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# **Guidance for Industry**

## **Labeling OTC Human Drug Products Updating Labeling in RLDs and ANDAs**

**U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Drug Evaluation and Research (CDER)**

**October 2002  
OTC**

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# Guidance for Industry

## Labeling OTC Human Drug Products

## Updating Labeling in RLDs and ANDAs

*Additional copies of this Guidance are available from:*

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## Guidance for Industry<sup>1</sup>

### Labeling OTC Human Drug Products Updating Labeling in RLDs and ANDAs

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

#### I. INTRODUCTION

This guidance is intended to assist manufacturers, packers, and distributors of over-the-counter (OTC) drug products marketed under abbreviated new drug applications (ANDAs) and the manufacturers of corresponding reference listed drugs (RLDs) implement the Agency's regulation on standardized content and format requirements for the labeling of OTC drug products. The guidance contains recommendations on how RLD and ANDA holders can update their labeling in a timely manner consistent with the regulation on OTC drug product labeling (21 CFR 201.66).

#### II. BACKGROUND

In the *Federal Register* of March 17, 1999 (64 FR 13254), the Food and Drug Administration (FDA) published a final regulation establishing standardized content and format requirements for the labeling of OTC drug products (Drug Facts Rule), codified at 21 CFR 201.66. Standardized labeling for OTC drug products is intended to make it easier for consumers to read and understand OTC drug product labeling and use such products safely and effectively.

The Drug Facts Rule covers all OTC drug and drug-cosmetic products, whether marketed under a new drug marketing application (NDA), abbreviated new drug application (ANDA), or OTC drug monograph (or product not yet the subject of a final OTC drug monograph). The implementation

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<sup>1</sup> This guidance has been prepared by the Division of Over-the-Counter (OTC) Drug Products and the Office of Generic Drugs (OGD) in the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration (FDA).

dates are the same for products that were legally marketed under an NDA or ANDA before the date of the final regulation.

Sections 201.66(c)(1) through (c)(9) of the Drug Facts Rule provide the content requirements for labeling information, including information about active ingredients, their purpose, use, warnings, directions, other information, and inactive ingredients.

After publication of the Drug Facts Rule, the Agency was asked whether manufacturers of products marketed under ANDAs could use the new labeling content and format requirements *before* the RLD holders had revised their labeling, or whether ANDA holders were required to wait for their respective RLD holders to revise their labeling before submitting new ANDA labeling to make it the same as that of the RLD. These questions were raised because, under section 505(j)(2) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 355(j)(2)), a drug product marketed under an ANDA must bear the "same labeling" as that approved for the RLD. The concern was that many generic manufacturers would not be able to comply with the compliance date for the Drug Facts Rule if they had to wait to copy the labeling updates of the RLDs.

To help clarify the Agency's expectations under the Drug Facts Rule, the Agency made available on February 22, 2001, a draft guidance for industry on Labeling OTC Human Drug Products Updating Labeling in ANDAs.

This is a final version of that guidance. It is intended to help RLDs and ANDAs meet the new OTC drug products labeling format requirement in light of the "same labeling" requirement set forth in section 505(j)(2) of the Act.

### III. THE DRAFT GUIDANCE

In the February 22, 2001, draft guidance, the Agency suggested that manufacturers of generic OTC drug products (i.e., products marketed under ANDAs) could implement the new labeling format for their products *before* the RLD holders had submitted their labeling revisions to FDA. In support of this suggestion, the Agency noted that the same labeling requirement in section 505(j)(2) of the Act does not require ANDA labeling to be *identical* to that of the RLD. Among permissible differences, FDA regulations at 21 CFR 314.94(a)(8)(iv) allow an ANDA holder to include labeling that is different from that of the RLD where the ANDA labeling revisions are made to comply with current FDA guidelines or other guidance. The Agency reasoned in the draft guidance that the changes made to ANDA labeling to accommodate the Drug Facts panel would be changes made in response to the requirements of such a regulation — the Drug Facts Rule (21 CFR 201.66).

The draft guidance also reasoned that the majority of the format changes required by the Drug Facts Rule could be submitted to the Agency in an annual report to an application under 21 CFR 314.70(d)(3)<sup>2</sup> and would not necessitate the submission of a labeling supplement for preapproval.

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<sup>2</sup> Changes to labeling that go beyond the interchangeable terms allowed in Agency regulations (i.e., in 21 CFR 330.1(i) or (j)) should be submitted to the Agency in a supplement for preapproval. Questions about the need to submit a labeling supplement for

In support of this suggestion, the draft guidance noted that the preamble to the Drug Facts Rule (64 FR 13254 at 13272) states that the adoption of the new labeling format for most OTC drug products marketed under an NDA or ANDA *would be considered an editorial or minor change*.

In addition, to help facilitate the relabeling process, the Agency drafted 10 updated labeling examples and posted them on the Internet for review.

#### **IV. GENERAL POLICY**

The Agency is exercising its enforcement discretion by providing manufacturers of generic OTC drug products two options for revising the labeling of their products to meet the new labeling requirements under 21 CFR 201.66. First, manufacturers may revise their product labeling at this time in accord with the Agency's product-specific labeling examples included with this guidance. Manufacturers may continue to use such labeling until the Agency approves revised labeling for the corresponding RLD that meets the requirements under § 201.66 and posts a copy of that approved labeling on the Internet. At that time, the ANDA holder should further revise its labeling using the Agency's May 2000 Guidance for Industry entitled "Revising ANDA Labeling Following Revision of the RLD Labeling." Second, manufacturers need not revise their product labeling at this time, but can wait until the Agency approves revised labeling for the RLD that meets the requirements under § 201.66 and posts a copy of that approved labeling on the Internet. At that time, the ANDA holder should revise its labeling using the May 2000 Guidance for Industry identified above. The Agency's exercise of this enforcement discretion commenced on May 16, 2002 (see 65 FR 38191 and 67 FR 16306) and continues for each specific ANDA product until the Agency approves revised labeling for the corresponding RLD.

The Agency believes its exercise of enforcement discretion will help ensure that both OTC RLD holders and OTC ANDA holders update their product labeling in a way that is consistent with the precise format and content requirements under 21 CFR 201.66 and the "same labeling" requirements under section 505(j)(2) of the Act. The Agency's exercise of enforcement discretion is prompted by the proximity of the Drug Facts Rule compliance date and the desire to relieve ANDA holders from the potential burden of having to relabel their products multiple times to comply with requirements of 21 CFR 201.66, 21 CFR 314.94(a), and 21 USC 505(j)(2).

##### **A. Implementation**

As part of this guidance, the Agency is making available and posting on the Internet 14 product-specific labeling examples, which apply to about 60 percent of all ANDA OTC drug products (see section V). The Agency also intends to prepare additional labeling examples for other OTC drugs marketed under ANDAs and add them to this guidance and post them on the Internet.

As part of the exercise of its enforcement discretion, the Agency is allowing any manufacturer of a generic OTC drug product (i.e., a product marketed under an ANDA) to implement the new Drug

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preapproval should be directed to the appropriate Agency division. See also CDER's guidance *Changes to an Approved NDA or ANDA* (November 1999).

Facts labeling format for its product *before* FDA posts approved labeling for its applicable RLD so long as the generic's labeling update complies with 21 CFR 201.66. The Agency recommends that ANDA holders use the Agency's labeling examples when revising their labeling before updated RLD labeling has been approved. ANDA holders that follow the Agency's labeling examples will be considered in compliance. During the period of enforcement discretion, the Agency will not initiate an enforcement action based upon 21 CFR 201.66 or 314.94(a)(8)(iv) against any OTC ANDA drug product that complies with 21 CFR 201.66, regardless of the status of the RLD's labeling or the "same labeling" requirements in 21 CFR 314.94 and 21 USC 355(j)(2).

However, once FDA posts the approved RLD labeling updates on the Internet, ANDA holders should update their product labeling, if necessary, to be the same as their corresponding RLDs. In May 2000, the Agency issued a Guidance for Industry entitled *Revising ANDA Labeling Following Revision of the RLD Labeling*. That guidance explains that the sponsor of an ANDA is responsible for ensuring that the labeling contained in its application is the same as the currently approved labeling of the RLD. Because the labeling of a generic drug product must be the same as its innovator (other than those differences described in 21 CFR 314.94(a)(8)(iv)), the guidance states that the revision should be made at the very earliest time possible. If an ANDA holder foresees potential delay in the revision of its generic drug labeling, that sponsor should contact the Office of Generic Drugs.

The May 2000 guidance further explains that prompt revision, submission to the Agency, and implementation of revised labeling are important to ensure the continued safe and effective use of generic drug products. The Agency believes that the Drug Facts labeling for all OTC drug products (especially those of the same type) should be as uniform and consistent as possible. Such uniformity ensures compliance with 21 CFR 314.94(a) and serves an important public health goal behind the Drug Facts Rule — reducing consumer confusion.

RLD holders that follow any of the Agency's product-specific labeling examples or otherwise comply with 21 CFR 201.66 need not file a preapproval supplement for their labeling revision and may submit the changes in their annual report in accord with 21 CFR 314.70(d). Similarly, ANDA products that follow the FDA's product-specific labeling examples or otherwise comply with 21 CFR 201.66 need not file a preapproval supplement for their labeling revision and may submit the changes in their annual report in accord with 21 CFR 314.97 and 314.70(d). This is also true for any updates that ANDA holders make to their OTC drug labeling to comply with 21 USC 355(j)(2), 21 CFR 314.94, 314.97 and/or 201.66 after the Agency posts the approved RLD labeling on the Internet.

The Agency has developed its labeling examples to assist both RLD and ANDA holders to update their labeling in an uniform manner and at a reduced cost. However, RLD and ANDA holders are not legally required to use the Agency's labeling examples. RLD holders may adopt an alternative approach so long as it complies with 21 CFR 201.66. Because ANDA holders eventually need to have the same labeling as the RLD, the Agency has decided to exercise its enforcement discretion with regard to OTC ANDA labeling. Manufacturers and repackers of OTC ANDA drug products who do not wish to update their labeling to meet section 201.66 before the expiration of the period of enforcement discretion are not required to do so.

The Drug Facts Rule requires all RLDs and ANDAs approved before May 16, 1999, to comply with the new labeling by May 16, 2002. The Drug Facts Rule also requires RLDs and ANDAs approved after May 16, 1999, to comply immediately upon approval of the application. Although the Agency has not enforced this requirement for ANDAs to date, it expects any OTC RLDs approved after May 16, 1999, to comply with the new Drug Facts labeling format by May 16, 2002, unless the manufacturer obtains or has obtained a deferral of this date.

As noted above, the Agency is granting a grace period for all currently marketed OTC ANDA products to relieve them of the potential burden of having to update their labeling more than once to comply with format changes made by their RLDs. This exercise of enforcement discretion is also being extended to any ANDA approved on or after May 16, 2002 until the RLD labeling for that product in the new Drug Facts format has been approved by FDA. These ANDA products will be allowed to use the existing RLD labeling or the Agency's recommended labeling examples for the product. Once the RLD labeling is approved in the Drug Facts format, the holders of these ANDA products should update their labeling, just like the ANDAs approved before May 16, 2002, so that all comparable ANDA products meet the requirements of 21 CFR 201.66, 21 CFR 314.94, and 21 USC 505(j)(2) at approximately the same time.

#### **B. Preapproval Supplements**

Manufacturers of OTC RLD drug products who believe they need to or wish to submit a preapproval supplement should submit that supplement as soon as possible if they have not already done so. Manufacturers of OTC ANDA drug products may also submit a preapproval supplement at their discretion. The Agency will review these supplements as expeditiously as possible and may develop additional labeling examples that all manufacturers of similar products can use. Any additional labeling examples that the Agency develops will be made available on the Internet as part of this guidance (see section V).

#### **C. Deferral Requests**

ANDA holders who do not believe they can comply by the end of the grace period should submit a deferral request in accordance with 201.66(e) and state why the request meets one or more of the criteria in that section and the amount of additional time that may be needed. The Agency is not providing an across-the-board extension of time for ANDA holders to update their labeling beyond the exercise of enforcement discretion mentioned throughout this guidance.

The Agency does not see the need to implement a Special Supplement - Changes Being Effected for the labeling revisions required by § 201.66. However, manufacturers may submit such a supplement if they wish to do so. This guidance describes when a manufacturer may submit the labeling changes in an annual report in accord with 21 CFR 314.97 and 314.70(d)(3) (see section VI). If a manufacturer finds the need for an expedited review of labeling that requires FDA approval of a supplement, it can request an expedited review under 21 CFR 314.70(b).

## V. FDA RECOMMENDED LABELING EXAMPLES FOR SOME PRODUCTS

The Agency stated in its Drug Facts Rule that it expects 522 submissions (350 to NDAs and 172 to ANDAs) for labeling changes under 21 CFR 201.66(c) and (d). Submissions to NDAs will vary as many different products are marketed under NDAs. However, submissions to ANDAs will be concentrated in the following products:

- ibuprofen tablets
- acetaminophen suppositories
- cimetidine tablets
- loperamide tablets and oral solution
- miconazole vaginal cream and suppositories
- minoxidil topical solution [2 %]
- naproxen sodium tablets

Thirty-five submissions are expected on ibuprofen, and more than five submissions are expected for each of the other drug products listed above. Together, these drugs constitute about 50 percent of all OTC drug product ANDAs.

To facilitate the implementation of the new Drug Facts section of the labeling for these pre-approved products, the Agency has developed labeling examples for RLD and ANDA manufacturers to follow for each of the products listed above. The labeling examples show each specific product's labeling in the new format. Since publication of the draft guidance, the Agency has also prepared four additional labeling examples for the following products:

- minoxidil topical solution [5 %]
- clemastine fumarate tablets
- doxylamine succinate tablets
- pseudoephedrine hydrochloride extended release tablets

The Agency considered previously approved RLD labeling in developing these examples, which the Agency considers as meeting the requirements of 21 CFR 201.66 and 314.70. Thus, manufacturers of RLDs who use these labeling examples do not need Agency preapproval. Similarly, as part of its exercise of enforcement discretion, the Agency will not initiate an enforcement action based upon 21 CFR 201.66 or 314.94(a)(8)(iv) against any OTC ANDA product that uses one of these labeling examples at any time between the date on which this guidance is published and the date on which the grace period expires, regardless of the status of the labeling for its corresponding RLD. As noted above, however, the ANDA's labeling may need to be updated at the end of the grace period to mirror the precise approved labeling updates made by its RLD.

The Agency's labeling examples can be found on the Internet with this guidance.<sup>3</sup> The Agency may develop additional labeling examples for other ANDA OTC drug products, and they also will be

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<sup>3</sup> This and other Agency guidances are available on the Internet at <http://www.fda.cder/guidance/index.htm>. The product-specific labeling examples and the approved RLD updates also are (and will be) available at [www.fda.gov/cder/otc/](http://www.fda.gov/cder/otc/).

made available for review at the same locations. Any person with any comment regarding any of the examples developed in the future may submit such comment to the public docket for this guidance.

When using the labeling examples, it should be noted that interchangeable terms can be used in certain places (see 21 CFR 330.1(i) and (j)). For example, although the Agency uses the word *doctor* in its labeling examples, the term *physician* can also be used where appropriate.

## **VI. SUBMISSION OF NEW LABELING IN AN ANNUAL REPORT**

Manufacturers of OTC RLDs can submit their Drug Facts labeling changes in their annual reports according to 21 CFR 314.70(d)(3) and need not submit a supplemental application to the Agency for preapproval under several different circumstances:

- If they follow the Agency's labeling examples to make their changes
- If they do not follow the Agency's labeling examples, but change their labeling in accordance with 21 CFR 201.66 and 330.1(i) or (j)
- Where the Agency has not provided any labeling examples, if they change their labeling in accordance with 21 CFR 201.66 and 330.1(i) or (j)

Manufacturers of OTC ANDA drug products may also submit such changes in their annual reports according to 21 CFR 314.97 and 314.70(d)(3) and need not submit a supplemental application for preapproval.

Manufacturers should submit preapproval supplements to their NDA or ANDA, as appropriate, if they make changes to the content of the labeling or wording changes that go beyond those provided for in 21 CFR 314.70, 314.97, 314.94, or 330.1(i) or (j).

Example Drug Facts Label for Ibuprofen 200 mg in a Tablet/Capsule Dosage Form

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**Drug Facts**

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<b>Active ingredient (in each [insert dosage unit])</b>	<b>Purposes</b>
Ibuprofen 200 mg.....	Pain reliever/fever reducer

---

**Uses**

- temporarily relieves minor aches and pains due to:
    - headache    ■ muscular aches    ■ minor pain of arthritis    ■ toothache
    - backache    ■ the common cold    ■ menstrual cramps
  - temporarily reduces fever
- 

**Warnings**

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

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

**Alcohol warning:** If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take ibuprofen or other pain relievers/fever reducers. Ibuprofen may cause stomach bleeding.

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

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**Ask a doctor before use if you have**

- stomach pain
  - problems or serious side effects from taking pain relievers or fever reducers
- 

**Ask a doctor or pharmacist before use if you are**

- under a doctor's care for any serious condition
  - taking any other drug
  - taking any other product that contains ibuprofen, or any other pain reliever/fever reducer
- 

**When using this product** take with food or milk if stomach upset occurs

---

**Stop use and ask a doctor if**

- an allergic reaction occurs. Seek medical help right away.
  - pain gets worse or lasts more than 10 days
  - fever gets worse or lasts more than 3 days
  - stomach pain or upset gets worse or lasts
  - redness or swelling is present in the painful area
  - any new symptoms appear
-

**If pregnant or breast-feeding**, ask a health professional before use. It is especially important not to use ibuprofen during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

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

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***Directions***<sup>1</sup>

- **do not take more than directed**
  - adults and children 12 years and older:
    - take 1 [insert dosage unit] every 4 to 6 hours while symptoms persist
    - if pain or fever does not respond to 1 [insert dosage unit], 2 [insert dosage unit(s)] may be used
    - do not exceed 6 [insert dosage unit(s)] in 24 hours, unless directed by a doctor
    - the smallest effective dose should be used
  - children under 12 years: ask a doctor
- 

***Other information***

- optional - tamper evident statement
  - store at 20-25° C (68-77° F). Avoid high humidity and excessive heat above 40° C (104° F).
  - optional - see [end or side] panel for lot number and expiration date
- 

***Inactive ingredients*** [list ingredients in alphabetical order]

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***Questions or comments?*** call toll free **1-800-XXX-XXXX**

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NOTE: The ***Drug Facts (continued)*** title should appear wherever the labeling continues onto another panel of the package.

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<sup>1</sup>The information for the two age groups may be presented in a table format in accord with 21 CFR 201.66(d)(9) with the "do not take more than directed" statement appearing above the top line of the table.

Example Drug Facts Label for Minoxidil Topical Solution 2% for Men and Women

---

**Drug Facts**

---

<b>Active ingredient</b>	<b>Purpose</b>
Minoxidil 2% w/v.....	Hair regrowth treatment

---

**Use**

- to regrow hair on the scalp
- 

**Warnings**

**For external use only**

**Flammability warning:** Keep away from fire or flame [Include if product meets the criteria in 16 CFR 1500.3(b)(10)]

---

**Do not use if**

- your degree of hair loss is more than that shown on the side of this carton. Minoxidil topical solution 2% may not work.
  - you have no family history of hair loss
  - hair loss is sudden and/or patchy
  - [Use for products for women] ■ hair loss is associated with childbirth
  - you do not know the reason for your hair loss
  - you are under 18 years of age. Do not use on babies and children.
  - scalp is red, inflamed, infected, irritated, or painful
  - you use other medicines on the scalp
- 

**When using this product**

- do not apply on other parts of the body
  - avoid contact with the eyes. In case of accidental contact, rinse eyes with large amounts of cool tap water.
  - it takes time to regrow hair. You may need to use this product 2 times a day for at least 4 months before you see results.
  - the amount of hair regrowth is different for each person. This product will not work for everyone.
- 

**Stop use and ask a doctor if**

- chest pain, rapid heart beat, faintness, or dizziness occurs
- sudden, unexplained weight gain occurs
- your hands or feet swell
- scalp irritation or redness occurs
- you get unwanted facial hair growth

- you do not see hair regrowth in [insert 8 for products for women and insert 12 for products for men] months
- 

[Use for products for women] **If pregnant or breast-feeding**, ask a health professional before use.

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

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### ***Directions***

- apply one [may use the numeral 1 here instead of one] mL with dropper or sprayer [insert number of sprays] [include sprayer information if a sprayer is included with the product] 2 times a day directly onto the scalp in the hair loss area
  - using more or more often will not improve results
  - continued use is necessary to increase and keep your hair regrowth, or hair loss will begin again
- 

### ***Other information***

- see hair loss pictures on side of this carton
  - before use, read all information on carton and enclosed booklet
  - keep the carton. It contains important information.
  - [Use for products for men] in clinical studies of mostly white men aged 18-45 years with moderate degrees of hair loss, the following response to minoxidil topical solution 2% was reported: 26% of men reported moderate to dense hair regrowth after using minoxidil topical solution 2% for 4 months (26% had moderate to dense regrowth; 33% had minimal regrowth). This compares with 11% of men reporting hair regrowth after using the placebo, the liquid without minoxidil in it, for 4 months (11% had moderate to dense regrowth; 31% had minimal regrowth).
  - [Use for products for women] in clinical studies of mostly white women aged 18-45 years with mild to moderate degrees of hair loss, the following response to minoxidil topical solution 2% was reported: 19% of women reported moderate hair regrowth after using minoxidil topical solution 2% for 8 months (19% had moderate regrowth; 40% had minimal regrowth). This compares with 7% of women reporting moderate hair regrowth after using the placebo, the liquid without minoxidil in it, for 8 months (7% had moderate regrowth; 33% had minimal regrowth).
  - optional - storage conditions [that are appropriate for the product in both <sup>o</sup> C and <sup>o</sup> F]
- 

***Inactive ingredients*** [list ingredients in alphabetical order; list alcohol as % v/v]

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***Questions or comments?*** call toll free 1-800-XXX-XXXX

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NOTE: The ***Drug Facts (continued)*** title should appear wherever the labeling continues onto another panel of the package.

Example Drug Facts Label for Naproxen Sodium 220 mg in a Tablet/Caplet/Gelcap Dosage Form

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**Drug Facts**

---

<b>Active ingredient (in each [insert dosage unit])</b>	<b>Purposes</b>
Naproxen sodium 220 mg (naproxen 200 mg).....	Pain reliever/fever reducer

---

**Uses**

- temporarily relieves minor aches and pains due to:
    - headache    ■ muscular aches    ■ minor pain of arthritis    ■ toothache
    - backache    ■ the common cold    ■ menstrual cramps
  - temporarily reduces fever
- 

**Warnings**

**Allergy alert:** Naproxen sodium may cause a severe allergic reaction which may include:

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

**Alcohol warning:** If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take naproxen sodium or other pain relievers/fever reducers.

Naproxen sodium may cause stomach bleeding.

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

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**Ask a doctor before use if you have** ever had serious side effects from any pain reliever or fever reducer

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**Ask a doctor or pharmacist before use if you are**

- under a doctor's care for any serious condition
  - taking any other drug
  - taking any other product that contains naproxen sodium, or any other pain reliever/fever reducer
- 

**Stop use and ask a doctor if**

- an allergic reaction occurs. Seek medical help right away.
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- you have difficulty swallowing
- it feels like the pill is stuck in your throat
- you develop heartburn
- stomach pain occurs or lasts, even if symptoms are mild

- redness or swelling is present in the painful area
- any new symptoms appear

**If pregnant or breast-feeding**, ask a health professional before use. It is especially important not to use naproxen sodium during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

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

**Directions**

- **do not take more than directed**
- drink a full glass of water with each dose

Adults and children 12 years and older	<ul style="list-style-type: none"> <li>■ take 1 [insert dosage unit] every 8 to 12 hours while symptoms last</li> <li>■ first dose - you may take 2 [insert dosage unit(s)] within the first hour</li> <li>■ the smallest effective dose should be used</li> <li>■ do not exceed 2 [insert dosage unit(s)] in any 8- to 12-hour period</li> <li>■ do not exceed 3 [insert dosage unit(s)] in a 24-hour period</li> </ul>
Adults over 65 years	<ul style="list-style-type: none"> <li>■ do not take more than 1 [insert dosage unit] every 12 hours unless directed by a doctor</li> </ul>
Children under 12 years	<ul style="list-style-type: none"> <li>■ ask a doctor</li> </ul>

**Other information**

- **each [insert dosage unit] contains:** sodium 20 mg
- optional - tamper evident statement
- store at 20-25° C (68-77° F). Avoid high humidity and excessive heat above 40° C (104° F)
- optional - see [end or side] panel for lot number and expiration date

**Inactive ingredients** [list ingredients in alphabetical order]

**Questions or comments?** call toll free 1-800-XXX-XXXX

NOTE: The **Drug Facts (continued)** title should appear wherever the labeling continues onto another panel of the package.

Example Drug Facts Label for Acetaminophen 650 mg in a Suppository Dosage Form

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**Drug Facts**

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<b>Active ingredient (in each rectal suppository)</b>	<b>Purposes</b>
Acetaminophen 650 mg.....	Pain reliever/fever reducer

---

**Uses** temporarily ■ reduces fever ■ relieves minor aches, pains, and headache

---

**Warnings**

**For rectal use only**

**Alcohol warning:** If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take acetaminophen or other pain relievers/fever reducers.

Acetaminophen may cause liver damage.

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**Do not use** in children under 12 years

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**Stop use and ask a doctor if**

- fever lasts more than 3 days (72 hours), or recurs
  - you need to use this product for pain for more than 10 days continuously
- Severe or recurrent pain, or high or continued fever may indicate a serious illness.
- 

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

**Keep out of reach of children.** If swallowed or in case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical in case of overdose for adults and for children even if you do not notice any signs or symptoms.

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**Directions<sup>1</sup>**

- **do not use more than directed**
  - remove foil wrapper
  - insert suppository well up into rectum
  - adults and children 12 years and older:
    - 1 suppository every 4 to 6 hours while symptoms persist
    - do not exceed 6 suppositories in any 24-hour period
  - **children under 12 years: do not use**
- 

**Other information**

- optional - tamper evident statement

---

<sup>1</sup> The information for the two age groups may be presented in a table format in accord with 21 CFR 201.66(d)(9) with the first three bulleted statements appearing above the top line of the table.

- store at 8-25° C (46-77° F)<sup>2</sup> or refrigerate
- optional - see [end or side] panel for lot number and expiration date

---

***Inactive ingredients*** [list ingredients in alphabetical order]

---

***Questions or comments?*** call toll free **1-800-XXX-XXXX**

---

NOTE: The ***Drug Facts (continued)*** title should appear wherever the labeling continues onto another panel of the package.

---

<sup>2</sup> These temperatures reflect the storage conditions for acetaminophen suppositories, USP. Manufacturers who have stability data in their ANDA to support storage up to 27° C (80° F) may use these temperatures in place of 25° C (77° F).

Example Drug Facts Label for Acetaminophen 325 mg in a Suppository Dosage Form

---

**Drug Facts**

---

**Active ingredient (in each rectal suppository)** **Purposes**  
Acetaminophen 325 mg.....Pain reliever/fever reducer

---

**Uses** temporarily ■ reduces fever ■ relieves minor aches, pains, and headache

---

**Warnings**

**For rectal use only**

**Alcohol warning:** If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take acetaminophen or other pain relievers/fever reducers. Acetaminophen may cause liver damage.

---

**Do not use** in children under 6 years

---

**Stop use and ask a doctor if**

- fever lasts more than 3 days (72 hours), or recurs
  - you need to use this product for pain for more than 10 days continuously
- Severe or recurrent pain, or high or continued fever may indicate a serious illness.
- 

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

**Keep out of reach of children.** If swallowed or in case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical in case of overdose for adults and for children even if you do not notice any signs or symptoms.

---

**Directions**

- **do not use more than directed**
- remove foil wrapper
- insert suppository well up into rectum

adults and children 12 years and older	2 suppositories every 4 to 6 hours while symptoms persist; do not exceed 12 suppositories in any 24-hour period
children 6 -12 years	1 suppository every 4 to 6 hours while symptoms persist; do not exceed 6 suppositories in any 24-hour period
<b>children under 6 years</b>	<b>Do not use</b>

---

**Other information**

- optional - tamper evident statement
  - store at 8-25° C (46-77° F)<sup>1</sup> or refrigerate
- 

<sup>1</sup> These temperatures reflect the storage conditions for acetaminophen suppositories, USP. Manufacturers who have stability data in their ANDA to support storage up to 27° C (80° F) may use these temperatures in place of 25° C (77° F).

- optional - see [end or side] panel for lot number and expiration date

---

***Inactive ingredients*** [list ingredients in alphabetical order]

---

***Questions or comments?*** call toll free **1-800-XXX-XXXX**

---

NOTE: The ***Drug Facts (continued)*** title should appear wherever the labeling continues onto another panel of the package.

*Example Drug Facts Label for Acetaminophen 120 mg in a Suppository Dosage Form*

---

**Drug Facts**

---

<b>Active ingredient (in each rectal suppository)</b>	<b>Purposes</b>
Acetaminophen 120 mg.....	Pain reliever/fever reducer

---

**Uses** temporarily ■ reduces fever ■ relieves minor aches, pains, and headache

---

**Warnings**

**For rectal use only**

---

**Stop use and ask a doctor if**

- fever lasts more than 3 days (72 hours), or recurs
  - you need to use this product for pain for more than 5 days continuously
- Severe or recurrent pain, or high or continued fever may indicate a serious illness.
- 

**Keep out of reach of children.** If swallowed or in case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical in case of overdose for children even if you do not notice any signs or symptoms.

---

**Directions<sup>1</sup>**

- **do not use more than directed**
  - remove foil wrapper
  - insert suppository well up into rectum
  - children 3 – 6 years:
    - 1 suppository every 4 to 6 hours while symptoms persist
    - do not exceed 6 suppositories in any 24-hour period
  - children under 3 years: ask a doctor
- 

**Other information**

- optional - tamper evident statement
  - store at 8-25° C (46-77° F)<sup>2</sup> or refrigerate
  - optional - see [end or side] panel for lot number and expiration date
- 

**Inactive ingredients** [list ingredients in alphabetical order]

---

**Questions or comments?** call toll free **1-800-XXX-XXXX**

---

<sup>1</sup> The information for the two age groups may be presented in a table format in accord with 21 CFR 201.66(d)(9) with the first three bulleted statements appearing above the top line of the table.

<sup>2</sup> These temperatures reflect the storage conditions for acetaminophen suppositories, USP. Manufacturers who have stability data in their ANDA to support storage up to 27° C (80° F) may use these temperatures in place of 25° C (77° F).

---

NOTE: The ***Drug Facts (continued)*** title should appear wherever the labeling continues onto another panel of the package.



Example Drug Facts Label for Cimetidine 200 mg in a Tablet Dosage Form

---

**Drug Facts**

---

<b>Active ingredient (in each tablet)</b>	<b>Purpose</b>
Cimetidine 200 mg.....	Acid reducer

---

**Uses**

- relieves heartburn associated with acid indigestion and sour stomach
  - prevents heartburn associated with acid indigestion and sour stomach brought on by eating or drinking certain food and beverages
- 

**Warnings**

**Allergy alert:** Do not use if you are allergic to cimetidine or other acid reducers.

---

**Do not use** with other acid reducers

---

**Ask a doctor before use if you have**

- trouble swallowing
- persistent abdominal pain

See a doctor right away because you may have a serious condition that may need a different treatment.

---

**Ask a doctor or pharmacist before use if you are** taking

- theophylline (oral asthma medicine)
- warfarin (blood thinning medicine)
- phenytoin (seizure medicine)

If you are not sure whether you are taking one of these medicines, ask your doctor or pharmacist.

---

**Stop use and ask a doctor if**

- you need to take this product for more than 2 weeks continuously
- 

**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 12 years and older:
  - to **relieve** symptoms, swallow 1 tablet with a glass of water

- to **prevent** symptoms, swallow 1 tablet with a glass of water **right before or any time up to 30 minutes before** eating food or drinking beverages that cause heartburn
  - can be used up to twice daily (up to 2 tablets in 24 hours)
  - children under 12 years: ask a doctor
- 

***Other information***

- optional - tamper evident statement
  - optional - storage conditions [that are appropriate for the product in both <sup>0</sup> C and <sup>0</sup> F]
  - optional - see [end or side] panel for lot number and expiration date
- 

***Inactive ingredients*** [list ingredients in alphabetical order]

---

***Questions or comments?*** call toll free **1-800-XXX-XXXX**

---

NOTE: The ***Drug Facts (continued)*** title should appear wherever the labeling continues onto another panel of the package.

Example Drug Facts Label for Loperamide HCl in a Tablet/Caplet Dosage Form

---

**Drug Facts**

---

<b>Active ingredient (in each [insert dosage unit])</b>	<b>Purpose</b>
Loperamide HCl 2 mg.....	Antidiarrheal

---

**Use**

- controls symptoms of diarrhea, including Travelers' Diarrhea
- 

**Warnings**

**Allergy alert:** Do not use if you have ever had a rash or other allergic reaction to loperamide HCl

---

**Do not use** if you have bloody or black stool

---

**Ask a doctor before use if you have**

- high fever (greater than 101<sup>0</sup>F)
  - mucus present in your stool
  - a history of liver disease
- 

**Ask a doctor or pharmacist before use if you are** taking antibiotics

---

**Stop use and ask a doctor if** diarrhea lasts for more than 2 days

---

[If applicable] Phenylketonurics: Contains Phenylalanine ( \_ ) mg Per (Dosage Unit)

---

**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**

- drink plenty of clear fluids to help prevent dehydration, which may accompany diarrhea
- find right dose on chart. If possible, use weight to dose; otherwise, use age.

[For chewable tablets] ■ chew each tablet and take with water

adults and children 12 years and older	2 tablets after the first loose bowel movement <sup>1</sup> ; 1 tablet after each subsequent loose bowel movement; but no more than 4 tablets a day
children 9 - 11 years (60 - 95 lbs)	1 tablet after the first loose bowel movement; 1/2 tablet after each subsequent loose bowel movement; but no more than 3 tablets a day
children 6 - 8 years (48 - 59 lbs)	1 tablet after the first loose bowel movement; 1/2 tablet after each subsequent loose bowel movement; but no more than 2 tablets a day

<sup>1</sup> The word "stool" may be used in place of the words "bowel movement" in the above table.

children under 6  
years (up to 47 lbs)

ask a doctor (not intended for use in children under 6 years old)

---

***Other information***

- optional – tamper evident statement
- optional - storage conditions [that are appropriate for the product in both ° C and ° F]
- optional – see [end or side] panel for lot number and expiration date

---

***Inactive ingredients*** [list ingredients in alphabetical order]

---

***Questions or comments?*** call toll free **1-800-XXX-XXXX**

---

NOTE: The ***Drug Facts (continued)*** title should appear wherever the labeling continues onto another panel of the package.

Example Drug Facts Label for Loperamide HCl in a Liquid Dosage Form

---

**Drug Facts**

---

<b>Active ingredient (in each 5 mL)</b>	<b>Purpose</b>
Loperamide HCl 1 mg .....	Antidiarrheal

---

**Use**

- controls symptoms of diarrhea, including Travelers' Diarrhea
- 

**Warnings**

**Allergy alert:** Do not use if you have ever had a rash or other allergic reaction to loperamide HCl

---

**Do not use** if you have bloody or black stool

---

**Ask a doctor before use if you have**

- high fever (greater than 101<sup>0</sup>F)
  - mucus present in your stool
  - a history of liver disease
- 

**Ask a doctor or pharmacist before use if you are** taking antibiotics

---

**Stop use and ask a doctor if** diarrhea lasts for more than 2 days

---

**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**

- use enclosed dosage cup to accurately measure dosage as noted below
- drink plenty of clear fluids to help prevent dehydration, which may accompany diarrhea
- find right dose on chart. If possible, use weight to dose; otherwise, use age.

adults and children 12 years and older	4 teaspoonfuls (1 dosage cup) after the first loose bowel movement <sup>1</sup> ; 2 teaspoonfuls (1/2 dosage cup) after each subsequent loose bowel movement; but no more than 8 teaspoonfuls a day
children 9 – 11 years (60 - 95 lbs)	2 teaspoonfuls (1/2 dosage cup) after the first loose bowel movement; 1 teaspoonful (1/4 dosage cup) after each subsequent loose bowel movement; but no more than 6 teaspoonfuls a day
children 6 – 8 years (48 – 59 lbs)	2 teaspoonfuls (1/2 dosage cup) after the first loose bowel movement; 1 teaspoonful (1/4 dosage cup) after each subsequent loose bowel movement; but no more than 4 teaspoonfuls a day

<sup>1</sup> The word "stool" may be used in place of the words "bowel movement" in the above table.

children under 6 years (up to 47 lbs)	ask a doctor (not intended for use in children under 6 years old)
---------------------------------------	---

---

***Other information***

- optional – tamper evident statement
- optional - storage conditions [that are appropriate for the product in both <sup>0</sup> C and <sup>0</sup> F]; avoid excessive heat
- optional – see [end or side] panel for lot number and expiration date

---

***Inactive ingredients*** [list ingredients in alphabetical order]

---

***Questions or comments?*** call toll free **1-800-XXX-XXXX**

---

NOTE: The ***Drug Facts (continued)*** title should appear wherever the labeling continues onto another panel of the package.

Example Drug Facts Label for Minoxidil Topical Solution 5% for Men

---

**Drug Facts**

---

<b>Active ingredient</b>	<b>Purpose</b>
Minoxidil 5% w/v.....	Hair regrowth treatment for men

---

**Use**

- to regrow hair on the top of the scalp (vertex only, see pictures on side of carton)
- 

**Warnings**

**For external use only. For use by men only.**

**Flammability warning:** Keep away from fire or flame [Include if product meets the criteria in 16 CFR 1500.3(b)(10)]

---

**Do not use if**

- you are a woman
  - your amount of hair loss is different than that shown on the side of this carton or your hair loss is on the front of the scalp. Minoxidil topical solution 5% is not intended for frontal baldness or receding hairline.
  - you have no family history of hair loss
  - hair loss is sudden and/or patchy
  - you do not know the reason for your hair loss
  - you are under 18 years of age. Do not use on babies and children.
  - scalp is red, inflamed, infected, irritated, or painful
  - you use other medicines on the scalp
- 

**When using this product**

- do not apply on other parts of the body
  - avoid contact with the eyes. In case of accidental contact, rinse eyes with large amounts of cool tap water.
  - it takes time to regrow hair. Results may occur at 2 months with twice a day usage. For some men, you may need to use this product for at least 4 months before you see results.
  - the amount of hair regrowth is different for each person. This product will not work for all men.
- 

**Stop use and ask a doctor if**

- chest pain, rapid heart beat, faintness, or dizziness occurs
- sudden, unexplained weight gain occurs
- your hands or feet swell
- scalp irritation or redness occurs

- you get unwanted facial hair growth
  - you do not see hair regrowth in 4 months
- 

**May be harmful if used when pregnant or breast-feeding.**

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

---

### ***Directions***

- apply one [may use the numeral 1 here instead of one] mL with dropper or sprayer [insert number of sprays] [include sprayer information if a sprayer is included with the product] 2 times a day directly onto the scalp in the hair loss area
  - using more or more often will not improve results
  - continued use is necessary to increase and keep your hair regrowth, or hair loss will begin again
- 

### ***Other information***

- see hair loss pictures on side of this carton
  - before use, read all information on carton and enclosed booklet
  - keep the carton. It contains important information.
  - clinical research in mostly white men aged 18-49 years with moderate degrees of hair loss, showed that minoxidil topical solution 5% for men provides more hair regrowth than minoxidil topical solution 2% for men. Hair regrowth has not been shown to last longer than 48 weeks of continuous treatment in large clinical trials with minoxidil topical solution 5% for men.
  - optional - storage conditions [that are appropriate for the product in both °C and °F]
- 

***Inactive ingredients*** [list ingredients in alphabetical order; list alcohol as % v/v]

---

***Questions or comments?*** call toll free 1-800-XXX-XXXX

---

NOTE: The ***Drug Facts (continued)*** title should appear wherever the labeling continues onto another panel of the package.

Example Drug Facts Label for Miconazole Nitrate Vaginal Products

There are a number of different miconazole nitrate vaginal products in the marketplace. There are 3- and 7-day treatments, creams and suppositories, and combinations (cream labeled for vaginal and external use, and suppository and external cream). The agency is providing a single example that updates the labeling currently used on various products. This labeling should be used for all products and should be adapted to fit the specific product (i.e., the active ingredient, uses, and directions sections of the labeling).

---

**Drug Facts**

---

[For products containing suppositories only]

<b>Active ingredient (in each vaginal suppository)</b>	<b>Purpose</b>
Miconazole nitrate (__) mg <sup>1</sup> .....	Vaginal antifungal

[For products containing vaginal cream only]

<b>Active ingredient</b>	<b>Purpose</b>
Miconazole nitrate (__)% <sup>1</sup> (__ mg <sup>1</sup> in each applicator).....	Vaginal antifungal

[For combination products containing suppositories or vaginal cream plus external cream]

<b>Active ingredients</b>	<b>Purpose</b>
Miconazole nitrate (__) mg <sup>1</sup> in each vaginal suppository <b>[or]</b> .....	Vaginal antifungal
Miconazole nitrate (__)% <sup>2</sup> (__ mg <sup>1</sup> in each applicator) <b>[and]</b> .....	Vaginal antifungal
Miconazole nitrate 2% (external cream) .....	Vaginal antifungal

---

**Use**

- treats vaginal yeast infections

[For combination products that include external application claims, change “Use” to “Uses” and add the following:]

- relieves external itching and irritation due to a vaginal yeast infection
- 

**Warnings**

**For vaginal use only**

---

**Do not use** if you have never had a vaginal yeast infection diagnosed by a doctor

---

---

<sup>1</sup> Insert appropriate number of milligrams

<sup>1</sup> Insert appropriate number

**Ask a doctor before use if you have**

- vaginal itching and discomfort for the first time
  - vaginal yeast infections often (such as once a month or 3 in 6 months). You could be pregnant or have a medical condition, such as diabetes or a weakened immune system.
  - lower abdominal, back, or shoulder pain, fever, chills, nausea, vomiting, or foul-smelling vaginal discharge
  - been exposed to the human immunodeficiency virus (HIV) that causes AIDS
- 

**Ask a doctor or pharmacist before use if you are** taking a prescription blood thinning medicine, such as warfarin, because bleeding or bruising may occur

---

**When using this product**

- do not have vaginal intercourse (sex)
  - do not use tampons, douches, spermicides, or other vaginal products
  - do not use condoms or diaphragms. They may be damaged by this product and not prevent pregnancy or sexually transmitted diseases (STDs).
- 

**Stop use and ask a doctor if**

- symptoms do not get better after 3 days
  - symptoms last more than 7 days
  - you get a rash, abdominal pain, fever, chills, nausea, vomiting, or foul-smelling vaginal discharge
- 

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

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

---

**Directions<sup>3</sup>**

- before using this product, read the enclosed [insert "brochure" or "leaflet"] for complete instructions
- [If applicable for cream products] ■ to open tube use cap to puncture seal
- adults and children 12 years of age and over:
- [Select appropriate directions for single-dosage form or combination products.]
- **vaginal cream:** insert one applicatorful into the vagina at bedtime for [insert "3" or "7" as appropriate] days in a row. [Add, as applicable: (For disposable applicators: "Throw applicator away after use.") (For reusable applicator: "Wash applicator after each use.")]
  - **suppositories:** insert one suppository into the vagina at bedtime for [insert "3" or "7" as appropriate] days in a row. Wash applicator after each use.
- 

<sup>3</sup> The information for the two age groups may be presented in a table format in accord with 21 CFR 201.66(d)(9) with the first bulleted statement appearing above the top line of the table.

- **external cream:** squeeze a small amount of cream onto your fingertip. Gently apply the cream onto the itchy, irritated skin outside the vagina. Use 2 times daily for up to 7 days as needed.
  - children under 12 years: ask a doctor
- 

***Other information***

- optional – tamper evident statement(s)
  - store at 20-25° C (68-77° F). Avoid heat over 30° C (86° F).
  - optional - see [end or side] panel for lot number and expiration date
- 

***Inactive ingredients*** [list ingredients in alphabetical order. For combination suppository and external cream products, the inactive ingredients should be listed separately following the headers “vaginal suppositories” and “external cream.” For combination vaginal cream and external cream products, if the inactive ingredients differ, they should be listed separately following the headers “vaginal cream” and “external cream.”]

---

***Questions or comments?*** call toll free **1-800-XXX-XXXX**

---

NOTE: The ***Drug Facts (continued)*** title should appear wherever the labeling continues onto another panel of the package.

Example Drug Facts Label for Clemastine Fumerate 1.34 mg in a Tablet Dosage Form

---

**Drug Facts**

---

<b>Active ingredient (in each tablet)</b>	<b>Purpose</b>
Clemastine fumerate 1.34 mg (equivalent to 1 mclemastine).....	Antihistamine

---

**Uses** temporarily relieves these symptoms of the common cold, hay fever, or other upper respiratory allergies:

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

**Warnings**

**Ask a doctor before use if you have**

- glaucoma
  - a breathing problem such as emphysema or chronic bronchitis
  - trouble urinating due to an enlarged prostate gland
- 

**Ask a doctor or pharmacist before use if you are** taking sedatives or tranquilizers

---

**When using this product**

- you may get drowsy
  - avoid alcoholic drinks
  - alcohol, sedatives, and tranquilizers may increase drowsiness
  - be careful when driving a motor vehicle or operating machinery
  - excitability may occur, especially in children
- 

**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 12 years and older: 1 tablet every 12 hours; not more than 2 tablets in 24 hours
  - children under 12 years: ask a doctor
- 

**Other information**

- optional - tamper evident statement
  - store at 20-25° C (68-77° F)
  - optional - see [end or side] panel for lot number and expiration date
- 

**Inactive ingredients** [list ingredients in alphabetical order]

---

**Questions or comments?** call toll free 1-800-XXX-XXXX

---

NOTE: The ***Drug Facts (continued)*** title should appear wherever the labeling continues onto another panel of the package.

Example Drug Facts Label for Pseudoephedrine HCl Extended-Release Tablets  
120 mg

---

**Drug Facts**

---

<b>Active ingredient (in each tablet)</b>	<b>Purpose</b>
Pseudoephedrine HCl 120 mg.....	Nasal decongestant

---

**Uses**

- temporarily relieves nasal congestion due to:
    - common cold
    - hay fever
    - upper respiratory allergies
    - sinusitis
  - temporarily restores freer breathing through the nose
  - promotes nasal and/or sinus drainage
  - temporarily relieves sinus congestion and pressure
- 

**Warnings**

**Do not use** if you are now 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 prescription drug contains a MAOI, ask a doctor or pharmacist before taking this product.

---

**Ask a doctor before use if you have**

- heart disease
  - high blood pressure
  - thyroid disease
  - diabetes
  - trouble urinating due to an enlarged prostate gland
- 

**When using this product**

- **do not use more than directed**
- 

**Stop use and ask a doctor if**

- you get nervous, dizzy, or sleepless
  - symptoms do not get better within 7 days or occur with a fever
- 

**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 12 years and older: 1 tablet every 12 hours; not more than 2 tablets in 24 hours
- children under 12 years: ask a doctor

---

***Other information***

- optional - tamper evident statement
- store at 20-25° C (68-77° F)
- optional - see [end or side] panel for lot number and expiration date

---

***Inactive ingredients*** [list ingredients in alphabetical order]

---

***Questions or comments?*** call toll free **1-800-XXX-XXXX**

---

NOTE: The *Drug Facts (continued)* title should appear wherever the labeling continues onto another panel of the package.

Example Drug Facts Label for Doxylamine Succinate 25 mg Tablet Dosage Form

---

**Drug Facts**

---

<b>Active ingredient (in each tablet)</b>	<b>Purpose</b>
Doxylamine succinate 25 mg.....	Nighttime sleep-aid

---

**Use** helps to reduce difficulty in falling asleep

---

**Warnings**

**Do not use** in children under 12 years old

---

**Ask a doctor before use if you have**

- glaucoma
  - a breathing problem such as emphysema or chronic bronchitis
  - trouble urinating due to an enlarged prostate gland
- 

**Ask a doctor or pharmacist before use if you are** taking any other drug, especially sedatives or tranquilizers

---

**When using this product**

- you may get drowsy. Use only at bedtime.
  - avoid alcoholic drinks
- 

**Stop use and ask a doctor if**

- sleeplessness does not go away for more than 2 weeks. This could be a sign of a serious condition.
- 

**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 12 years and older: 1 tablet 30 minutes before bedtime; not more than 1 tablet each day
  - children under 12 years: do not use
- 

**Other information**

- optional - tamper evident statement
  - store at 20-25° C (68-77° F)
  - optional - see [end or side] panel for lot number and expiration date
- 

**Inactive ingredients** [list ingredients in alphabetical order]

---

**Questions or comments?** call toll free 1-800-XXX-XXXX

---

NOTE: The ***Drug Facts (continued)*** title should appear wherever the labeling continues onto another panel of the package.