

Wyeth Consumer Healthcare
 NDA Resubmission
 October 14, 2002

NDA 21-375
 Alavert Allergy
 Loratadine/10 mg/Orally Disintegrating Tablets (OTC)

3 0573-2620-12 1



FPO

Questions or comments? call weekdays from 9 AM to 6 PM EST at 1-800-ALAVERT (1-800-262-8378)

Inactive Ingredients artificial & natural flavor, aspartame, citric acid, colloidal silicon dioxide, corn syrup solids, crospovidone, magnesium stearate, mannitol, microcrystalline cellulose, modified food starch, sodium bicarbonate

Other Information ■ Phenylethanamines: Contains Phenylethanamine 8.4 mg per tablet ■ store at 20-25°C (68-77°F) ■ keep in a dry place

Age	adults and children 6 years and over	1 tablet daily; do not use more than 1 tablet daily
children under 6	ask a doctor	
consumers who have liver or kidney disease	ask a doctor	

Directions ■ tablet melts in mouth. Can be taken with or without water.

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

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 use more than directed. Taking more than recommended may cause drowsiness. 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

Warnings


Ask a doctor before use if you have liver or kidney disease.

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


Active Ingredient (in each tablet) Loratadine 10 mg Antihistamine

Drug Facts

42-01707-900



FPO



ALAVERT™
 Non-Drowsy* Allergy Relief

EACH TABLET IS BLISTER SEALED.
 DO NOT USE IF SEAL IS BROKEN.

*When taken as directed. See Drug Facts Panel.

NEW!
 One Tablet - 24 hrs.

allergy

ALAVERT™

(Loratadine Orally Disintegrating Tablet, 10mg, Antihistamine)
Non-Drowsy* Allergy Relief

24-Hour Relief of

- Sneezing
- Runny Nose
- Itchy, Watery Eyes
- Itching of Nose & Throat

MELTS IN YOUR MOUTH

12 Orally Disintegrating Tablets

UK24027-1

ALAVERT™ allergy
 Non-Drowsy* Allergy Relief

Wyeth®
 Distributed by
 Wyeth Consumer Healthcare
 Madison, NJ 07940

LOT & EXP. TARGET AREA

LOT EXP

LOT EXP

Alavert Allergy provides 24 hours of allergy symptom relief without causing drowsiness when taken as directed (See Drug Facts Panel). It contains prescription strength loratadine. Just one tablet a day relieves runny nose, sneezing and itchy, watery eyes. It is safe and effective for adults and children 6 years and over. The mint flavored tablet melts in your mouth. So convenient, it can be taken without water.

Visit our website at www.alavert.com

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.

When using this product do not use more than directed. Taking more than recommended 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 ■ tablet melts in mouth. Can be taken with or without water.

Age	1 tablet daily; do not use more than 1 tablet daily
adults and children 6 years and over	ask a doctor
children under 6	ask a doctor

consumers who have liver or kidney disease

Other information
 ■ store at 20-25°C (68-77°F) ■ keep in a dry place
 ■ Phenylethanamine 8.4 mg per tablet

Inactive ingredients artificial & natural flavor, aspartame, citric acid, colloidal silicon dioxide, corn syrup solids, croscellulose, magnesium stearate, mannitol, microcrystalline cellulose, modified food starch, sodium bicarbonate

Questions or comments? call weekdays from 9 AM to 5 PM EST at 1-800-ALAVERT (1-800-252-8378)

42-01715-900





EACH TABLET IS BLISTER SEALED.
DO NOT USE IF SEAL IS BROKEN.

UK24026-1

*When taken as directed. See Drug Facts Panel.

NEW!
One Tablet - 24 hrs.



allergy

ALAVERT™

(Loratadine Orally Disintegrating Tablet, 10mg, Antihistamine)
Non-Drowsy* Allergy Relief

24-Hour Relief of

- Sneezing
- Runny Nose
- Itchy, Watery Eyes
- Itching of Nose & Throat

MELTS IN YOUR MOUTH

24 Orally Disintegrating Tablets



Wyeth
 Distributed by:
 Wyeth Consumer Healthcare, Madison, NJ 07940

LOT
EXP

3 0573-2620-24 4



*When taken as directed. See Drug Facts Panel.

Visit our website at www.alavert.com

The mint flavored tablet melts in your mouth. So convenient, it can be taken without water.

safe and effective for adults and children 6 years and over.

Just one tablet a day relieves runny nose, sneezing and itchy, watery eyes. It is prescription strength loratadine.

Alavert Allergy provides 24 hours of allergy symptom relief without causing drowsiness when taken as directed (See Drug Facts Panel). It contains

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NDA 21-375
 Alavert Allergy
 Loratadine/10 mg/Orally Disintegrating Tablets (OTC)

42-01691-900

EPO.

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.
When using this product do not use more than directed. Taking more than recommended 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 ■ tablet melts in mouth. Can be taken with or without water.

Age	adults and children 6 years and over	1 tablet daily; do not use more than 1 tablet daily
Dose		

children under 6 ask a doctor
 consumers who have liver or kidney disease ask a doctor

Other information
 ■ Phenylethanolamine 8.4 mg per tablet ■ store at 20-25°C (68-77°F) ■ keep in a dry place

Inactive ingredients artificial & natural flavor, aspartame, citric acid, colloidal silicon dioxide, corn syrup solids, croscopolone, magnesium stearate, mannitol, microcrystalline cellulose, modified food starch, sodium bicarbonate

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UK24025-1

NEW!
 One Tablet - 24 hrs.

allergy

ALAVERT™

(Loratadine Orally Disintegrating Tablet, 10mg, Antihistamine)

Non-Drowsy* Allergy Relief

24-Hour Relief of

- Sneezing
- Runny Nose
- Itchy, Watery Eyes
- Itching of Nose & Throat

MELTS IN YOUR MOUTH

48 Orally Disintegrating Tablets

*When taken as directed. See Drug Facts Panel.

allergy

ALAVERT™

Non-Drowsy* Allergy Relief

EACH TABLET IS
 BLISTER SEALED.
 DO NOT USE IF
 SEAL IS BROKEN

3 0573-2620-48 0

UK24025-1

NEW!
 One Tablet - 24 hrs.

allergy

ALAVERT™

(Loratadine Orally Disintegrating Tablet, 10mg, Antihistamine)

Non-Drowsy* Allergy Relief

24-Hour Relief of

- Sneezing
- Runny Nose
- Itchy, Watery Eyes
- Itching of Nose & Throat

MELTS IN YOUR MOUTH

48 Orally Disintegrating Tablets

*When taken as directed. See Drug Facts Panel.

allergy

ALAVERT™

Non-Drowsy* Allergy Relief

MELTS IN YOUR MOUTH

48 Orally Disintegrating Tablets

*When taken as directed. See Drug Facts Panel.

LOT

EXP.

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 Wyeth Consumer Healthcare,
 Madison, NJ 07740

allergy

ALAVERT™

Non-Drowsy* Allergy Relief

Visit our website at www.alavert.com

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