

March 30,
 2006

ATTACH LEGEND ON ALL
 DIGITAL MECHANICALS

STANDARD FORMAT
 Helvetica Condensed
 Variable horizontal scale address to 39 characters
 per inch

Drug Facts - 9 pt Helvetica Cnd. Bold Italic
Drug Facts (continued)
Drug Facts - 8 pt Helvetica Cnd. Bold Italic
 (Continued) - 8 pt Helvetica Cnd.

Headings - 8 pt Helvetica Cnd. Bold Italic
Sub Heads - 6 pt Helvetica Cnd. Bold
Text - 6 pt Helvetica Cnd. minimum leading 6.5
 Square Bullets - 3.5 pt Zapf Dingbats no compression
 Border - 1 pt rule, 3/64" gap all around
 Barline - 1 pt rule _____
 Hairline - .5 pt rule _____

Certified by: _____

Allergy

5 CHEWABLE TABLETS

Children's
Claritin

New!
 ages 2 years and older

Children's
Claritin

Allergy

loratadine tablets 5 mg/antihistamine

24 Hour Relief*
 Non-Drowsy*

- Runny Nose
- Itchy, Watery Eyes
- Itchy Throat or Nose

Grape Flavored
CHEWABLES

Actual Size

NDC 11523-7198-2

Children's

Code Area
 No Varnish
 No Ink

No Varnish

29012008

Glue

No Varnish

Drug Facts

Active ingredient (in each tablet)
 Loratadine 5 mg

Purpose
 Antihistamine

Uses
 temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

- itchy, watery eyes
- sneezing
- itching of the nose or throat

Warnings
 Do not use 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 or kidney disease. Your doctor should determine if you need a different dose.

When using this product do not take more than directed. Taking more than directed may cause drowsiness.

Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away.

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

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Drug Facts (continued)

Directions
 adults and children 6 years and over: chew 2 tablets daily; not more than 2 tablets in 24 hours
 children 2 to under 6 years of age: chew 1 tablet daily; not more than 1 tablet in 24 hours
 children under 2 years of age: ask a doctor
 consumers with liver or kidney disease: ask a doctor

Other information

- phenylethanamines: contains phenylethylamine 1.4 mg per tablet
- safety sealed: do not use if the individual blister unit imprinted with Children's Claritin[®] is open or torn
- store between 20° to 25°C (68° to 77°F)

Inactive ingredients
 aspartame, citric acid anhydrous, colloidal silicon dioxide, D&C red No. 27 aluminum lake, FD&C blue No. 2 aluminum lake, flavor, magnesium stearate, mannitol, microcrystalline cellulose, sodium starch glycolate, stearic acid

Questions or comments?
 1-800-8-CLARITIN (1-800-252-7484) or www.claritin.com

No Varnish

29012008

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Border - 1 pt rule, 3/64 gap all around

Barline - 1 pt rule _____

Hairline - .5 pt rule _____

Certified by: _____

NO VARNISH

29012105

Drug Facts

Active ingredient (in each tablet)
Loratadine 5 mg

Purpose
Antihistamine

Uses
temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

- runny nose
- sneezing
- itching of the nose or throat

Warnings
Do not use 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 or kidney disease. Your doctor should determine if you need a different dose.

When using this product do not take more than directed. Taking more than directed may cause drowsiness.

Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away.

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

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Drug Facts (continued)

Directions
adults and children 6 years and over: chew 2 tablets in 24 hours
children 2 to under 6 years of age: chew 1 tablet daily; not more than 1 tablet in 24 hours
children under 2 years of age: ask a doctor

ask a doctor
consumers with liver or kidney disease

Other information

- phenylephrine: contains phenylephrine 1.4 mg per tablet
- safety sealed: do not use if the individual blister unit is impaired with Children's Claritin's is open or torn
- store between 20° to 25°C (68° to 77°F)

Inactive ingredients
aspartame, citric acid, anhydrous colloidal silicon dioxide, D&C Red No. 27 aluminum lake, FD&C Blue No. 2 aluminum lake, flavor, magnesium stearate, mannitol, microcrystalline cellulose, sodium starch glycolate, stearic acid

Questions or comments?
1-888-232-7464 (1-800-908-1 MILLI) or www.claritin.com

NO VARNISH

29012105

NO VARNISH

29012105

Children's Claritin Allergy

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*When taken as directed, see Drug Facts Panel.

Code Area
No Varnish
No Ink

BACK

ATTACH LEGEND ON ALL DIGITAL MECHANICALS

STANDARD FORMAT
 Helvetica Condensed
 Variable horizontal scale adheres to 39 characters per inch

Drug Facts - 9 pt Helvetica Cnd. Bold Italic

Drug Facts (continued)

Drug Facts - 8 pt Helvetica Cnd. Bold Italic (continued) - 8 pt Helvetica Cnd.

Headings - 8 pt Helvetica Cnd. Bold Italic

Sub Heads - 6 pt Helvetica Cnd. Bold

Text - 6 pt Helvetica Cnd, minimum leading 6.5

Square Bullets - 3.5 pt Zaph Dingbats no compression

Border - 1 pt rule, 3/64" gap all around

Barline - 1 pt rule _____

Hairline - .5 pt rule _____

Certified by: rp

<p>Drug Facts (continued)</p> <p>When using this product do not take more than directed. Taking more than directed may cause drowsiness.</p> <p>Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away.</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.</p>		<p>Drug Facts (continued)</p> <p>Other information</p> <ul style="list-style-type: none"> phenylketonurics: contains phenylalanine 1.4 mg per tablet safety sealed: do not use if the individual blister unit imprinted with Children's Claritin® is open or torn store between 20° to 25°C (68° to 77°F) <p>Inactive ingredients aspartame, citric acid anhydrous, colloidal silicon dioxide, D&C red No. 27 aluminum lake, FD&C blue No. 2 aluminum lake, flavor, magnesium stearate, mannitol, microcrystalline cellulose, sodium starch glycolate, stearic acid</p> <p>Questions or comments? 1-800-CLARITIN (1-800-252-7484) or www.claritin.com</p> <p><small>© Copyright & Distributed by Schering-Plough HealthCare Products, Inc., Kenilworth, NJ 07033 USA. All Rights Reserved. 27780-00</small></p>								
<p>Directions</p> <table border="1"> <tr> <td>adults and children 6 years and over</td> <td>chew 2 tablets daily, not more than 2 tablets in 24 hours</td> </tr> <tr> <td>children 2 to under 6 years of age</td> <td>chew 1 tablet daily, not more than 1 tablet in 24 hours</td> </tr> <tr> <td>children under 2 years of age</td> <td>ask a doctor</td> </tr> <tr> <td>consumers with liver or kidney disease</td> <td>ask a doctor</td> </tr> </table>		adults and children 6 years and over	chew 2 tablets daily, not more than 2 tablets in 24 hours	children 2 to under 6 years of age	chew 1 tablet daily, not more than 1 tablet in 24 hours	children under 2 years of age	ask a doctor	consumers with liver or kidney disease	ask a doctor	
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children 2 to under 6 years of age	chew 1 tablet daily, not more than 1 tablet in 24 hours									
children under 2 years of age	ask a doctor									
consumers with liver or kidney disease	ask a doctor									

Sample - Not for Sale

Drug Facts

Active ingredient	Purpose
Loratadine 5 mg	Antihistamine

Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

- runny nose
- itchy, watery eyes
- sneezing
- itching of the nose or throat

Warnings
Do not use 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 or kidney disease. Your doctor should determine if you need a different dose.

#When taken as directed. See Drug Facts Panel.

FRONT

Code Area
 Lot & Exp

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Drug Facts

Active ingredient (in each tablet) Purpose
 Loratadine 5 mg Antihistamine

Uses Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
 • sneezing
 • runny nose
 • itchy, watery eyes
 • itchy of the nose or throat

Warnings
 Do not use 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 or kidney disease. Your doctor should determine if you need a different dose.
 When using this product do not take more than directed. Taking more than directed may cause drowsiness.
 Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away.
 If pregnant or breast-feeding, ask a health professional before use.
 Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Drug Facts (continued)

Directions
 adults and children
 chew 2 tablets daily; not more than 2 tablets in 24 hours
 6 years and over
 chew 1 tablet daily; not more than 1 tablet in 24 hours
 children under 6 years of age
 ask a doctor
 2 years of age
 ask a doctor
 or kidney disease
 consumers with liver

Other information
 • phenylephrine: contains phenylephrine 1.4 mg per tablet
 • safety sealed: do not use if the individual blister unit is imprinted with Children's Claritin's is open or torn
 • store between 20° to 25°C (68° to 77°F)

Inactive ingredients
 aspartame, citric acid anhydrous, colloidal silicon dioxide, D5C, red No. 27 aluminum lake, FD&C blue No. 2 aluminum lake, flavor, magnesium stearate, mannitol, microcrystalline cellulose, sodium starch glycolate, stearic acid

Questions or comments?
 1-800-CLARITIN (1-800-252-7441) or www.claritin.com

2 CHEWABLE TABLETS

Claritin

SAMPLE & COUPON ENCLOSED

ages 2 years and older

Children's

Claritin

Allergy

loratadine tablets 5 mg/antihistamine

2 CHEWABLE TABLETS

*When taken as directed. See Drug Facts Panel.

**Non-Drowsy*
 24 Hour Relief of:**

- Sneezing
- Runny Nose
- Itchy, Watery Eyes
- Itchy Throat or Nose



PRODUCT SAMPLE - NOT FOR RETAIL SALE

OUTSIDE

Lot & Exp
 Coda Area

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Drug Facts	
Active ingredient (in each tablet)	Loratadine 5 mg, Antihistamine
Purpose	temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: sneezing, runny nose, itchy, watery eyes, itchy throat or nose, itching of the nose or throat.
Warnings	Do not use 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 or kidney disease. Your doctor should determine if you need a different dose. When using this product do not take more than directed. Taking more than directed may cause drowsiness. Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away. If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.
Directions	chew 2 tablets daily, not more than 2 tablets in 24 hours children 2 years and over chew 1 tablet in 24 hours children under 2 years of age ask a doctor ask a doctor consumers with liver or kidney disease ask a doctor
Other information	phenylethanolamine 1.4 mg per tablet safety sealed; do not use if the individual blister unit is opened or torn store between 20° to 25°C (68° to 77°F) inactive ingredients: aspartame, citric acid anhydrous, colloidal silicon dioxide, D&C red No. 27 aluminum lake, FD&C blue No. 2 aluminum lake, flavor, magnesium stearate, mannitol, microcrystalline cellulose, sodium starch glycolate, stearic acid
Questions or comments?	1-800-CLARITIN (1-800-252-7484) or www.claritin.com

2 CHEWABLE TABLETS

Claritin

ages 2 years and older
Children's Claritin[®]

Allergy
 loratadine tablets 5 mg/antihistamine

2 CHEWABLE TABLETS

*When taken as directed. See Drug Facts Panel.

- Non-Drowsy*
 24 Hour Relief of:**
- Sneezing
 - Runny Nose
 - Itchy, Watery Eyes
 - Itchy Throat or Nose



PRODUCT SAMPLE - NOT FOR RETAIL SALE

OUTSIDE

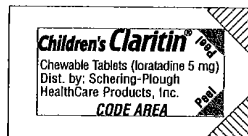
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Border - 1 pt rule, 3/64" gap all around
Barcode - 1 pt rule _____
Hairline - .5 pt rule _____

Certified by: VM



Aug. 2, 2005



NDA 21-891, S-000
1.14.1 Draft Labeling
1.14.1.1 Blister Version I

