

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**Application Number 21-587**

**FINAL PRINTED LABELING**

EDR  
 2/6, 2004



UNPRINTED AREA FOR DATE & LOT NUMBER -  
 UNVARNISHED

DRUG FACTS TEXT DEFINED	TYPE SIZE
• DRUG FACTS Title	9 pt
• DRUG FACTS CONTINUED	8 pt
• HEADINGS	8 pt
• SUBHEADS/BODY TEXT	6 pt
• LEADING	6.5 pt
• # OF CHARACTERS PER INCH	<39
• BULLETS	5 pt
• SPACE AFTER BULLETED SECTION	2 ems
• BARLINES, HAIRLINES	1.5 pt, .5 pt
• SPACE BETWEEN HAIRLINES AND BOX END	2 spaces

100%



3/16" X 3/16" DATA MATRIX CODE (ECC200), PRINTED IN BLACK OR DARK BLUE ON UNPRINTED WHITE BACKGROUND WITH A MINIMUM OF 1/8" QUIET ZONE ALL 4 SIDES.

UNVARNISHED UNPRINTED AREA FOR LOT & EXP.

200%

**See box for important warnings and save for future use.**  
 Uses: temporarily relieves these symptoms associated with hay fever or other upper respiratory allergies, and the common cold: runny nose, sneezing, itchy, watery eyes, itching of the nose and throat, nasal congestion, headache, fever, minor aches and pains, and sinus pressure.  
**Warnings:** Allergy alert: Ibuprofen may cause a severe allergic reaction which may include: hives, facial swelling, asthma (wheezing), shock.  
**Stomach bleeding warning:** Taking more than recommended may cause stomach bleeding.  
 Do not use if the child has ever had an allergic reaction to any pain reliever/fever reducer, nasal decongestant, or antihistamine. Stop use and ask a doctor if an allergic reaction occurs. Seek medical help right away. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

**Do Not Use if breakable ring on bottle cap is separated or missing.**  
**Directions:** Do not give more than directed or shake well before using to find right dose on chart below. If possible, use weight to dose; otherwise use age. If needed, repeat dose every 6 hours while symptoms persist. Do not use more than 4 times a day. Measure only with dosing cup provided.

**Dosing Chart**

Weight (lb)	Age (yrs)	Dose (teaspoons)
under 48	under 6	ask a doctor
48 - 95	6 - 11	2 teaspoons

**Active Ingredients**  
*(in each 5 mL teaspoon)*

Chlorpheniramine maleate 1 mg	Antihistamine
Ibuprofen 100 mg	Pain reliever/Fever reducer
Pseudoephedrine HCl 15 mg	Nasal decongestant

**Berry Flavored Liquid**  
 1 FL OZ (30 mL)

Wyeth Consumer Healthcare  
 Madison, NJ 07940 U.S.A. U0183-10-1.FDA05

DRUG FACTS TEXT DEFINED	TYPE SIZE
• HEADINGS	4.5 pt
• SUBHEADS/BODY TEXT	4.5 pt
• LEADING	4.5 pt
• BULLETS	3.5 pt
• SPACE BEFORE BULLETED SECTION	2 ems
• BOX LINE	5 pt

100%

6

9/16

2 1/2 2 1/16

LOT & EXP UNVARNISHED AREA

**See box for important warnings and save for future use.**

**Active ingredients (in each 5 mL teaspoon)**      **Purposes**  
 Chlorpheniramine maleate 1 mg ..... Antihistamine  
 Ibuprofen 100 mg ..... Pain reliever/fever reducer  
 Pseudoephedrine HCl 15 mg ..... Nasal decongestant

**Uses:** temporarily relieves these symptoms associated with hay fever or other upper respiratory allergies, and the common cold: runny nose, sneezing, itchy, watery eyes, itching of the nose and throat, nasal congestion, headache, fever, minor aches and pains, and sinus pressure

**Warnings:**  
**Allergy alert:** Ibuprofen may cause a severe allergic reaction which may include:  
 ■ hives   ■ facial swelling   ■ asthma (wheezing)   ■ shock  
**Stomach bleeding warning:** Taking more than recommended may cause stomach bleeding.  
**Do not use if the child has ever had an allergic reaction to any pain reliever/fever reducer, nasal decongestant, or antihistamine.**  
**Stop use and ask a doctor if an allergic reaction occurs. Seek medical help right away.**  
**Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.**

**Directions:**  
 ■ do not give more than directed  
 ■ shake well before using  
 ■ find right dose on chart below. If possible, use weight to dose; otherwise use age.  
 ■ if needed, repeat dose every 8 hours while symptoms persist.  
 ■ do not use more than 4 times a day  
 ■ measure only with dosing cup provided

Weight (lb)	Age (yrs)	Dose (teaspoons)
under 48	under 6	ask a doctor
48 - 95	6 - 11	2 teaspoons

**Other information:**  
 ■ each 5 mL teaspoon contains: sodium 10 mg  
 ■ store at 20-25°C (68-77°F)

**Questions or comments?** call weekdays from 9AM to 5PM EST at 1-800-88-ADVIL, or ask your pharmacist, doctor or healthcare professional.

Wyeth Consumer Healthcare,  
 Madison, NJ 07940 U.S.A.  
 www.advil.com      U0183-30-1.FDA05

150%

**See box for important warnings and save for future use.**

**Active ingredients (in each 5 mL teaspoon)**      **Purposes**  
 Chlorpheniramine maleate 1 mg ..... Antihistamine  
 Ibuprofen 100 mg ..... Pain reliever/fever reducer  
 Pseudoephedrine HCl 15 mg ..... Nasal decongestant

**Uses:** temporarily relieves these symptoms associated with hay fever or other upper respiratory allergies, and the common cold: runny nose, sneezing, itchy, watery eyes, itching of the nose and throat, nasal congestion, headache, fever, minor aches and pains, and sinus pressure

**Warnings:**  
**Allergy alert:** Ibuprofen may cause a severe allergic reaction which may include:  
 ■ hives   ■ facial swelling   ■ asthma (wheezing)   ■ shock  
**Stomach bleeding warning:** Taking more than recommended may cause stomach bleeding.  
**Do not use if the child has ever had an allergic reaction to any pain reliever/fever reducer, nasal decongestant, or antihistamine.**  
**Stop use and ask a doctor if an allergic reaction occurs. Seek medical help right away.**  
**Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.**

**Directions:**  
 ■ do not give more than directed  
 ■ shake well before using  
 ■ find right dose on chart below. If possible, use weight to dose; otherwise use age.  
 ■ if needed, repeat dose every 8 hours while symptoms persist.  
 ■ do not use more than 4 times a day  
 ■ measure only with dosing cup provided

Weight (lb)	Age (yrs)	Dose (teaspoons)
under 48	under 6	ask a doctor
48 - 95	6 - 11	2 teaspoons

**Other information:**  
 ■ each 5 mL teaspoon contains: sodium 10 mg  
 ■ store at 20-25°C (68-77°F)

**Questions or comments?** call weekdays from 9AM to 5PM EST at 1-800-88-ADVIL, or ask your pharmacist, doctor or healthcare professional.

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DRUG FACTS TEXT DEFINED	TYPE SIZE
• HEADINGS	8 pt
• SUBHEADS/BODY TEXT	6 pt
• LEADING	6.5 pt
• BULLETS	5 pt
• SPACE AFTER BULLETED SECTION	2 ems
• BOX LINE	.5 pt
• SMALLEST ®, TM etc.	5.75 pt



UNPRINTED AREA FOR DATE & LOT NUMBER -  
 UNVARNISHED

DRUG FACTS TEXT DEFINED	TYPE SIZE
• DRUG FACTS TRM	9 pt
• DRUG FACTS CONTINUED	8 pt
• HEADINGS	8 pt
• SUBHEADS/BODY TEXT	6 pt
• LEADING	0.5 pt
• # OF CHARACTERS PER INCH	<39
• BULLETS	5 pt
• SPACE AFTER BULLETED SECTION	2 ems
• BARLINES, HAIRLINES	1.5 pt, .5 pt
• SPACE BETWEEN HAIRLINES AND BOX END	2 spaces

**Drug Facts (continued)**

- Ask a doctor or pharmacist before use if the child is
  - under a doctor's care for any continuing medical condition
  - taking medicines or tranquilizers
  - taking any other product that contains Aspirin, or any other pain reliever/fever reducer
  - taking any other product that contains pseudoephedrine or chlorpheniramine or any other nasal decongestant or antihistamine
  - taking a prescription drug for anticoagulation (blood thinning) or a diuretic
  - taking any other drug
- When using this product
  - do not give more than directed
  - irritation may occur, sedatives and tranquilizers may increase drowsiness
  - irritability may occur, especially in children
  - give with food or milk if stomach upset occurs
- Stop use and ask a doctor if
  - an allergic reaction occurs. Seek medical help right away.
  - nasal congestion lasts for more than 7 days
  - pain or fever gets worse or lasts for more than 3 days
  - the child gets nervous, dizzy, or sleepless
  - symptoms continue or get worse
  - stomach pain occurs
  - any new symptoms appear
- Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

**Directions**

- in adults and children using
- use right dose on chart below. If possible, use weight to dose, otherwise use age.
- if needed, repeat dose every 6 hours while symptoms persist
- do not use more than 4 times a day
- measures only with dosing cap provided

Dosing Chart		
Weight (lb)	Age (yrs)	Dose (teaspoons)
under 48	under 6	ask a doctor
48-95	6-11	2 teaspoons

**Drug Facts (continued)**

**Other information**

- each 5 mL suspension contains: sodium 10 mg
- store at 20-25°C (68-77°F)
- in most all warnings and directions below use: Keep carton.

**Inactive ingredients**

artificial flavor, carbonylmethylcellulose sodium, citric acid, dibutyl sebacate, FDAC blue no. 1, FDAC red no. 40, glycerin, lactic acid, microcrystalline cellulose, polyethylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol, croscarmellose, xanthan gum

**Questions or comments?**

call weekdays from 9AM to 5PM EST at 1-800-80-ADVI, or ask your pharmacist, doctor or healthcare professional



Paracetamol 100 mg / Fever Reducer: Pain Reliever  
Pseudoephedrine HCl 15 mg / Nasal Decongestant  
Chlorpheniramine Maleate 1 mg / Antihistamine  
per 5 mL

**Allergy Sinus**

Runny Nose, Sneezing  
Itchy, Watery Eyes  
Nasal Congestion  
Headaches

**Berry Flavor**  
for ages 6-11 years

**Important:** Read all product information before using. Keep this box for important information. This product is intended for use in children ages 6 years-11 years.

**Drug Facts**

**Active ingredients**  
(In each 5 mL suspension)

Active ingredient	Purpose
Ibuprofen 100 mg	Pain reliever/fever reducer
Pseudoephedrine HCl 15 mg	Nasal decongestant

**Uses:** Temporarily relieves these symptoms associated with hay fever or other upper respiratory allergies, and the common cold:

- runny nose
- itchy, watery eyes
- itching of the nose or throat
- coughing
- nasal congestion
- sinus pressure
- headache
- ear, nose and pain
- throat

**Warnings:**

Allergy alert: Respiratory may cause a severe allergic reaction which may include:

- hives
- facial swelling
- difficulty breathing
- throat

Stomach bleeding warning: Taking more than recommended may cause stomach bleeding.

**Do not use**

- if the child has ever had an allergic reaction to any other pain reliever/fever reducer, nasal decongestant, or antihistamine
- in a child who is taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or medicinal conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.

**Ask a doctor before use if the child has**

- a bleeding problem such as chronic bronchitis
- heart disease
- high blood pressure
- bygone disease
- diabetes
- liver disease
- bleeding problems
- had problems or serious side effects from taking pain reliever/fever reducers
- stomach problems that last or come back, such as heartburn, upset stomach or pain
- are not been drinking fluids
- lost a lot of fluid due to continued vomiting or diarrhea

UC4038-1 F0405



DRUG FACTS TEXT DEFINED	TYPE SIZE
• DRUG FACTS TITLE	9 pt
• DRUG FACTS CONTINUED	8 pt
• HEADINGS	8 pt
• SUBHEADS/BODY TEXT	6 pt
• LEADING	6.5 pt
• # OF CHARACTERS PER INCH	<39
• BULLETS	5 pt
• SPACE BEFORE BULLET	2 ems
• BARLINES, HAIRLINES	1.5 pt, 5 pt
• SPACE BETWEEN HAIRLINES AND BOX END	2 spaces

CONFIDENTIAL

100%



3/16" X 3/16" DATA MATRIX CODE (ECC206), PRINTED IN BLACK OR DARK BLUE ON UNPRINTED WHITE BACKGROUND WITH A MINIMUM OF 1/8" QUIET ZONE ALL 4 SIDES.

UNVARNISHED  
 UNPRINTED AREA  
 FOR LOT & EXP.

200%

**See box for important warnings and save for future use.**

**Uses:** temporarily relieves these symptoms associated with hay fever or other upper respiratory allergies, and the common cold: runny nose, sneezing, itchy, watery eyes, itching of the nose and throat, nasal congestion, headache, fever, minor aches and pains, and sinus pressure.

**Warnings:** Allergy alert: Ibuprofen may cause a severe allergic reaction which may include: hives, facial swelling, asthma (wheezing), shock.

**Stomach bleeding warning:** Taking more than recommended may cause stomach bleeding.

Do not use if the child has ever had an allergic reaction to any pain reliever/fever reducer, nasal decongestant, or antihistamine. Stop use and ask a doctor if an allergic reaction occurs. Seek medical help right away. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

**Do Not Use** if breakable ring on bottle cap is separated or missing.

**Directions:** do not give more than directed in shake well before using and find right dose on chart below. If possible, use weight to dose; otherwise use age. If needed, repeat dose every 6 hours while symptoms persist.

do not use more than 4 times a day

measure only with dosing cup provided

**Dosing Chart**

Weight (lb)	Age (yrs)	Dose (teaspoons)
under 48	under 6	ask a doctor
48 - 95	6 - 11	2 teaspoons

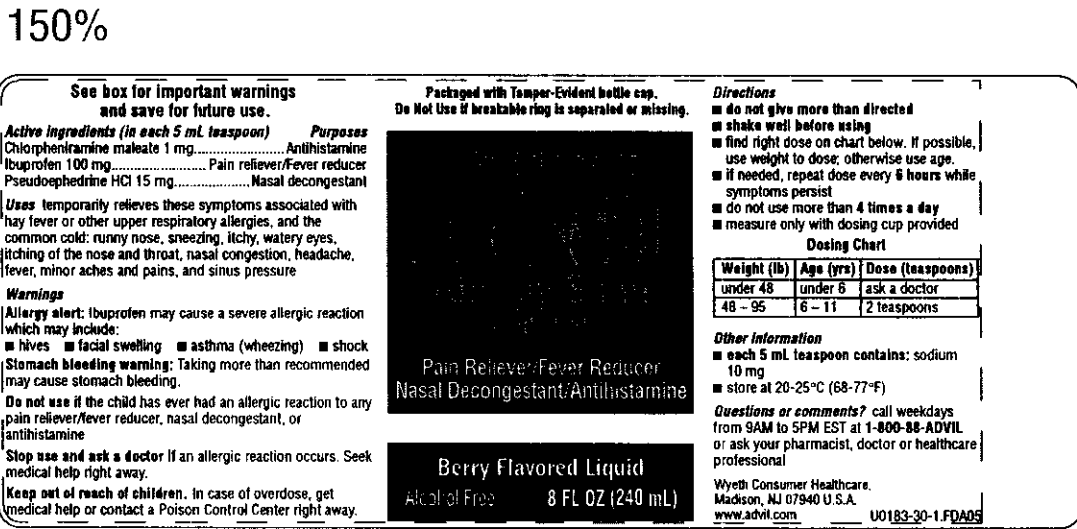
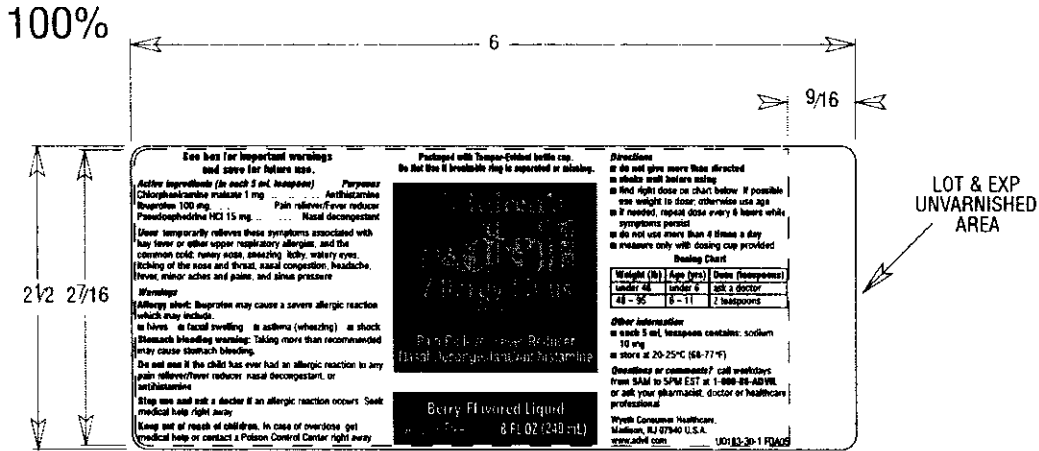
**Active Ingredients:**  
 (in each 5 mL teaspoon)

Ingredient	Purposes
Chlorpheniramine maleate 1 mg	Antihistamine
Ibuprofen 100 mg	Pain reliever/Fever reducer
Pseudoephedrine HCl 15 mg	Nasal decongestant

Berry Flavored Liquid  
 1 FL OZ (30 mL)

Wyeth Consumer Healthcare  
 Madison, NJ 07940 U.S.A. U0183-10-1.FDA05

DRUG FACTS TEXT DEFINED	TYPE SIZE
• HEADINGS	4.5 pt
• SUBHEADS/BODY TEXT	4.5 pt
• LEADING	4.5 pt
• BULLETS	3.5 pt
• SPACE BEFORE BULLETED SECTION	2 ems
• BOX LINE	.5 pt



**See box for important warnings and save for future use.**

**Active Ingredients (in each 5 mL teaspoon)**

Chlorpheniramine maleate 1 mg	Antihistamine
Ibuprofen 100 mg	Pain reliever/Fever reducer
Pseudoephedrine HCl 15 mg	Nasal decongestant

**Uses** temporarily relieves these symptoms associated with hay fever or other upper respiratory allergies, and the common cold: runny nose, sneezing, itchy, watery eyes, itching of the nose and throat, nasal congestion, headache, fever, minor aches and pains, and sinus pressure

**Warnings**  
**Allergy alert:** Ibuprofen may cause a severe allergic reaction which may include:  
 ■ hives ■ facial swelling ■ asthma (wheezing) ■ shock  
**Stomach bleeding warning:** Taking more than recommended may cause stomach bleeding.  
**Do not use if the child has ever had an allergic reaction to any pain reliever/fever reducer, nasal decongestant, or antihistamine.**  
**Stop use and ask a doctor if an allergic reaction occurs.** Seek medical help right away.  
**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

**Packaged with Tamper-Evident bottle cap. Do Not Use if breakable ring is separated or missing.**

**Directions**  
 ■ do not give more than directed  
 ■ shake well before using  
 ■ find right dose on chart below. If possible, use weight to dose; otherwise use age.  
 ■ if needed, repeat dose every 6 hours while symptoms persist  
 ■ do not use more than 4 times a day  
 ■ measure only with dosing cup provided

**Dosing Chart**

Weight (lb)	Age (yrs)	Dose (teaspoons)
under 48	under 6	ask a doctor
48 - 95	6 - 11	2 teaspoons

**Other information**  
 ■ each 5 mL teaspoon contains: sodium 10 mg  
 ■ store at 20-25°C (68-77°F)

**Questions or comments?** call weekdays from 9AM to 5PM EST at 1-800-88-ADVIL or ask your pharmacist, doctor or healthcare professional

Wyeth Consumer Healthcare,  
Madison, NJ 07940 U.S.A.  
www.advil.com U0183-30-1.FDA05

**Berry Flavored Liquid**  
Alcohol Free 8 FL OZ (240 mL)

DRUG FACTS TEXT DEFINED	TYPE SIZE
+ HEADINGS	6 pt
+ SUBHEADS/BODY TEXT	6 pt
+ LEADING	6.5 pt
+ BULLETS	5 pt
+ SPACE AFTER BULLETED SECTION	2 ems
+ BOX LINE	.5 pt
+ SMALLEST @, TM etc.	5.75 pt





UNPRINTED AREA FOR DATE & LOT NUMBER -  
 UNVARNISHED

DRUG FACTS TEXT DEFINED	TYPE SIZE
• DRUG FACTS Title	9 pt
• DRUG FACTS CONTINUED	8 pt
• HEADINGS	8 pt
• SUBHEADS/BODY TEXT	8 pt
• LEADING	6.5 pt
• # OF CHARACTERS PER INCH	<39
• BULLETS	5 pt
• SPACE AFTER BULLETED SECTION	2 ems
• BARLINES, HAIRLINES	1.5 pt, .5 pt
• SPACE BETWEEN HAIRLINES AND BOX END	2 spaces



**Drug Facts (continued)**

Ask a doctor or pharmacist before use if the child is:  
 • taking sedatives or tranquilizers  
 • taking any other product that contains ibuprofen, or any other pain reliever/fever reducer  
 • taking any other product that contains pseudoephedrine or chlorpheniramine or any other nasal decongestant or antihistamine  
 • taking a prescription drug for anticoagulation (blood thinning) or a diuretic  
 • taking any other drug

When using this product:  
 • do not give more than directed  
 • drowsiness may occur; sedatives and tranquilizers may increase drowsiness  
 • irritability may occur, especially in children  
 • give with food or milk if stomach upset occurs

Stop use and ask a doctor if:  
 • an allergic reaction occurs. Seek medical help right away.  
 • nasal congestion lasts for more than 7 days  
 • pain or fever gets worse or lasts for more than 3 days  
 • the child gets drowsy, dizzy, or dizzy  
 • symptoms continue or get worse  
 • stomach pain occurs  
 • any new symptoms appear

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

**Directions**

• Shake well before using  
 • Read right dose on chart below. If possible, use weight to dose whenever use age.  
 • If needed, repeat dose every 6 hours while symptoms persist.  
 • Do not use more than 6 doses a day.  
 • Measure only with dosing cup provided.

**Dosing Chart**

Weight (lb)	Age (yrs)	Dose (teaspoons)
under 40	under 6	ask a doctor
40-65	6-11	2 teaspoons

**Drug Facts (continued)**

**Other information**

• Each 5 mL suspension contains: sodium 10 mg  
 • Store at 20-25°C (68-77°F)  
 • See all warnings and directions before use. Keep carton

**Inactive ingredients**

artificial flavors, Carbonylmethylcellulose sodium, citric acid, edetate disodium, FD&C blue no. 1, FD&C red no. 40, glycerin, lactic acid, microcrystalline cellulose, polyethylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol solution, sucralose, xanthan gum

**Questions or comments?**  
 Call weekdays from 8AM to 5PM EST at 1-800-86-ADVI, or ask your pharmacist, doctor or healthcare professional



(Ibuprofen 100 mg) • Fever Reducer Pain Reliever  
 Pseudoephedrine HCl 15 mg • Nasal Decongestant  
 Chlorpheniramine HCl 1 mg • Antihistamine  
 per 5 mL

**Allergy Sinus**  
 Runny Nose, Sneezing  
 Itchy, Watery Eyes  
 Nasal Congestion  
 Headaches

**Berry Flavor**  
 for ages 6-11 years

**Important:** Read all product information before using. Keep this box for important information. This product is intended for use in children ages 6 years-11 years.

**Drug Facts**

**Active ingredients**  
 (in each 5 mL teaspoon)

Ingredient	Purpose
Ibuprofen 100 mg	Pain reliever/fever reducer
Pseudoephedrine HCl 15 mg	Nasal decongestant

**Uses:** Immediately relieve those symptoms associated with hay fever or other upper respiratory allergies, and the common cold:

- runny nose
- itching of the nose or throat
- nasal congestion
- headaches
- fever
- itchy, watery eyes
- sneezing
- sinus pressure
- minor aches and pains

**Warnings:**  
 Allergy alert: Ibuprofen may cause a severe allergic reaction which may include:  
 • hives  
 • facial swelling  
 • asthma (wheezing)  
 • shock  
 Stomach bleeding warning: Taking more than recommended may cause stomach bleeding.

Do not use:  
 • if the child has ever had an allergic reaction to any other pain reliever/fever reducer, nasal decongestant, or antihistamine  
 • in a child who is taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or nutritional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.

Ask a doctor before use if the child has:  
 • a breathing problem such as chronic bronchitis  
 • heart disease  
 • high blood pressure  
 • thyroid disease  
 • diabetes  
 • kidney disease  
 • bleeding problems  
 • had problems or serious side effects from taking pain reliever/fever reducers  
 • stomach problems that last or come back, such as heartburn, upset stomach or pain  
 • not been drinking fluids  
 • had a lot of fluid loss in continued vomiting or diarrhea

DRUG FACTS TEXT DEFINED	TYPE SIZE
• DRUG FACTS Title	9 pt
• DRUG FACTS CONTINUED	8 pt
• HEADINGS	8 pt
• SUBHEADS/BODY TEXT	6 pt
• LEADING	6.5 pt
• # OF CHARACTERS PER INCH	<39
• BULLETS	5 pt
• SPACE BEFORE BULLET	2 nms
• BARLINES, HAIRLINES	1.5 pt, 5 pt
• SPACE BETWEEN HAIRLINES AND BOX END	2 spaces

100%



3/16" X 3/16" DATA MATRIX CODE (ECC200), PRINTED IN BLACK OR DARK BLUE ON UNPRINTED WHITE BACKGROUND WITH A MINIMUM OF 1/8" QUIET ZONE ALL 4 SIDES.

UNVARNISHED UNPRINTED AREA FOR LOT & EXP.

200%

**See box for important warnings and save for future use.**  
 Use temporarily relieves these symptoms associated with hay fever or other upper respiratory allergies, and the common cold: runny nose, sneezing, itchy, watery eyes, itching of the nose and throat, nasal congestion, headache, fever, minor aches and pains, and sinus pressure.

**Warnings:** Allergy alert: Ibuprofen may cause a severe allergic reaction which may include: hives, facial swelling, asthma (wheezing), shock.  
 Stomach bleeding warning: Taking more than recommended may cause stomach bleeding.  
 Do not use if the child has ever had an allergic reaction to any pain reliever/fever reducer, nasal decongestant, or antihistamine. Stop use and ask a doctor if an allergic reaction occurs. Seek medical help right away. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

**Do Not Use if breakable ring on bottle cap is separated or missing.**  
 Directions: do not give more than directed or shake well before using.  
 Find right dose on chart below. If possible, use weight to dose; otherwise use age.  
 If needed, repeat dose every 6 hours while symptoms persist.  
 Do not use more than 4 times a day.  
 Measure only with dosing cup provided.

**Active Ingredients (in each 5 mL suspension):**  
 Chlorpheniramine maleate 1 mg, Antihistamine  
 Ibuprofen 100 mg, Pain reliever/fever reducer  
 Pseudoephedrine HCl 15 mg, Nasal decongestant

**Purposes:**  
 Antihistamine  
 Pain reliever/fever reducer  
 Nasal decongestant

**Dosing Chart**

Weight (lb)	Age (yrs)	Dose (teaspoons)
under 48	under 6	ask a doctor
48 - 95	6 - 11	2 teaspoons

Berry Flavored Liquid  
 1 FL OZ (30 mL)  
 Wyeth Consumer Healthcare  
 Madison, NJ 07940 U.S.A. U0183-10-1.FDA05

DRUG FACTS TEXT DEFINED	TYPE SIZE
• HEADINGS	4.5 pt
• SUBHEADS/BODY TEXT	4.5 pt
• LEADING	4.5 pt
• BULLETS	3.5 pt
• SPACE BEFORE BULLETED SECTION	2 ems
• BOX LINE	.5 pt

100%

6

9/16

2 1/2 27/16

LOT & EXP UNVARNISHED AREA

**See box for important warnings and save for future use.**

**Active Ingredients (in each 5 mL teaspoon)**      **Purposes**  
 Chlorpheniramine maleate 1 mg ..... Antihistamine  
 Ibuprofen 100 mg ..... Pain reliever/Fever reducer  
 Pseudoephedrine HCl 15 mg ..... Nasal decongestant

**Uses:** temporarily relieves these symptoms associated with hay fever or other upper respiratory allergies, and the common cold: runny nose, sneezing, itchy, watery eyes, itching of the nose and throat, nasal congestion, headache, fever, minor aches and pains, and sinus pressure

**Warnings:**  
**Allergy alert:** Ibuprofen may cause a severe allergic reaction which may include:  
 ■ hives   ■ facial swelling   ■ asthma (wheezing)   ■ shock  
**Stomach bleeding warning:** Taking more than recommended may cause stomach bleeding.  
 Do not use if the child has ever had an allergic reaction to any pain reliever/fever reducer, nasal decongestant, or antihistamine.  
**Stop use and ask a doctor** if an allergic reaction occurs. Seek medical help right away.  
**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

**Pain Reliever/Fever Reducer  
 Nasal Decongestant/Antihistamine**

**Berry Flavored Liquid**  
 Alcohol Free      8 FL OZ (240 mL)

**Directions:**  
 ■ do not give more than directed  
 ■ shake well before using  
 ■ find right dose on chart below. If possible, use weight to dose; otherwise use age.  
 ■ if needed, repeat dose every 6 hours while symptoms persist  
 ■ do not use more than 4 times a day  
 ■ measure only with dosing cup provided

**Dosing Chart**

Weight (lb)	Age (yrs)	Dose (teaspoons)
under 48	under 6	ask a doctor
48 - 95	6 - 11	2 teaspoons

**Other information**  
 ■ each 5 mL teaspoon contains: sodium 10 mg  
 ■ store at 20-25°C (68-77°F)

**Questions or comments?** call weekdays from 9AM to 5PM EST at 1-800-88-ADVIL or ask your pharmacist, doctor or healthcare professional.

Wyeth Consumer Healthcare,  
 Madison, NJ 07940 U.S.A.  
 www.advil.com      U0183-30-1.FDA02

150%

**See box for important warnings and save for future use.**

**Active Ingredients (in each 5 mL teaspoon)**      **Purposes**  
 Chlorpheniramine maleate 1 mg ..... Antihistamine  
 Ibuprofen 100 mg ..... Pain reliever/Fever reducer  
 Pseudoephedrine HCl 15 mg ..... Nasal decongestant

**Uses:** temporarily relieves these symptoms associated with hay fever or other upper respiratory allergies, and the common cold: runny nose, sneezing, itchy, watery eyes, itching of the nose and throat, nasal congestion, headache, fever, minor aches and pains, and sinus pressure

**Warnings:**  
**Allergy alert:** Ibuprofen may cause a severe allergic reaction which may include:  
 ■ hives   ■ facial swelling   ■ asthma (wheezing)   ■ shock  
**Stomach bleeding warning:** Taking more than recommended may cause stomach bleeding.  
 Do not use if the child has ever had an allergic reaction to any pain reliever/fever reducer, nasal decongestant, or antihistamine.  
**Stop use and ask a doctor** if an allergic reaction occurs. Seek medical help right away.  
**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

**Pain Reliever/Fever Reducer  
 Nasal Decongestant/Antihistamine**

**Berry Flavored Liquid**  
 Alcohol Free      8 FL OZ (240 mL)

**Directions:**  
 ■ do not give more than directed  
 ■ shake well before using  
 ■ find right dose on chart below. If possible, use weight to dose; otherwise use age.  
 ■ if needed, repeat dose every 6 hours while symptoms persist  
 ■ do not use more than 4 times a day  
 ■ measure only with dosing cup provided

**Dosing Chart**

Weight (lb)	Age (yrs)	Dose (teaspoons)
under 48	under 6	ask a doctor
48 - 95	6 - 11	2 teaspoons

**Other information**  
 ■ each 5 mL teaspoon contains: sodium 10 mg  
 ■ store at 20-25°C (68-77°F)

**Questions or comments?** call weekdays from 9AM to 5PM EST at 1-800-88-ADVIL or ask your pharmacist, doctor or healthcare professional.

Wyeth Consumer Healthcare,  
 Madison, NJ 07940 U.S.A.  
 www.advil.com      U0183-30-1.FDA02

DRUG FACTS TEXT DEFINED	TYPE SIZE
• HEADINGS	6 pt
• SUBHEADS/BODY TEXT	6 pt
• LEADING	6.5 pt
• BULLETS	5 pt
• SPACE AFTER BULLETED SECTION	2 ems
• BOX LINE	5 pt
• SMALLEST ®, TM etc.	5.75 pt

**Drug Facts (continued)**

Ask a doctor or pharmacist before use if the child is

- in taking medicine or tranquilizers
- in taking any other product that contains diphenhydramine, or any other pain reliever/fever reducer
- in taking any other product that contains pseudoephedrine or chlorpheniramine or any other nasal decongestant or antihistamine
- in taking a prescription drug for anticoagulation (blood thinning) or a diuretic
- in taking any other drug

When using this product

- do not give more than directed
- diarrhea may occur, and nausea and tranquilizers may increase diarrhea
- irritability may occur, especially in children
- do not give with food or milk if stomach upset occurs

Do not use and ask a doctor if

- an allergic reaction occurs. Seek medical help right away.
- nasal congestion lasts for more than 7 days
- pain or fever gets worse or lasts for more than 3 days
- the child gets nervous, dizzy, or sleepless
- symptoms continue or get worse
- stomach pain occurs
- any new symptoms appear

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

**Directions**

- shake well before using
- read right side on chart below. If possible, use weight to dose.
- children use age.
- if needed, repeat dose every 6 hours while symptoms persist.
- do not use more than 4 doses a day
- measure only with dosing cup provided

Dosing Chart

Weight (lb)	Age (yrs)	Dose (suspension)
under 48	under 6	ask a doctor
48-95	6-11	2 teaspoons

**Drug Facts (continued)**

**Other information**

- each 5 mL suspension contains: sodium 10 mg
- store at 20-25°C (68-77°F)
- read all warnings and directions before use. Keep carton.

**Inactive ingredients**

artificial flavor, carbonyl diethanolamine sodium, citric acid, edetate disodium, FD&C Blue no. 1, FD&C Red no. 40, glycine, lactic acid, microcrystalline cellulose, polyethylene glycol, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol sodium, sucralose, xanthan gum

**Questions or comments?**

Call weekdays from 9AM to 5PM EST at 1-800-88-ADVI, or ask your pharmacist, doctor or healthcare professional

Wyeth



UK24038-1 F0405

Children's Advil Allergy/Dimetapp Allergy & Sinus

IBU 100mg/PSEI 5mg/CHLOR 1mg/5mL Suspension

Paracetamol 100 mg, Fenbufen 100 mg, Chlorpheniramine Maleate 1 mg, Pseudoephedrine HCl 15 mg, Diphenhydramine HCl 1 mg per 5 mL

**Allergy Sinus**

Runny Nose, Sneezing  
Itchy, Watery Eyes  
Nasal Congestion  
Headache

Berry Flavor  
for ages 6-11 years

**Important:** Read all product information before using. Keep this box for important information. This product is intended for use in children ages 6 years-11 years.

**Drug Facts**

**Active ingredients (in each 5 mL (teaspoon))**

Active ingredients	Purposes
Chlorpheniramine maleate 1 mg	Antihistamine
Ibuprofen 100 mg	Pain reliever/fever reducer
Pseudoephedrine HCl 15 mg	Nasal decongestant

**Uses:** temporarily relieves those symptoms associated with hay fever or other upper respiratory allergies, and the common cold.

- in runny nose
- in itching of the nose or throat
- in nasal congestion
- in headache
- in fever
- in itchy, watery eyes
- in sneezing
- in sinus pressure
- in muscle aches and pains

**Warnings**

Allergy alert: Ibuprofen may cause a severe allergic reaction which may include:

- in hives
- in swelling
- in asthma (wheezing)
- in shock

**Stomach bleeding warning:** Taking more than recommended may cause stomach bleeding.

Do not use

- if the child has ever had an allergic reaction to any other pain reliever/fever reducer, nasal decongestant, or antihistamine
- in a child who is taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.

Ask a doctor before use if the child has

- a bleeding problem such as chronic bronchitis
- in heart disease
- in high blood pressure
- in thyroid disease
- in diabetes
- in kidney disease
- in bleeding problems
- in bad problems or serious side effects from taking pain reliever/fever reducers
- in stomach problems that last or come back, such as heartburn, upset stomach or pain
- in not been drinking fluids
- in lost a lot of fluid due to continued vomiting or diarrhea

DRUG FACTS TEXT DEFINED	TYPE SIZE
• DRUG FACTS Title	9 pt
• DRUG FACTS CONTINUED	8 pt
• HEADINGS	8 pt
• SUBHEADS/BODY TEXT	6 pt
• LEADING	6.5 pt
• # OF CHARACTERS PER INCH	<39
• BULLETS	5 pt
• SPACE BEFORE BULLET	2 ems
• BARLINES, HAIRLINES	1.5 pt, 5 pt
• SPACE BETWEEN HAIRLINES AND BOX END	2 spaces

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