

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

20-944

FINAL PRINTED LABELING

Attachment no. 1 - Child Blister Carton label

APPROVED

DEC 18 1998

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20-944 Child Blister Carton label 12-9-98

Children's Advil® Chewable Tablet 50 mg:

Carton for 24's Blister Packaging

Blister Back

Attachment no. 1--Child Blister Carton label

Front Panel:

NEW Fruit (or Grape) Flavor

Lasts up to
8 Hours

Children's
Advil®
IBUPROFEN TABLETS 50 mg

Fever Reducer/Pain Reliever

24 CHEWABLE TABLETS

Attachment no. 1—Child Blister Carton label

Back Panel:

Active ingredient (in each tablet)	Purposes
Ibuprofen 50 mg.....	Fever reducer/pain reliever.

- Uses** Temporarily:
- reduces fever
 - relieves minor aches and pains due to common cold, flu, sore throat, headaches and toothaches
-

Warnings

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

- hives • facial swelling • asthma (wheezing) • shock

Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- if your child has problems or serious side effects from taking fever reducers/pain relievers
- if your child is dehydrated (significant fluid loss) due to continued vomiting, diarrhea, or lack of fluid intake
- if blister back is broken or open

Ask a doctor before use if your child

- is under a doctor's care for any serious condition or is taking any other drug
- has redness or swelling present in the painful area
- is taking any other product that contains ibuprofen, or any other pain reliever/fever reducer
- has stomach pain

Stop use and ask a doctor if

- an allergic reaction occurs. Seek medical help right away.
- fever or pain lasts for more than 3 days
- your child does not get relief within the first day (24 hours) of treatment, or pain or fever gets worse
- stomach upset gets worse or lasts
- sore throat is severe, lasts for more than 2 days or occurs with fever, headache, rash, nausea, or vomiting
- any new symptoms appear

Keep out of reach of children. In case of overdose, seek professional assistance or contact a poison control center right away.

Back Panel

Directions

Attachment no. 1—Child Blister Carton label

5. If stomach upset occurs while taking this product give with food or milk.

Weight (lb)	Age (yr)	Tablets
Under 24	Under 2	Consult Doctor
24-35	2-3	2
36-47	4-5	3
48-59	6-8	4
60-71	9-10	5
72-95	11	6

One Dose Lasts 6-8 Hours

Important: Read all product information before using. Keep this box for important information.

This product is intended for use in children only.

Dietary information

Phenylketonurics: Contains phenylalanine 2.1 mg per tablet.

(N.B: The phenylalanine content for Junior strength is 4.2 mg per tablet. "phenylalanine" should not be capitalized.)

Long Lasting:

Up to 8 hours of fever and pain relief.

Great Convenience:

Long duration means fewer doses needed per day.

Left Panel:

Inactive Ingredients Aspartame, cellulose acetate phthalate, D&C Red # 27 Lake, FD&C Red # 40 Lake, gelatin, magnasweet, magnesium stearate, mannitol, microcrystalline cellulose, natural and artificial flavors, silicon dioxide, sodium starch glycolate. (Fruit flavor)

Inactive Ingredients Artificial flavor, aspartame, cellulose acetate phthalate, D&C Red # 30 Lake, FD&C Blue # 2 Lake, gelatin, magnasweet, magnesium stearate, mannitol, microcrystalline cellulose, silicon dioxide, sodium starch glycolate. (Grape flavor)

See side of box for lot number and expiration date.

Store in a dry place at 20°-25°C (68°-77°F).

Telephone: Questions or Comments

Call toll free 1-800-88-ACET.

Ask your Pharmacist, Doctor or Health Care Professional.

Attachment no. 1—Child Blister Carton label

Top Panel:

Children's
Advil®
IBUPROFEN TABLETS 50 mg

Fever Reducer
Pain Reliever

Do not use if blister back is broken or open.

Right Panel:

Children's
Advil®
IBUPROFEN TABLETS 50 mg

Fever Reducer
Pain Reliever

Lot

Exp:

Attachment no.2 Child Bottle Carton Label

chdbotr3.crt

20-944 Child Bottle Carton Label 12-1-98

Children's Advil® Chewable Tablet 50 mg:

Carton for 24's Bottle

Bottle Label

Attachment no.2 Child Bottle Carton Label

Front Panel:

NEW Fruit (or Grape) Flavor

Lasts
up to
8 Hours

Children's
Advil®
IBUPROFEN TABLETS 50 mg

Fever Reducer/Pain Reliever

24 CHEWABLE Tablets

Bottom Panel and Back Panel: (Use arrow to direct consumer from bottom panel to next (back) panel where appropriate)

<i>Active ingredient (in Each Tablet)</i>	<i>Purposes</i>
Ibuprofen 50 mg.....	Fever Reducer/Pain Reliever

Uses temporarily:

- Reduces fever
- Relieves minor aches and pains due to common cold, flu, sore throat, headaches and toothaches

Warnings (Move to left margin.)

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

- hives • facial swelling • asthma (wheezing) • shock

Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer

- if your child has problems breathing side effects from

- if your child has problems breathing or persistent fluid in

Attachment no.2 Child Bottle Carton Label

Back Panel:

Warnings (continued)

Ask a doctor before use if your child

- is under a doctor's care for any serious condition or is taking any other drug
- has redness or swelling present in the painful area
- is taking any other product that contains ibuprofen, or any other pain reliever/fever reducer
- has stomach pain

Stop use and ask a doctor if

- an allergic reaction occurs. Seek medical help right away.
- fever or pain lasts for more than 3 days
- your child does not get relief within the first day (24 hours) of treatment, or pain or fever gets worse
- stomach upset gets worse or lasts
- sore throat is severe, lasts for more than 2 days or occurs with fever, headache, rash, nausea, or vomiting
- any new symptoms appear

Keep out of reach of children. In case of overdose, seek professional assistance or contact a poison control center right away.

Top Panel:

Directions

1. Use this product only with chart provided.
2. Find right dose on chart. If possible, use weight to dose. Otherwise use age.
3. Repeat dose every 6-8 hours, if needed.
4. Do not use more than 4 times a day.
5. If stomach upset occurs while taking this product give with food or milk.

Weight (lb)	Age (yr)	Tablets
Under 24	Under 2	Consult Doctor
24-35	2-3	2
36-47	4-5	3
48-59	6-8	4
60-71	9-10	5
72-84	11	6

One Dose Lasts 6-8 Hours

Attachment no.2 Child Bottle Carton Label

Dietary information

Phenylketonurics: Contains phenylalanine 2.1 mg per tablet.
(N.B: The phenylalanine content for Junior strength is 4.2 mg per tablet.
"phenylalanine" should not be capitalized.)

~~Long Lasting:~~

~~Up to 8 hours of fever and pain relief.~~

~~Great Convenience:~~

~~Long duration means fewer doses needed per day.~~

~~Fruit (or Grape) Flavored Tablet:~~

~~Specially developed for children.~~

Inactive ingredients Aspartame, cellulose acetate phthalate, D&C Red # 27 Lake, FD&C Red # 40 Lake, gelatin, magnasweet, magnesium stearate, mannitol, microcrystalline cellulose, natural and artificial flavors, silicon dioxide, sodium starch glycolate. (Fruit flavor)

Inactive ingredients: Artificial flavor, aspartame, cellulose acetate phthalate, D&C Red # 30 Lake, FD&C Blue # 2 Lake, gelatin, magnasweet, magnesium stearate, mannitol, microcrystalline cellulose, silicon dioxide, sodium starch glycolate. (Grape flavor)

See side of box for lot number and expiration date.

Store at 20°-25°C (68°-77°F).

Telephone

Questions or Comments?

Symbol

Call toll free 1-800-88-ADVIL.

Or ask your Pharmacist, Doctor or Health Care Professional.

Right Panel:

Child-Resistant Safety Cap

Children's

ADVIL

NSAID TABLETS

Attachment no.2 Child Bottle Carton Label

Fever Reducer/Pain Reliever

**Do Not Use if Foil Seal Imprinted "SEALED for YOUR PROTECTION"
Under Cap is Broken or Missing**

WHITEHALL-ROBINS HEALTHCARE
Madison, NJ 07940 Made in USA

Left Panel:

UPC Code

Lot

Exp:

Attachment no. 3--Child Pouch Dispenser

chdpchr3.dsp
20-944 Child pouch dispenser label 12-1-98

Children's Advil® Chewable Tablet 50 mg:

Dispenser for Pouches

2's Pouch

Attachment no. 3--Child Pouch Dispenser

Upper Front Panel:

NEW Fruit (or Grape) Flavor

FOR PROFESSIONAL USE ONLY
Not For Retail Sale

Children's
Advil®
IBUPROFEN
• TABLETS 50 mg

Lower Front Panel:

Fever Reducer/Pain Reliever

Lasts up to 8 hours

50 PACKETS OF 2 CHEWABLE TABLETS
Fruit (or Grape) Flavor

Left Panel:

FOR PROFESSIONAL USE ONLY
Not For Retail Sale

Children's
Advil®

IBUPROFEN
— TABLETS 50 mg

Fever Reducer/Pain Reliever

Active ingredient (in Each Tablet)

•Purposes

Fever Reducer/Pain Reliever

throat, headaches and toothaches

Warnings (move header to left margin)

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

- hives • facial swelling • asthma (wheezing) • shock

Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- if your child has problems or serious side effects from taking fever reducers/pain relievers
- if your child is dehydrated (significant fluid loss) due to continued vomiting, diarrhea, or lack of fluid intake
- if pouch is open or broken

Ask a doctor before use if your child

- is under a doctor's care for any serious condition or is taking any other drug
- has redness or swelling present in the painful area
- is taking any other product that contains ibuprofen, or any other pain reliever/fever reducer
- has stomach pain

Stop use and ask a doctor if

- an allergic reaction occurs. Seek medical help right away.
- fever or pain lasts for more than 3 days
- your child does not get relief within the first day (24 hours) of treatment, or pain or fever gets worse
- stomach upset gets worse or lasts
- sore throat is severe, lasts for more than 2 days or occurs with fever, headache, rash, nausea, or vomiting
- any new symptoms appear

Keep out of reach of children. In case of overdose, seek professional assistance or contact a poison control center right away.

Continued on opposite panel

Right Panel:

FOR PROFESSIONAL USE ONLY
Not For Retail Sale

Children's

Advil

IBUPROFEN
100 mg/5 mL Suspension

Attachment no. 3--Child Pouch Dispenser

Directions

1. Use this product only with chart provided.
2. Find right dose on chart. If possible, use weight to dose. Otherwise use age.
3. Repeat dose every 6-8 hours, if needed.
4. Do not use more than 4 times a day.
5. If stomach upset occurs while taking this product give with food or milk.

Weight (lb)	Age (yr)	Tablets
Under 24	Under 2	Consult Doctor
24-35	2-3	2
36-47	4-5	3
48-59	6-8	4
60-71	9-10	5
72-95	11	6

One Dose Lasts 6-8 Hours

Important: Read all product information before using. Keep this box for important information.

This product is intended for use in children only.

Dietary information

Phenylketonurics: Contains phenylalanine 2.1 mg per tablet.

(N.B: The phenylalanine content for Junior strength is 4.2 mg per tablet. "phenylalanine" should not be capitalized.)

Inactive ingredients: Aspartame, Cellulose Acetate Pphthalate, D&C Red # 27 Lake, FD&C Red # 40 Lake, Ggelatin, Mmagnasweet, Mmagnesium Sstearate, Mmannitol, Mmicrocrystalline Ccellulose, Nnatural and Aartificial Fflavors, Ssilicon Ddioxide, Ssodium Sstarch Gglycolate. (Fruit favor)

Inactive ligredients: Artificial Fflavor, Aaspartame, Ccellulose Acetate Pphthalate, D&C Red No. 30 Lake, FD&C Blue # 2 Lake, Ggelatin, Mmagnasweet, Mmagnesium Sstearate, Mmannitol, Mmicrocrystalline Ccellulose, Ssilicon Ddioxide, Ssodium Sstarch Gglycolate. (Grape flavor)

Attachment no. 3--Child Pouch Dispenser

WHITEHALL-ROBINS HEALTHCARE

Madison, NJ 07940

Made in USA

Back Panel:

FOR PROFESSIONAL USE ONLY
Not For Retail Sale

Children's
Advil®

IBUPROFEN TABLETS 50 mg
Fever Reducer/Pain Reliever
Lasts up to 8 hours

50 packets of 2 chewable tablets
Fruit (or Grape) Flavor

Lot/Exp. date

Do not use if pouch is open or broken.

Attachment no. 3--Child Pouch Dispenser

Top Panel:

Children's
Advil®
IBUPROFEN TABLETS 50 mg
Fever Reducer/Pain Reliever
Lasts up to 8 hours

Bottom Panel:

Children's
Advil®
IBUPROFEN TABLETS 50 mg
Fever Reducer/Pain Reliever
—Lasts up to 8 hours

Attachment no. 4--child blister back label

chdblsr3.lbl

20-944 child blister back label 12-9-98

Blister Back:

Children's Advil®	Component Code No.
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IBUPROFEN TABLETS 50 mg each

Fever Reducer/Pain Reliever

2 Tablets Read Carton Labeling Before Taking.

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

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

**Do not use if you have ever had an allergic reaction to
any other pain reliever/fever reducer.**

Stop use and ask a doctor if an allergic reaction occurs.

Seek medical help right away.

*(N.B: The "Allergy alert," "Do not use," and "Stop use and ask
a doctor if" headers should be in bold.)*

See carton for additional warnings.

WHITEHALL-ROBINS HEALTHCARE

Madison, NJ 07940 Made in USA

EXP.

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XXXX

Attachment no. 5— child bottle label

chdbotr3.lbl

20-944 child bottle label 12-9-98

Front Panel:

Do Not Use if Foil Seal Imprinted "SEALED for
YOUR PROTECTION" Under Cap is Broken or Missing

Children's
Advil®

24 Chewable Tablets
50 mg each

IBUPROFEN
TABLETS

Fever Reducer/Pain Reliever
Lasts up to 8 Hours

FRUIT (or GRAPE) FLAVOR

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

Left Panel:

Active ingredient: Ibuprofen

Uses temporarily:

- reduces fever
- relieves minor aches and pains due to common cold, flu, sore throat, headaches and toothaches

Warnings

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

- hives • facial swelling • asthma (wheezing) • shock

Do not use if you have ever had an allergic reaction to any other pain reliever/fever reducer.

Stop use and ask a doctor if an allergic reaction occurs.

Seek medical help right away.

Read the "Allergy alert," "Do not use," and "Stop use and ask a doctor

if needed" sections.

Attachment no. 5—child bottle label

chdbotr3.tbl

20-944 child bottle label 12-1-98

See box for additional warnings.

Right Panel:

Directions:

1. Use this product only with chart provided.
2. Find right dose on chart. If possible, use weight to dose. Otherwise use age.
3. Repeat dose every 6-8 hours, if needed.
4. Do not use more than 4 times a day.
5. If stomach upset occurs while taking this product, give with food or milk.

Weight (lb)	Age (yr)	Tablets
Under 24	Under 2	Consult Doctor
24-35	2-3	2
36-47	4-5	3
48-59	6-8	4
60-71	9-10	5
72-95	11	6

One Dose Lasts 6-8 Hours

Store at 20°-25°C (68°-77°F).

Telephone Questions or comments? Call us toll-free at 1-800-88-ADVIL.

Or ask your pharmacist, doctor or health care professional.

WHITEHALL-ROBINS HEALTHCARE
Madison, NJ 07940 Made in USA

Component code no.

Attachment no 6—child pouch label

chdpchr3.tbl

20-944 child pouch label 12-9-98

Front of Pouch:

To Open: Fold Back On Dotted Line.
Tear On Arrow Or Use Scissors. Sealed Child
Resistant Package. Do Not Use If Pouch Is Open Or Broken.

FOR PROFESSIONAL USE ONLY
Not For Retail Sale

Children's Advil®
IBUPROFEN TABLETS 50 mg

2 Chewable Tablets Fruit (or Grape) Flavor
Fever Reducer/Pain Reliever Lasts up to 8 hours

Read Consumer Leaflet before using this product *(Add this statement)*

Uses: Temporarily • Reduces fever • Relieves minor aches and
pains due to common cold, flu, sore throat, headaches and toothaches

Warnings (move header to left margin; use bold italics)

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

• hives • facial swelling • asthma (wheezing) • shock

Stop use and ask a doctor if an allergic reaction occurs.

Seek medical help right away.

warnings continued on back

Back of Pouch:

Warnings (continued)

Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- if your child has problems or serious side effects from taking fever reducers/pain relievers
- if your child is dehydrated (significant fluid loss) due to continued vomiting, diarrhea, or lack of fluid intake
- if pouch is open or broken

See Consumer Leaflet for additional warnings.

Keep out of the reach of children. In case of overdose, seek professional assistance or contact a poison control center right away.

Directions

1. Use this product only with chart provided.
2. Find right dose on chart. If possible, use weight to dose. Otherwise use age.
3. Repeat dose every 6-8 hours, if needed.
4. Do not use more than 4 times a day.
5. If stomach upset occurs while taking this product give with food or milk.

Weight (lb)	Age (yr)	Tablets
Under 24	Under 2	Consult Doctor
24-35	2-3	2
36-47	4-5	3
48-59	6-8	4
60-71	9-10	5
72-95	11	6

Important: Read consumer leaflet before using.

This product is intended for use in children only.

Phenylketonurics: Contains Pphenylalanine 2.1 mg per tablet. (N.B: The word "Important:" should appear in bold type and be followed by a colon. The phenylalanine content for Junior strength is 4.2 mg per tablet. "phenylalanine" should not be capitalized.)

Store at 20°-25°C (68°-77°F) Store at room temperature 15°-30°C (59°-86°F).

Attachment no 6--child pouch label

chdpchr3.lbl
20-944 child pouch label 12-1-98

Madison, NJ 07940
Made in USA

Component Code No

