

**NDA 21-512**  
**Draft Labeling**  
**Push Through Blister Package**  
**4 Count**

**LORATADINE 10 mg**  
**1 TABLET**

**PUSH TABLET  
THROUGH FOIL**

MANUFACTURED BY PERRIGO  
ALLEGAN, MI 49010 USA  
27584 FA X1-10

LOT#

EXP. DATE:

**LORATADINE 10 mg**  
**1 TABLET**

**PUSH TABLET  
THROUGH FOIL**

MANUFACTURED BY PERRIGO  
ALLEGAN, MI 49010 USA  
27584 FA X1-10

LOT#

EXP. DATE:

**LORATADINE 10 mg**  
**1 TABLET**

**PUSH TABLET  
THROUGH FOIL**

MANUFACTURED BY PERRIGO  
ALLEGAN, MI 49010 USA  
27584 FA X1-10

LOT#

EXP. DATE:

**LORATADINE 10 mg**  
**1 TABLET**

**PUSH TABLET  
THROUGH FOIL**

MANUFACTURED BY PERRIGO  
ALLEGAN, MI 49010 USA  
27584 FA X1-10

LOT#

EXP. DATE:

# NDA 21-512

## Draft Labeling

### Push Through Blister Package

### 12 Count

**LORATADINE 10 mg**  
**1 TABLET**

**PUSH TABLET THROUGH FOIL**

MANUFACTURED BY PERRIGO  
ALLEGAN, MI 49010 USA

LOT#  
EXP. DATE:

**LORATADINE 10 mg**  
**1 TABLET**

**PUSH TABLET THROUGH FOIL**

MANUFACTURED BY PERRIGO  
ALLEGAN, MI 49010 USA

LOT#  
EXP. DATE:

**LORATADINE 10 mg**  
**1 TABLET**

**PUSH TABLET THROUGH FOIL**

MANUFACTURED BY PERRIGO  
ALLEGAN, MI 49010 USA

LOT#  
EXP. DATE:

**LORATADINE 10 mg**  
**1 TABLET**

**PUSH TABLET THROUGH FOIL**

MANUFACTURED BY PERRIGO  
ALLEGAN, MI 49010 USA

LOT#  
EXP. DATE:

**LORATADINE 10 mg**  
**1 TABLET**

**PUSH TABLET THROUGH FOIL**

MANUFACTURED BY PERRIGO  
ALLEGAN, MI 49010 USA

LOT#  
EXP. DATE:  
27553 FA X1-1

**LORATADINE 10 mg**  
**1 TABLET**

**PUSH TABLET THROUGH FOIL**

MANUFACTURED BY PERRIGO  
ALLEGAN, MI 49010 USA

LOT#  
EXP. DATE:

**LORATADINE 10 mg**  
**1 TABLET**

**PUSH TABLET THROUGH FOIL**

MANUFACTURED BY PERRIGO  
ALLEGAN, MI 49010 USA

LOT#  
EXP. DATE:

**LORATADINE 10 mg**  
**1 TABLET**

**PUSH TABLET THROUGH FOIL**

MANUFACTURED BY PERRIGO  
ALLEGAN, MI 49010 USA

LOT#  
EXP. DATE:

**LORATADINE 10 mg**  
**1 TABLET**

**PUSH TABLET THROUGH FOIL**

MANUFACTURED BY PERRIGO  
ALLEGAN, MI 49010 USA

LOT#  
EXP. DATE:

**LORATADINE 10 mg**  
**1 TABLET**

**PUSH TABLET THROUGH FOIL**

MANUFACTURED BY PERRIGO  
ALLEGAN, MI 49010 USA

LOT#  
EXP. DATE:

**LORATADINE 10 mg**  
**1 TABLET**

**PUSH TABLET THROUGH FOIL**

MANUFACTURED BY PERRIGO  
ALLEGAN, MI 49010 USA

LOT#  
EXP. DATE:

**LORATADINE 10 mg**  
**1 TABLET**

**PUSH TABLET THROUGH FOIL**

MANUFACTURED BY PERRIGO  
ALLEGAN, MI 49010 USA

LOT#  
EXP. DATE:

NDA 21-512  
Draft Labeling  
Blister Carton  
4 Count

EFB 186

MANUFACTURED BY  
**PPERRIGO**  
ALLEGAN, MI 49010 U.S.A.

If you have questions of a medical nature, please contact your pharmacist, doctor or health care professional.

**Inactive ingredients** lactose monohydrate, magnesium stearate, povidone, pregelatinized starch.

**Other information**

- protect from excessive moisture
- do not use if individual blister is open or torn
- store at 20°-25°C (68°-77°F)

**Directions**

adults and children 6 years and over  
1 tablet daily; not more than 1 tablet in 24 hours

children under 6 years of age  
ask a doctor

consumers with liver or kidney disease  
ask a doctor

right away.

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

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

**Stop use 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.

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

**Active ingredient (in each tablet) Purpose**

Loratadine 10 mg.....Antihistamine

**Drug Facts**

**Loratadine Tablets, 10 mg**  
Antihistamine  
24 Hour  
**Non-Drowsy**  
\*When taken as directed. See Drug Facts Panel.

**Non-Drowsy**  
24 Hour  
**Loratadine Tablets, 10 mg**  
Antihistamine

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

**NEW!**  
Original Prescription Strength

4 days of relief

**Non-Drowsy\***

**Compare to the active ingredient in Claritin® Tablets**

**Loratadine Tablets, 10 mg**

**Antihistamine**

**24 Hour**

Relief of:

- Sneezing
- Itchy, watery eyes
- Runny nose
- Itchy throat or nose

**4 Tablets**

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

Actual Size



**FORMAT: STANDARD**

**TYPE SIZES:**

**TITLE:** 10 pt Helvetica Bold Cond. Italic  
**TITLE (continued):** 8 pt Helvetica Bold Cond. Italic  
**(continued)** 8 pt Helvetica Cond. Medium  
**HEADINGS:** 8 pt Helvetica Bold Cond. Italic  
**SUBHEADINGS:** 6 pt Helvetica Bold  
**TEXT:** 6 pt Helvetica Cond. Medium  
**LEADING:** 6.5 pt  
**BULLETS:** 5 pt Square with 2 M'S spacing between statements  
**HEAVY LINES:** 1.5 pt  
**HAIRLINES:** 0.5 pt

27584 FA-C4-1

**Code Area**

**OPEN OTHER END**

**CONVENIENT RECLOSING TAB**

EFB 186

MANUFACTURED BY  
**PERRIGO**  
ALLEGAN, MI 49010 U.S.A.

If you have questions of a medical nature, please contact your pharmacist, doctor or health care professional.

**Inactive Ingredients** lactose monohydrate, magnesium stearate, povidone, pregelatinized starch

- protect from excessive moisture
- store at 20°-25°C (68°-77°F)
- do not use if individual blister is open or torn

**Other Information**

adults and children 6 years and over  
1 tablet daily, not more than 1 tablet in 24 hours

**Directions**

ask a doctor  
ask a doctor  
ask a doctor

**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.

**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

**Active ingredient (in each tablet) Purpose** Loratadine 10 mg.....Antihistamine

**Drug Facts** Antihistamine

When taken as directed. See Drug Facts Panel.

**Loratadine Tablets, 10 mg**

24 Hour

Non-Drowsy

Non-Drowsy

24 Hour

**Loratadine Tablets, 10 mg**

Antihistamine

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

NEW!

Original Prescription Strength

12 days of relief

Non-Drowsy\*

Compare to the active ingredient in Claritin® Tablets

**Loratadine Tablets, 10 mg**

Antihistamine

24 Hour

Relief of:

- Sneezing
- Itchy, watery eyes
- Runny nose
- Itchy throat or nose

12 Tablets

Actual Size



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

27553 FA 02-1

Code Area

OPEN OTHER END

CONVENIENT RECLOSING TAB



**FORMAT: STANDARD**

**TYPE SIZES:**

**TITLE:** 10 pt Helvetica Bold Cond. Italic  
**TITLE (continued):** 8 pt Helvetica Bold Cond. Italic  
**(continued)** 8 pt Helvetica Cond. Medium  
**HEADINGS:** 8 pt Helvetica Bold Cond. Italic  
**SUBHEADINGS:** 6 pt Helvetica Bold  
**TEXT:** 6 pt Helvetica Cond. Medium  
**LEADING:** 6.5 pt  
**BULLETS:** 5 pt Square with 2 M'S spacing between statements  
**HEAVY LINES:** 1.5 pt  
**HAIRLINES:** 0.5 pt

# NDA 21-512 Draft Labeling Bottle Label 10 Count

ELA 17A

Non-Drowsy\*

## Loratadine Tablets, 10 mg

Antihistamine

24  
Hour

10 Tablets

\*When taken  
as directed.

Sealed with printed foil under cap

**Active Ingredient**  
(in each tablet)

**Purpose**  
Loratadine 10 mg..... 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.

**Directions:**

■ **adults and children 6 years and over:**  
1 tablet daily; not more than 1 tablet in  
24 hours  
■ **children under 6 years of age:** ask a  
doctor  
■ **consumers with liver or  
kidney disease:** ask a doctor  
Store at 20-25°C (68-77°F).

MANUFACTURED BY  
**PERRIGO**  
ALLEGAN, MI 49010 U.S.A.

**CODE  
AREA**

27552 FA F3-1

## FORMAT: STANDARD

### TYPE SIZES:

**TITLE: 4.75 pt Helvetica Cond. Bold Italic**

**HEADINGS: 4.75 pt Helvetica Cond. Bold Italic**

**SUBHEADINGS: 4.75 pt Helvetica Bold Cond.**

**TEXT: 4.75 pt Helvetica Cond. Medium**

**LEADING: 4.75 pt**

**BULLETS: 4.5 pt Square with  
2 M'S spacing between statements**

**HEAVY LINES: 1 pt**

**HAIRLINES: 0.5 pt**

# NDA 21-512 Draft Labeling Bottle Label 30 Count

ELA 17A

Non-Drowsy

## Loratadine Tablets, 10 mg

Antihistamine

24  
Hour

30 Tablets

\*When taken  
as directed.

Sealed with printed foil under cap

**Active Ingredient**  
(in each tablet)

**Purpose**  
Loratadine 10 mg.....Antihistamine

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

runny nose ■ sneezing  
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.

**Directions**

**adults and children 6 years and over:**  
1 tablet daily, not more than 1 tablet in  
24 hours.  
■ **children under 6 years of age:** ask a  
health professional before use.  
■ **consumers with liver or  
kidney disease:** ask a doctor  
Store at 20-25°C (68-77°F).

MANUFACTURED BY  
**PERRIGO**  
ALLEGAN, MI 49010 U.S.A.

**CODE  
AREA**

27565 FA F-13

## FORMAT: STANDARD

### TYPE SIZES:

**TITLE: 4.75 pt Helvetica Cond. Bold Italic**

**HEADINGS: 4.75 pt Helvetica Cond. Bold Italic**

**SUBHEADINGS: 4.75 pt Helvetica Bold Cond.**

**TEXT: 4.75 pt Helvetica Cond. Medium**

**LEADING: 4.75 pt**

**BULLETS: 4.5 pt Square with  
2 M'S spacing between statements**

**HEAVY LINES: 1 pt**

**HAIRLINES: 0.5 pt**

# NDA 21-512 Draft Labeling Bottle Label 300 Count

ELA 17A

Non-Drowsy\*

Loratadine  
Tablets, 10 mg

Antihistamine

24  
Hour

300 Tablets

\*When taken  
as directed.

Sealed with printed foil under cap

**Active Ingredient**

**Purpose**

Loratadine 10 mg..... 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.

**Directions**

**adults and children 6 years and over:** 2 tablets daily, not more than 1 tablet in 24 hours.

**children under 6 years of age:** ask a health professional before use.

**consumers with liver or kidney disease:** ask a doctor.

Store at 20-25°C (68-77°F).

MANUFACTURED BY  
**PERRIGO**  
ALLEGAN, MI 49010 U.S.A.

**CODE  
AREA**

27587 FA F3-3

## FORMAT: STANDARD

### TYPE SIZES:

**TITLE:** 4.75 pt Helvetica Cond. Bold Italic

**HEADINGS:** 4.75 pt Helvetica Cond. Bold Italic

**SUBHEADINGS:** 4.75 pt Helvetica Bold Cond.

**TEXT:** 4.75 pt Helvetica Cond. Medium

**LEADING:** 4.75 pt

**BULLETS:** 4.5 pt Square with  
2 M'S spacing between statements

**HEAVY LINES:** 1 pt

**HAIRLINES:** 0.5 pt

**NDA 21-512  
Draft Labeling  
Bottle Carton  
10 Count**

**EFB 350**

**Drug Facts (continued)**

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

**Directions**

adults and children 6 years and over | 1 tablet daily; not more than 1 tablet in 24 hours  
 children under 6 years of age | ask a doctor  
 ask a doctor

consumers with liver or kidney disease | ask a doctor

**Drug Facts**

**Active ingredient (in each tablet)** Loratadine 10 mg; Antihistamine

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

**NEW!** Original Prescription Strength

Compare to the active ingredient in Claritin® Tablets

**Non-Drowsy\***


**Loratadine Tablets, 10 mg**

Antihistamine

**24 Hour**

**10 Tablets**

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

Actual Size 

**Non-Drowsy\*** 10 days of relief

**Loratadine Tablets, 10 mg**

Antihistamine

Relief of:

- Sneezing
- Runny nose
- Itchy, watery eyes
- Itchy throat or nose

**Drug Facts (continued)**

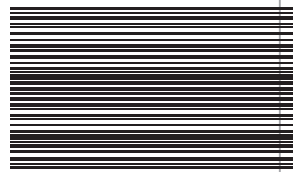
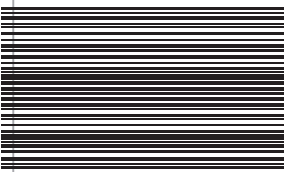
**Other information**

- sealed with printed foil under cap for your protection
- store at 20°-25°C (68°-77°F)
- lactose monohydrate, magnesium stearate, povidone, pregelatinized starch

**Inactive ingredients**

MANUFACTURED BY **PERRIGO** ALLEGAN, MI 49010 U.S.A.

If you have questions of a medical nature, please contact your pharmacist, doctor or health care professional.



EXP. 27552 FA-05-1

LOT NO. 000000000000

**CODE AREA**

**FORMAT: STANDARD**

**TYPE SIZES:**

- TITLE: 10 pt Helvetica Bold Italic**
- TITLE (continued): 8 pt Helvetica Bold Italic**
- (continued) 8 pt Helvetica Regular**
- HEADINGS: 8 pt Helvetica Bold Italic**
- SUBHEADINGS: 6 pt Helvetica Bold**
- TEXT: 6 pt Helvetica Regular**
- LEADING: 6.5 pt**
- BULLETS: 5 pt Square with 2 M'S spacing between statements**
- HEAVY LINES: 1.5 pt**
- HAIRLINES: 0.5 pt**



**NDA 21-512  
Draft Labeling  
Bottle Carton  
30 Count**

**EFB 350**

**Drug Facts (continued)**  
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**  
adults and children 6 years and over 1 tablet daily; not more than 1 tablet in 24 hours  
children under 6 years of age ask a doctor  
ask a doctor

**Drug Facts**  
**Active ingredient (in each tablet)**  
Loratadine 10 mg; Antihistamine  
**Uses** temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:  
■ runny nose ■ sneezing ■ 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.

LOT NO. 00000000000000000000  
EXP. AREA  
CODE AREA  
27565 FA C4-1

**NEW!** Original Prescription Strength

Compare to the active ingredient in Claritin® Tablets

**Non-Drowsy\***

**Loratadine Tablets, 10 mg**

Antihistamine

**24 Hour**

**30 Tablets**

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

Actual Size 

**Non-Drowsy\*** 30 days of relief

**Loratadine Tablets, 10 mg**

Antihistamine

Relief of:

- ✓ Sneezing
- ✓ Runny nose
- ✓ Itchy, watery eyes
- ✓ Itchy throat or nose

**Drug Facts (continued)**  
**Other information**  
■ store at 20°-25°C (68°-77°F)  
■ sealed with printed foil under cap for your protection  
**Inactive ingredients** lactose monohydrate, magnesium stearate, povidone, pregeatinized starch  
MANUFACTURED BY **PERIGO** ALLEGAN, MI 49010 U.S.A.

**FORMAT: STANDARD**

**TYPE SIZES:**  
**TITLE: 10 pt Helvetica Bold Italic**  
**TITLE (continued): 8 pt Helvetica Bold Italic**  
**(continued) 8 pt Helvetica Regular**  
**HEADINGS: 8 pt Helvetica Bold Italic**  
**SUBHEADINGS: 6 pt Helvetica Bold**  
**TEXT: 6 pt Helvetica Regular**  
**LEADING: 6.5 pt**  
**BULLETS: 5 pt Square with 2 M'S spacing between statements**  
**HEAVY LINES: 1.5 pt**  
**HAIRLINES: 0.5 pt**

NDA 21-512  
Draft Labeling  
Bottle Carton  
300 Count

EFB 350

**Drug Facts (continued)**  
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**  
adults and children 6 years and over 1 tablet daily; not more than 1 tablet in 24 hours  
children under 6 years of age ask a doctor  
ask a doctor  
ask a doctor  
ask a doctor

**Drug Facts**  
**Active ingredient (in each tablet)**  
Loratadine 10 mg.....Antihistamine  
**Purpose**  
temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:  
■ runny nose ■ sneezing ■ 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.

**NEW!** Original Prescription Strength

Compare to the active ingredient in Claritin® Tablets

**Non-Drowsy\***

**Loratadine Tablets, 10 mg**

Antihistamine

**300 Tablets**

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

Actual Size 

**24 Hour**

**Non-Drowsy\*** 300 days of relief

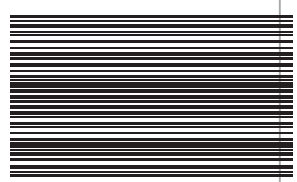
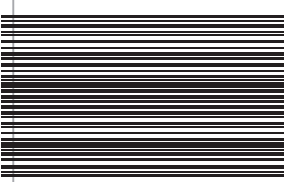
**Loratadine Tablets, 10 mg**

Antihistamine

Relief of:

- Sneezing
- Runny nose
- Itchy, watery eyes
- Itchy throat or nose

**Drug Facts (continued)**  
**Other information**  
■ sealed with printed foil under cap for your protection  
■ store at 20°-25°C (68°-77°F)  
**Inactive ingredients** lactose monohydrate, magnesium stearate, povidone, pregelatinized starch  
MANUFACTURED BY **PERIGO**  
ALLEGAN, MI 49010 U.S.A.



LOT NO. 0 000000 000000 0

EXP. AREA

27587 FA 05-1

**FORMAT: STANDARD**

**TYPE SIZES:**  
**TITLE: 10 pt Helvetica Bold Italic**  
**TITLE (continued): 8 pt Helvetica Bold Italic**  
**(continued) 8 pt Helvetica Regular**  
**HEADINGS: 8 pt Helvetica Bold Italic**  
**SUBHEADINGS: 6 pt Helvetica Bold**  
**TEXT: 6 pt Helvetica Regular**  
**LEADING: 6.5 pt**  
**BULLETS: 5 pt Square with 2 M'S spacing between statements**  
**HEAVY LINES: 1.5 pt**  
**HAIRLINES: 0.5 pt**