckrodt

**MALLINCKRODT**

LABEL NO. half-strength shelfpack

Size \_\_\_\_\_ DATE 01/11/07

Prepared by vl2

- Colors:
- A) YELLOW 
  - B) BLACK 
  - C) BLUE 2945 
  - D) BLUE 306 

**PMS Yellow**

**PMS 2945**

**PMS 306**

**SPECIMEN**

**TussiCaps™**  
**(Hydrocodone Polistirex and  
Chlorpheniramine Polistirex)**  
**Extended-Release Capsules**



**5 mg/4 mg  
(half-strength)**

Each capsule contains:  
Hydrocodone Polistirex equivalent to 5 mg hydrocodone bitartrate  
Chlorpheniramine Polistirex equivalent to 4 mg chlorpheniramine maleate

**Not to be sold – physician's professional samples.**

**Rx ONLY**

tyco Healthcare Mallinckrodt

Mallinckrodt Pharmaceuticals

**CONTAINS  
FIVE PATIENT  
SAMPLE BOXES**

Each box contains two capsules

Store in a tight, light-resistant container at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

This product is protected with sealed blister units. Do not use if any are torn or broken.

This unit-dose package is not child-resistant. Keep out of the reach of children.

tyco Healthcare Mallinckrodt

**Rx ONLY**

Not to be sold – physician's professional samples.

Each capsule contains:  
Hydrocodone Polistirex equivalent to 10 mg hydrocodone bitartrate  
Chlorpheniramine Polistirex equivalent to 8 mg chlorpheniramine maleate

**10 mg/8 mg (full-strength)**

**TussiCaps™**  
(Hydrocodone Polistirex and Chlorpheniramine Polistirex) Extended-Release Capsules



Not to be sold – physician's professional samples.

CONTAINS FIVE PATIENT SAMPLE BOXES

Each box contains two capsules

**Rx ONLY**

Not to be sold – physician's professional samples.

Each box contains two capsules

**10 mg/8 mg (full-strength)**

**TussiCaps™**  
(Hydrocodone Polistirex and Chlorpheniramine Polistirex) Extended-Release Capsules



**TussiCaps™**  
(Hydrocodone Polistirex and Chlorpheniramine Polistirex) Extended-Release Capsules

**10 mg/8 mg (full-strength)**

**Rx ONLY**



Store in a tight, light-resistant container at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

This product is protected with sealed blister units. Do not use if any are torn or broken.

This unit-dose package is not child-resistant. Keep out of the reach of children.

**USUAL DOSAGE: Adults:** 1 full-strength capsule every 12 hours; do not exceed 2 capsules in 24 hours. **Not recommended for children.**

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Rev 010407

lot & exp{n}larea



FOR POSITION ONLY

**CONTAINS FIVE PATIENT SAMPLE BOXES**

Each box contains two capsules

Store in a tight, light-resistant container at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

This product is protected with sealed blister units. Do not use if any are torn or broken.

This unit-dose package is not child-resistant. Keep out of the reach of children.

**tyco** / Healthcare / **Mallinckrodt**

**TussiCaps™**  
(Hydrocodone Polistirex and Chlorpheniramine Polistirex) Extended-Release Capsules

**10 mg/8 mg (full-strength)**

**Rx ONLY**

Not to be sold – physician's professional samples.

**tyco** / Healthcare / **Mallinckrodt** **Mallinckrodt Pharmaceuticals**



**CONTAINS FIVE PATIENT SAMPLE BOXES**

Each box contains two capsules

Store in a tight, light-resistant container at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

This product is protected with sealed blister units. Do not use if any are torn or broken.

This unit-dose package is not child-resistant. Keep out of the reach of children.

**tyco** / Healthcare / **Mallinckrodt**

**MALLINCKRODT** LABEL NO. full-strength shelfpack

Size \_\_\_\_\_ DATE 01/11/07

Prepared by vl2

Colors: A) YELLOW   
 B) BLACK   
 C) BLUE 2945   
 D) RED 185 

**PMS Yellow PMS 2945 PMS 185**

**SPECIMEN**

**MALLINCKRODT**

LABEL NO. 3080-20

SIZE 4.375 x 1.75

DATE 10/06/06

Prepared by     vml    

- Colors:
- A) PANTONE YELLOW 
  - B) BLACK 
  - C) BLUE 2945C 
  - C) BLUE 306C 

## SPECIMEN

Exp.:      Lot No.:      NDC 0406-3080-20      20 CAPSULES

**TussiCaps™**   
(Hydrocodone Polistirex and Chlorpheniramine Polistirex)  
Extended-Release Capsules

**5 mg/4 mg**  
*(half-strength)*

Each capsule contains:  
Hydrocodone Polistirex equivalent to 5 mg hydrocodone bitartrate  
Chlorpheniramine Polistirex equivalent to 4 mg chlorpheniramine maleate

**Rx only**

**Mallinckrodt**

**USUAL DOSAGE: Children 6-12:**  
1 half-strength capsule every 12 hours; do not exceed 2 capsules in 24 hours.  
**Not recommended for children under 6 years of age.**

**INDICATIONS:** See package insert.

**STORAGE:** Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Dispense in a well-closed container.

Do not accept if seal over bottle opening is broken or missing.

Mallinckrodt Inc.  
St. Louis, Missouri  
63134, U.S.A.

**tyco** | Healthcare

0406-3080-20  
100606

NO VARNISH

# MALLINCKRODT

LABEL NO. 3080-01

SIZE 4.375 x 1.75

DATE 10/06/06

Prepared by      vml

- Colors:
- A) PANTONE YELLOW 
  - B) BLACK 
  - C) BLUE 2945C 
  - C) BLUE 306C 

## SPECIMEN

Exp.:      Lot No.:      NDC 0406-3080-01      100 CAPSULES

**TussiCaps™** 

**(Hydrocodone Polistirex and Chlorpheniramine Polistirex)**

**Extended-Release Capsules**

**5 mg/4 mg**  
**(half-strength)**

Each capsule contains:  
Hydrocodone Polistirex equivalent to 5 mg hydrocodone bitartrate  
Chlorpheniramine Polistirex equivalent to 4 mg chlorpheniramine maleate

**Rx only**  
This package is not for household use.

**Mallinckrodt**

**USUAL DOSAGE: Children 6-12:**  
1 half-strength capsule every 12 hours; do not exceed 2 capsules in 24 hours.  
**Not recommended for children under 6 years of age.**

**INDICATIONS:** See package insert.

**STORAGE:** Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Dispense in a well-closed container.

Do not accept if seal over bottle opening is broken or missing.

Mallinckrodt Inc.  
St. Louis, Missouri  
63134, U.S.A.

**tyco** / Healthcare

0406-3080-01  
FPO  
NO VARNISH  
100606

**MALLINCKRODT**

LABEL NO. 3080-05

SIZE 6 x 2.4375

DATE 10/06/06

Prepared by     vml    

- Colors:
- A) PANTONE YELLOW 
  - B) BLACK 
  - C) BLUE 2945C 
  - C) BLUE 306C 

**SPECIMEN**

Lot No.:  
Exp.:

NO VARNISH

100906

0406-3080-05



NDC 0406-3080-05

500 CAPSULES

**TussiCaps**<sup>TM</sup>



**(Hydrocodone Polistirex and  
Chlorpheniramine Polistirex)  
Extended-Release Capsules**

**5 mg/4 mg  
(half-strength)**

Each capsule contains:  
Hydrocodone Polistirex equivalent to 5 mg  
hydrocodone bitartrate  
Chlorpheniramine Polistirex equivalent to 4 mg  
chlorpheniramine maleate

**Rx only**

This package is not for household use.

**Mallinckrodt**

**USUAL DOSAGE: Children 6-12:**  
1 half-strength capsule every 12 hours;  
do not exceed 2 capsules in 24 hours.  
**Not recommended for children  
under 6 years of age.**

**INDICATIONS:** See package insert.

**STORAGE:** Store at 20° to 25°C  
(68° to 77°F) [see USP Controlled  
Room Temperature].

Dispense in a well-closed container.

Do not accept if seal over bottle open-  
ing is broken or missing.

Mallinckrodt Inc.  
St. Louis, Missouri  
63134, U.S.A.

**tyco** / Healthcare



# MALLINCKRODT

LABEL NO. 6159-20

SIZE 4.375 x 1.75

DATE 10/06/06

Prepared by      vml

- Colors:
- A) PANTONE YELLOW 
  - B) BLACK 
  - C) BLUE 2945C 
  - C) RED 185C 

## SPECIMEN

Lot No.:  
Exp.:  
**NO VARNISH**



0406-6159-20

100606

NDC 0406-6159-20      20 CAPSULES

**TussiCaps™** 

(Hydrocodone Polistirex and Chlorpheniramine Polistirex)

Extended-Release Capsules

**10 mg/8 mg**  
**(full-strength)**

Each capsule contains:  
Hydrocodone Polistirex equivalent to 10 mg hydrocodone bitartrate  
Chlorpheniramine Polistirex equivalent to 8 mg chlorpheniramine maleate

Rx only

**Mallinckrodt**

**USUAL DOSAGE: Adults:**

1 full-strength capsule every 12 hours; do not exceed 2 capsules in 24 hours. **Not recommended for children.**

**INDICATIONS:** See package insert.

**STORAGE:** Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Dispense in a well-closed container.

Do not accept if seal over bottle opening is broken or missing.

Mallinckrodt Inc.  
St. Louis, Missouri  
63134, U.S.A.

**tyco** / Healthcare

# MALLINCKRODT

LABEL NO. 6159-01

SIZE 4.375 x 1.75

DATE 10/06/06

Prepared by      vml

- Colors:
- A) PANTONE YELLOW 
  - B) BLACK 
  - C) BLUE 2945C 
  - C) RED 185C 

## SPECIMEN

Lot No.:  
Exp.:  
**NO VARNISH**



0406-6159-01

100606

NDC 0406-6159-01 100 CAPSULES

**TussiCaps™**   
(Hydrocodone Polistirex and  
Chlorpheniramine Polistirex)  
Extended-Release Capsules

**10 mg/8 mg**  
(full-strength)

Each capsule contains:  
Hydrocodone Polistirex equivalent to 10 mg  
hydrocodone bitartrate  
Chlorpheniramine Polistirex equivalent to 8 mg  
chlorpheniramine maleate

**Rx only**  
This package is not for household use.

**Mallinckrodt**

**USUAL DOSAGE: Adults:**  
1 full-strength capsule every 12  
hours; do not exceed 2 capsules in  
24 hours. **Not recommended for  
children.**

**INDICATIONS:** See package insert.

**STORAGE:** Store at 20° to 25°C (68°  
to 77°F) [see USP Controlled Room  
Temperature].

Dispense in a well-closed container.  
Do not accept if seal over bottle open-  
ing is broken or missing.

Mallinckrodt Inc.  
St. Louis, Missouri  
63134, U.S.A.

**tyco** / Healthcare

**MALLINCKRODT**

LABEL NO. 6159-05

SIZE 6.5 x 3

DATE 10/06/06

Prepared by      vml

- Colors:
- A) PANTONE YELLOW 
  - B) BLACK 
  - C) BLUE 2945C 
  - C) RED 185C 

## SPECIMEN

NDC 0406-6159-05

500 CAPSULES

**TussiCaps™**   
 (Hydrocodone Polistirex and  
 Chlorpheniramine Polistirex)  
 Extended-Release Capsules

**10 mg/8 mg**  
*(full-strength)*

Each capsule contains:  
 Hydrocodone Polistirex equivalent to 10 mg  
 hydrocodone bitartrate  
 Chlorpheniramine Polistirex equivalent to 8 mg  
 chlorpheniramine maleate

**Rx only**

This package is not for household use.

**USUAL DOSAGE: Adults:**

1 full-strength capsule every 12 hours;  
 do not exceed 2 capsules in 24 hours.  
**Not recommended for children.**

**INDICATIONS:** See package insert.

**STORAGE:** Store at 20° to 25°C (68° to  
 77°F) [see USP Controlled Room  
 Temperature].

Dispense in a well-closed container.

Do not accept if seal over bottle opening is broken or missing.

Mallinckrodt Inc.  
 St. Louis, Missouri  
 63134, U.S.A.

**Mallinckrodt**

**tyco** / Healthcare

Lot No.:  
Exp.:

NO VARNISH



100806

**MALLINCKRODT**

LABEL NO. 6159-10

SIZE 6 x 3

DATE 10/06/06

Prepared by vml

- Colors:
- A) PANTONE YELLOW 
  - B) BLACK 
  - C) BLUE 2945C 
  - C) RED 185C 

## SPECIMEN

NDC 0406-6159-10

1000 CAPSULES

**TussiCaps™**  
(Hydrocodone Polistirex and  
Chlorpheniramine Polistirex)  
Extended-Release Capsules



**10 mg/8 mg**  
*(full-strength)*

Each capsule contains:  
Hydrocodone Polistirex equivalent to 10 mg  
hydrocodone bitartrate  
Chlorpheniramine Polistirex equivalent to 8 mg  
chlorpheniramine maleate

**Rx only**

This package is not for household use.

**USUAL DOSAGE: Adults:**

1 full-strength capsule every 12 hours;  
do not exceed 2 capsules in 24 hours.

**Not recommended for children.**

**INDICATIONS:** See package insert.

**STORAGE:** Store at 20° to 25°C (68° to  
77°F) [see USP Controlled Room  
Temperature].

Dispense in a well-closed container.

Do not accept if seal over bottle open-  
ing is broken or missing.

Mallinckrodt Inc.  
St. Louis, Missouri  
63134, U.S.A.

**Mallinckrodt**

**tyco** / Healthcare

Lot No.:  
Exp.:

NO VARNISH



100606

# SPECIMEN



TussiCaps™  
(Hydrocodone  
Polistirex and  
Chlorpheniramine  
Polistirex)  
Extended-Release  
Capsules

Rx only

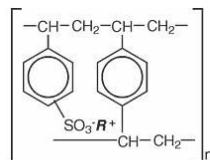
## TussiCaps™ (Hydrocodone Polistirex and Chlorpheniramine Polistirex) Extended-Release Capsules

Rx only

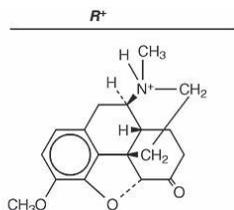
### DESCRIPTION

Each full-strength TussiCaps™ (hydrocodone polistirex and chlorpheniramine polistirex) extended-release capsule contains hydrocodone polistirex equivalent to 10 mg of hydrocodone bitartrate and chlorpheniramine polistirex equivalent to 8 mg of chlorpheniramine maleate. Each half-strength TussiCaps™ (hydrocodone polistirex and chlorpheniramine polistirex) extended-release capsule contains hydrocodone polistirex equivalent to 5 mg of hydrocodone bitartrate and chlorpheniramine polistirex equivalent to 4 mg of chlorpheniramine maleate. TussiCaps™ extended-release capsules provide up to 12-hour relief per dose. Hydrocodone is a centrally-acting narcotic antitussive. Chlorpheniramine is an antihistamine. TussiCaps™ extended-release capsules are for oral use only.

Hydrocodone Polistirex: sulfonated styrene-divinylbenzene copolymer complex with 4,5 $\alpha$ -epoxy-3-methoxy-17-methylmorphinan-6-one.

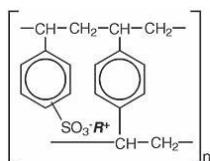


Polistirex

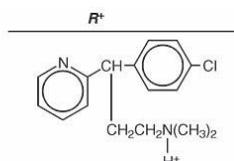


Hydrocodone

Chlorpheniramine Polistirex: sulfonated styrene-divinylbenzene copolymer complex with 2-[p-chloro- $\alpha$ -[2-(dimethylamino)ethyl]-benzyl]pyridine.



Polistirex



Chlorpheniramine

Inactive Ingredients: Butyl alcohol, dehydrated alcohol, gelatin, iron oxide black JPE, isopropyl alcohol, microcrystalline cellulose, propylene glycol, purified water, SDA 3A alcohol (27 CFR), shellac, shellac glaze-45% in SD-45 alcohol, strong ammonia solution, titanium dioxide, D&C yellow #10, D&C yellow #10 aluminum lake, FD&C blue #1/brilliant blue FCF aluminum lake, FD&C blue #2 aluminum lake, FD&C blue #2/indigo carmine aluminum lake, and FD&C red #40/allura red AC aluminum lake.

### CLINICAL PHARMACOLOGY

Hydrocodone is a semisynthetic narcotic antitussive and analgesic with multiple actions qualitatively similar to those of codeine. The precise mechanism of action of hydrocodone and other opiates is not known; however, hydrocodone is believed to act directly on the cough center. In excessive doses, hydrocodone, like other opium derivatives, will depress respiration. The effects of hydrocodone in therapeutic doses on the cardiovascular system are insignificant. Hydrocodone can produce miosis, euphoria, physical and psychological dependence.

Chlorpheniramine is an antihistamine drug (H<sub>1</sub> receptor antagonist) that also possesses anticholinergic and sedative activity. It prevents released histamine from dilating capillaries and causing edema of the respiratory mucosa.

Hydrocodone and chlorpheniramine release from TussiCaps™ extended-release capsules is controlled by use of an ion-exchange polymer matrix.

Following multiple dosing with hydrocodone polistirex and chlorpheniramine polistirex extended-release suspension, hydrocodone mean (S.D.) peak plasma concentrations of 22.8 (5.9) ng/mL occurred at 3.4 hours. Chlorpheniramine mean (S.D.) peak plasma concentrations of 58.4 (14.7) ng/mL occurred at 6.3 hours following multiple dosing. Peak plasma levels obtained with an immediate-release syrup occurred at approximately 1.5 hours for hydrocodone and 2.8 hours for chlorpheniramine. The plasma half-lives of hydrocodone and chlorpheniramine have been reported to be approximately 4 and 16 hours, respectively.

### INDICATIONS AND USAGE

TussiCaps™ (hydrocodone polistirex and chlorpheniramine polistirex) extended-release capsules are indicated for relief of cough and upper respiratory symptoms associated with allergy or a cold.

### CONTRAINDICATIONS

Known allergy or sensitivity to hydrocodone or chlorpheniramine.

### WARNINGS

**Respiratory Depression** – As with all narcotics, TussiCaps™ extended-release capsules produce dose-related respiratory depression by directly acting on brain stem respiratory centers. Hydrocodone affects the center that controls respiratory rhythm, and may produce irregular and periodic breathing. Caution should be exercised when TussiCaps™ extended-release capsules are used postoperatively and in patients with pulmonary disease or whenever ventilatory function is depressed. If respiratory depression occurs, it may be antagonized by the use of naloxone hydrochloride and other supportive measures when indicated (see **OVERDOSAGE**).

**Head Injury and Increased Intracranial Pressure** – The respiratory depressant effects of narcotics and their capacity to elevate cerebrospinal fluid pressure may be markedly exaggerated in the presence of head injury, other intracranial lesions or a pre-existing increase in intracranial pressure. Furthermore, narcotics produce adverse reactions which may obscure the clinical course of patients with head injuries.

**Acute Abdominal Conditions** – The administration of narcotics may obscure the diagnosis or clinical course of patients with acute abdominal conditions.

**Obstructive Bowel Disease** – Chronic use of narcotics may result in obstructive bowel disease especially in patients with underlying intestinal motility disorder.

**Pediatric Use** – In pediatric patients, as well as adults, the respiratory center is sensitive to the depressant action of narcotic cough suppressants in a dose-dependent manner. Benefit to risk ratio should be carefully considered especially in pediatric patients with respiratory embarrassment (e.g., croup) (see **PRECAUTIONS**).

### PRECAUTIONS

#### General

Caution is advised when prescribing this drug to patients with narrow-angle glaucoma, asthma or prostatic hypertrophy.

**Special Risk Patients** – As with any narcotic agent, TussiCaps™ extended-release capsules should be used with caution in elderly or debilitated patients and those with severe impairment of hepatic or renal function, hypothyroidism, Addison's disease, prostatic hypertrophy or urethral stricture. The usual precautions should be observed and the possibility of respiratory depression should be kept in mind.

#### Information for Patients

As with all narcotics, TussiCaps™ extended-release capsules may produce marked drowsiness and impair the mental and/or physical abilities required for the performance of potentially hazardous tasks such as driving a car or operating machinery; patients should be cautioned accordingly. TussiCaps™ extended-release capsules must not be diluted with fluids or mixed with other drugs as this may alter the resin-binding and change the absorption rate, possibly increasing the toxicity.

Keep out of the reach of children.

**Cough Reflex** – Hydrocodone suppresses the cough reflex; as with all narcotics, caution should be exercised when TussiCaps™ extended-release capsules are used postoperatively, and in patients with pulmonary disease.

#### Drug Interactions

Patients receiving narcotics, antihistamines, antipsychotics, anti-anxiety agents or other CNS depressants (including alcohol) concomitantly with TussiCaps™ extended-release capsules may exhibit an additive CNS depression. When combined therapy is contemplated, the dose of one or both agents should be reduced.

The use of MAO inhibitors or tricyclic antidepressants with hydrocodone preparations may increase the effect of either the antidepressant or hydrocodone.

The concurrent use of other anticholinergics with hydrocodone may produce paralytic ileus.

#### Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenicity, mutagenicity and reproductive studies have not been conducted with TussiCaps™ extended-release capsules.

#### Pregnancy

**Teratogenic Effects. Pregnancy Category C** – Hydrocodone has been shown to be teratogenic in hamsters when given in doses 700 times the human dose. There are no adequate and well-controlled studies in pregnant women. TussiCaps™ extended-release capsules should be

# SPECIMEN



Rx only

used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

**Nonteratogenic Effects** – Babies born to mothers who have been taking opioids regularly prior to delivery will be physically dependent. The withdrawal signs include irritability and excessive crying, tremors, hyperactive reflexes, increased respiratory rate, increased stools, sneezing, yawning, vomiting and fever. The intensity of the syndrome does not always correlate with the duration of maternal opioid use or dose.

### Labor and Delivery

As with all narcotics, administration of TussiCaps™ extended-release capsules to the mother shortly before delivery may result in some degree of respiratory depression in the newborn, especially if higher doses are used.

### Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from TussiCaps™ extended-release capsules, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

### Pediatric Use

Safety and effectiveness of TussiCaps™ extended-release capsules in pediatric patients under six have not been established (see **WARNINGS**).

### Geriatric Use

Clinical studies of hydrocodone polistirex and chlorpheniramine polistirex extended-release did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

### ADVERSE REACTIONS

**Central Nervous System** – Sedation, drowsiness, mental clouding, lethargy, impairment of mental and physical performance, anxiety, fear, dysphoria, euphoria, dizziness, psychic dependence, mood changes.

**Dermatologic System** – Rash, pruritus.

**Gastrointestinal System** – Nausea and vomiting may occur; they are more frequent in ambulatory than in recumbent patients. Prolonged administration of TussiCaps™ extended-release capsules may produce constipation.

**Genitourinary System** – Ureteral spasm, spasm of vesicle sphincters and urinary retention have been reported with opiates.

**Respiratory Depression** – TussiCaps™ extended-release capsules may produce dose-related respiratory depression by acting directly on brain stem respiratory centers (see **OVERDOSAGE**).

**Respiratory System** – Dryness of the pharynx, occasional tightness of the chest.

### DRUG ABUSE AND DEPENDENCE

TussiCaps™ extended-release capsules are Schedule III narcotics. Psychic dependence, physical dependence and tolerance may develop upon repeated administration of narcotics; therefore, TussiCaps™ extended-release capsules should be prescribed and administered with caution. However, psychic dependence is unlikely to develop when TussiCaps™ extended-release capsules are used for a short time for the treatment of cough. Physical dependence, the condition in which continued administration of the drug is required to prevent the appearance of a withdrawal syndrome, assumes clinically significant proportions only after several weeks of continued oral narcotic use, although some mild degree of physical dependence may develop after a few days of narcotic therapy.

### OVERDOSAGE

**Signs and Symptoms** – Serious overdosage with hydrocodone is characterized by respiratory depression (a decrease in respiratory rate and/or tidal volume, Cheyne-Stokes respiration, cyanosis), extreme somnolence progressing to stupor or coma, skeletal muscle flaccidity, cold and clammy skin, and sometimes bradycardia and hypotension. Although miosis is characteristic of narcotic overdose, mydriasis may occur in terminal narcosis or severe hypoxia. In severe overdosage, apnea, circulatory collapse, cardiac arrest and death may occur. The manifestations of chlorpheniramine overdosage may vary from central nervous system depression to stimulation.

**Treatment** – Primary attention should be given to the reestablishment of adequate respiratory exchange through provision of a patent airway and the institution of assisted or controlled ventilation. The narcotic antagonist naloxone hydrochloride is a specific antidote for respiratory depression which may result from overdosage or unusual sensitivity to narcotics including hydrocodone. Therefore, an appropriate dose of naloxone hydrochloride should be administered, preferably by the intravenous route, simultaneously with efforts at respiratory resuscitation. Since the duration of action of hydrocodone in this formulation may exceed that of the antagonist, the patient should be kept under continued surveillance and repeated doses of the antagonist should be administered as needed to maintain adequate respiration. For further information, see full prescribing information for naloxone hydrochloride. An antagonist should not be administered in the absence of clinically significant respiratory depression. Oxygen, intravenous fluids, vasopressors and other supportive measures should be employed as indicated. Gastric emptying may be useful in removing unabsorbed drug.

### DOSAGE AND ADMINISTRATION

**Adults** – 1 full-strength TussiCaps™ extended-release capsule (hydrocodone polistirex equivalent to 10 mg of hydrocodone bitartrate and chlorpheniramine polistirex equivalent to 8 mg of chlorpheniramine maleate) every 12 hours; **do not exceed 2 capsules in 24 hours**.

**Children 6 to 12** – 1 half-strength TussiCaps™ extended-release capsule (hydrocodone polistirex equivalent to 5 mg of hydrocodone bitartrate

and chlorpheniramine polistirex equivalent to 4 mg of chlorpheniramine maleate) every 12 hours; **do not exceed 2 capsules in 24 hours**.

Not recommended for children under 6 years of age (see **PRECAUTIONS**).

### HOW SUPPLIED

**Full-Strength: 10 mg/8 mg TussiCaps™ (hydrocodone polistirex and chlorpheniramine polistirex) extended-release capsules**

Each full-strength capsule contains hydrocodone polistirex equivalent to 10 mg hydrocodone bitartrate and chlorpheniramine polistirex equivalent to 8 mg chlorpheniramine maleate. It is available as an Ivory/Ivory capsule printed in blue with “M” on the cap and “HP/CP” over “10/8” on the body.

Bottles of 20 . . . . . NDC 0406-6159-20

Bottles of 100 . . . . . NDC 0406-6159-01

Bottles of 500 . . . . . NDC 0406-6159-05

Bottles of 1000 . . . . . NDC 0406-6159-10

**Half-Strength: 5 mg/4 mg TussiCaps™ (hydrocodone polistirex and chlorpheniramine polistirex) extended-release capsules**

Each half-strength capsule contains hydrocodone polistirex equivalent to 5 mg hydrocodone bitartrate and chlorpheniramine polistirex equivalent to 4 mg chlorpheniramine maleate. It is available as an Ivory/Ivory capsule printed in black with “M” on the cap and “HP/CP” over “5/4” on the body.

Bottles of 20 . . . . . NDC 0406-3080-20

Bottles of 100 . . . . . NDC 0406-3080-01

Bottles of 500 . . . . . NDC 0406-3080-05

Bottles of 1000 . . . . . NDC 0406-3080-10

**Storage:** Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Dispense in a well-closed container.

A Schedule CIII Narcotic.

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Mallinckrodt Inc.  
St. Louis, Missouri 63134, U.S.A.

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