

March 30,  
2006

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 heading 6.5

**Square Bullets** - 3.5 pt 7/24th Dingbats no compression

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

**Barline** - 1 pt rule

**Hairline** - .5 pt rule

Certified by: mh

29012008



No Varnish

Glue

No Varnish

Questions or comments?  
1-800-1-MINIRIN (1-800-622-522-7484) or www.claritin.com

**Inactive ingredients**  
acetaminophen, 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

**Other information**  
■ phenylephrine 1.4 mg  
per tablet  
■ do not use if the individual blister unit  
is sealed, do not use if the individual blister unit  
is open or torn  
■ store between 20° to 25° C (68° to 77° F)

**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 in 24 hours  
children under  
2 years of age  
ask a doctor  
consumers with liver  
or kidney disease  
ask a doctor

**Drug Facts** (continued)

No Varnish



29012008

**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  
■ itchy, watery eyes  
■ 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.**

**Children's**  
**Claritin**  
**Grape**  
**Flavored**  
**Chewables**  
**Allergy**  
**5 CHEWABLE**  
**TABLETS**

NDC 11523-7198-2

**New!**  
**2 years**  
**ages**  
**and older**

**Children's**  
**Claritin**  
**Allergy**  
**5 CHEWABLE TABLETS**

**Allergy**

loratadine tablets 5 mg/antihistamine

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

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

**Grape**  
**Flavored**  
**Chewables**  
**Actual**  
**Size**

Code Area  
No Varnish  
No Ink

**Children's**  
**Claritin**  
**Allergy**

# ATTACH LEGEND ON ALL DIGITAL MECHANICALS

## STANDARD FORMAT

Helvetica Condensed  
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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: \_\_\_\_\_

\_\_\_\_\_

29012105



NO VARNISH

Glue HSINRYA ON

**Questions or comments?**  
1-800-CLARITIN (1-800-252-252-7484) or [www.claritin.com](http://www.claritin.com)

**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, microcrystalline cellulose, polyethylene glycol, polyethylene glycol stearate, stearic acid

**Other information**  
■ Contains phenylephrine 1.4 mg per tablet  
■ Do not use if the individual blister unit is opened or tampered with  
■ Store between 20° to 25° (68° to 77°F)

**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

**Drug Facts** (continued)

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

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

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

**Ask a doctor before use** if you have liver or kidney disease. Your doctor should determine if you need a different dose.

**Warnings**  
Do not use if you have ever had an allergic reaction to this product or any of its ingredients.

**Uses**  
temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:  
■ runny nose  
■ sneezing  
■ itching of the nose or throat

**Drug Facts**  
**Active ingredient (in each tablet)** Purpose  
Loratadine 5 mg.....Antihistamine

**Children's Claritin**  
**Grape Flavored Chewables** 10 CHEWABLE TABLETS  
NDC 11523-7198-1

**Children's Claritin**  
**Non-Drowsy\***  
**24 Hour Relief of:**  
• Sneezing  
• Runny Nose  
• Itchy, Watery Eyes  
• Itchy Throat or Nose

**Allergy**  
loratadine tablets 5 mg/antihistamine

**10 CHEWABLE TABLETS**

\*When taken as directed. See Drug Facts Panel.



Code Area  
No Varnish  
No Ink

**Children's Claritin**  
**Allergy**

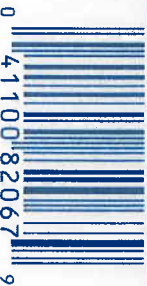
NO VARNISH



29012105

**Children's Claritin**  
**Allergy**  
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# ATTACH LEGEND ON ALL DIGITAL MECHANICALS

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**Drug Facts** (continued)

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

Barline - 1 pt rule \_\_\_\_\_

Hairline - .5 pt rule \_\_\_\_\_

Certified by: rp  
\_\_\_\_\_  
\_\_\_\_\_

BACK

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                           |                                                                                                                                                                                                                                                                                          |                                                           |                                    |                                                         |                               |              |                                        |              |                                                                                                                                                                                                                                                                  |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------|------------------------------------|---------------------------------------------------------|-------------------------------|--------------|----------------------------------------|--------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Drug Facts (continued)</b><br>When using this product do not take more than directed. Taking more than directed may cause drowsiness.<br><b>Stop use and ask a doctor</b> if an allergic reaction to this product occurs. Seek medical help right away.<br><b>If pregnant or breast-feeding</b> , ask a health professional before use.<br><b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away. |                                                           | <b>Drug Facts (continued)</b><br><b>Other information</b><br>■ phenylketonurics: contains phenylalanine 1.4 mg per tablet<br>■ safety sealed: do not use if the individual blister unit imprinted with Children's Claritin® is open or torn<br>■ store between 20° to 25°C (68° to 77°F) |                                                           |                                    |                                                         |                               |              |                                        |              |                                                                                                                                                                                                                                                                  |
| <b>Directions</b><br><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 | <b>Inactive ingredients</b><br>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 |
| 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                                              |                                                                                                                                                                                                                                                                                          |                                                           |                                    |                                                         |                               |              |                                        |              |                                                                                                                                                                                                                                                                  |
| <b>Questions or comments?</b><br>1-800-CLARITIN (1-800-252-7484) or<br><a href="http://www.claritin.com">www.claritin.com</a>                                                                                                                                                                                                                                                                                                                                            |                                                           | © Copyright & Distributed by Schering-Plough HealthCare Products, Inc., Kenilworth, NJ 07033 USA All Rights Reserved. 27780-00                                                                                                                                                           |                                                           |                                    |                                                         |                               |              |                                        |              |                                                                                                                                                                                                                                                                  |

Sample - Not for Sale

**Children's Claritin** Non-Drowsy\*  
24 Hour Relief of:  
 • Sneezing  
 • Runny Nose  
 • Itchy, Watery Eyes  
 • Itchy Throat or Nose

**Allergy**  
loratadine tablets 5 mg/antihistamine

**2 CHEWABLE TABLETS**  
Grape Flavored Chewables

\*When taken as directed. See Drug Facts Panel.

|                                                                                                       |  |                                                                                                                                                                                                                                                            |
|-------------------------------------------------------------------------------------------------------|--|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Drug Facts</b><br><b>Active ingredient (in each tablet)</b><br>Loratadine 5 mg ..... Antihistamine |  | <b>Purpose</b><br>temporarily relieves these symptoms due to hay fever or other upper respiratory allergies.                                                                                                                                               |
| <b>Uses</b><br>■ runny nose<br>■ itchy, watery eyes<br>■ sneezing<br>■ itching of the nose or throat  |  | <b>Warnings</b><br><b>Do not use</b> if you have ever had an allergic reaction to this product or any of its ingredients<br><b>Ask a doctor before use if you have</b> liver or kidney disease. Your doctor should determine if you need a different dose. |

FRONT

Code Area  
Lot & Exp

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|                                                                                                                                                                                                                                                                                                                |                                                           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------|
| <b>Drug Facts</b>                                                                                                                                                                                                                                                                                              |                                                           |
| <b>Active ingredient (in each tablet)</b>                                                                                                                                                                                                                                                                      | Loratadine 5 mg                                           |
| <b>Purpose</b>                                                                                                                                                                                                                                                                                                 | Antihistamine                                             |
| <b>Uses</b>                                                                                                                                                                                                                                                                                                    |                                                           |
| temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:                                                                                                                                                                                                                     |                                                           |
| <ul style="list-style-type: none"> <li>■ sneezing</li> <li>■ runny nose</li> <li>■ itchy, watery eyes</li> <li>■ itching of the nose or throat</li> </ul>                                                                                                                                                      |                                                           |
| <b>Warnings</b>                                                                                                                                                                                                                                                                                                |                                                           |
| 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.                                                                                                                                                                                            |                                                           |
| <b>Questions or comments?</b>                                                                                                                                                                                                                                                                                  |                                                           |
| 1-800-CLARITIN (1-800-232-7461) or www.claritin.com                                                                                                                                                                                                                                                            |                                                           |
| <b>Inactive ingredients</b>                                                                                                                                                                                                                                                                                    |                                                           |
| 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                                                                              |                                                           |
| <b>Other information</b>                                                                                                                                                                                                                                                                                       |                                                           |
| <ul style="list-style-type: none"> <li>■ phenylethanolamine: contains phenylethanolamine 1.4 mg per tablet</li> <li>■ safety sealed: do not use if the individual blister unit is imprinted with Children's Claritin<sup>®</sup> is open or torn</li> <li>■ store between 20° to 25°C (68° to 77°F)</li> </ul> |                                                           |
| <b>Directions</b>                                                                                                                                                                                                                                                                                              |                                                           |
| 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                                              |
| <b>Drug Facts (continued)</b>                                                                                                                                                                                                                                                                                  |                                                           |

2 CHEWABLE TABLETS

Claritin

**SAMPLE & COUPON ENCLOSED**

ages  
2 years  
and older

**Children's**

**Claritin<sup>®</sup>**

**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



**Grape  
Flavored  
Chewables**

Actual  
Size

**PRODUCT SAMPLE - NOT FOR RETAIL SALE**

OUTSIDE

Code Area  
Lot & Exp

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|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |  |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
| <b>Drug Facts</b><br><b>Active ingredient (in each tablet)</b><br>Loratadine 5 mg; Antihistamine                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |  |
| <b>Uses</b><br>Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:<br>• sneezing<br>• runny nose<br>• itchy, watery eyes<br>• itching of the nose or throat                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |  |
| <b>Warnings</b><br>Do not use if you have ever had an allergic reaction to this product or any of its ingredients.<br>Ask a doctor before use if you have liver or kidney disease. Your doctor should determine if you need a different dose.<br>When using this product do not take more than directed. Taking more than directed may cause drowsiness.<br>Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away.<br>If pregnant or breast-feeding, ask a health professional before use.<br>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. |  |
| <b>Other information</b><br>• phenylephrine: contains phenylephrine 1.4 mg per tablet<br>• safety sealed: do not use if the individual blister unit is imprinted with Children's Claritin is open or torn<br>• store between 20° to 25° C (68° to 77° F)                                                                                                                                                                                                                                                                                                                                                                                                           |  |
| <b>Inactive ingredients</b><br>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                                                                                                                                                                                                                                                                                                                                                                                                   |  |
| <b>Questions or comments?</b><br>1-800-CLARITIN (1-800-252-7441) or www.claritin.com                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |  |

**Claritin**  
2 CHEWABLE TABLETS

ages 2 years and older  
**Children's Claritin®**

**Allergy**  
loratadine tablets 5 mg/antihistamine

2 CHEWABLE TABLETS

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



\*When taken as directed. See Drug Facts Panel.

PRODUCT SAMPLE - NOT FOR RETAIL SALE

OUTSIDE

ATTACH LEGEND ON ALL  
DIGITAL MECHANICALS

**STANDARD FORMAT**  
Helvetica Condensed  
Variable horizontal scale adheres to 39 characters  
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**Drug Facts** - 9 pt Helvetica Cnd. Bold Italic  
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**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  
**Baseline** - 1 pt rule  
**Hairline** - .5 pt rule

Certified by: WMA  
\_\_\_\_\_  
\_\_\_\_\_

  
**Claritin®**  
**Allergy**  
loratadine tablets 5 mg/antihistamine

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

**25 Samples of 2 Chewable Tablets**

\*When taken as directed. See Drug Facts Panel.

PRODUCT SAMPLE - NOT FOR RETAIL SALE



\*When taken as directed.  
See Drug Facts Panel.

PRODUCT SAMPLE - NOT FOR RETAIL SALE

Glue/No Ink  
No Varnish

Schering Plough  
S16155CR1.EPS  
Print Side Up  
Sharp Corporation  
21-Mar-2006

Glue/No Ink No Varnish

[illegible]

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2 years  
and older

**Children's**

**Claritin®**

**Allergy**

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

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

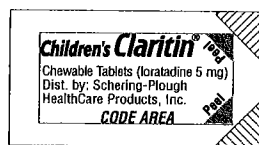
**Grape Flavored**  
**Chewable**

\*When taken as directed.  
See Drug Facts Panel.

**PRODUCT SAMPLE - NOT FOR RETAIL SALE**

Glue/No Ink  
No Varnish

Aug. 2, 2005



NDA 21-891, S-000  
1.14.1 Draft Labeling  
1.14.1.1 Blister Version 1



NDA 21-891, S-000  
1.14.1 Draft Labeling  
1.14.1.1 Blister Version 2