Guidance

Useful Written Consumer Medication Information (CMI)

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

July 2006
Procedural

Guidance

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Contains Nonbinding Recommendations

Guidance on Useful Written Consumer Medication Information (CMI) [1]

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. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. INTRODUCTION

This guidance is intended to assist individuals or organizations (e.g., pharmacies, private vendors, healthcare associations) in developing useful written consumer medication information (CMI). CMI is written information about prescription drugs developed by organizations or individuals other than a drug's manufacturer that is intended for distribution to consumers at the time of drug dispensing. Since neither FDA nor a drug's manufacturer reviews or approves CMI, FDA recommends that the developers of written medication information use the guidance contained in this document to help ensure that their CMI is useful to consumers.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

Traditionally, FDA has believed that people are able to make better decisions about their healthcare and better use of the prescription medications available to them when they are well informed about the medications they take. Access to useful written information about prescription medications is important to ensuring appropriate use of these products. Over the years, FDA has undertaken a number of efforts to help ensure that consumers receive useful,

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[1] This guidance has been prepared by the Office of Drug Safety in the Center for Drug Evaluation and Research (CDER), in consultation with the Center for Biologics Evaluation and Research, at the Food and Drug Administration.

reader-friendly written information regarding their prescription medications. These efforts are described briefly here.

Since 1968, FDA regulations have required that patient package inserts, written specifically for patients, be distributed to patients when certain prescription drugs, or classes of prescription drugs, are dispensed (see 21 CFR 310.501 for oral contraceptives and 310.515 for estrogens). In the 1970s, however, FDA began evaluating the general usefulness of patient labeling for prescription drugs, resulting in a series of regulatory steps to help ensure the availability of useful written consumer information:

- In 1979, FDA proposed regulations that would require written patient information for all prescription drugs (44 FR 40016; July 6, 1979).
- In 1980, FDA finalized those regulations. They established requirements and procedures for the preparation and distribution of manufacturer-prepared and FDA-approved patient labeling for a limited number of prescription drugs (45 FR 60754; September 12, 1980).
- In 1982, FDA revoked those regulations, in part based on assurances by pharmaceutical manufacturers, healthcare professional associations, and private-sector providers of written medication information for patients that the goals of the final rule would be met more effectively and with greater innovation without regulation (47 FR 39147, September 7, 1982).

FDA committed to monitor the progress of this private-sector effort. Unfortunately, periodic FDA surveys showed that, although the distribution of written prescription drug information increased, the usefulness of the information was highly variable. As a result:

- In 1995, FDA proposed a regulation entitled *Prescription Drug Product Labeling: Medication Guide Requirements* (60 FR 44182; August 24, 1995), designed to set specific distribution and quality goals and time frames for distributing written information.

  The regulation had the following goals:

  - By the year 2000, 75 percent of people receiving new prescriptions would receive useful written patient information with their prescriptions.
  - By 2006, 95 percent of people receiving new prescriptions would receive useful written patient information with their prescriptions.

The proposed rule would also require manufacturers to prepare and distribute Medication Guides for a limited number of prescription drug products that posed a serious and significant public

health concern. In addition, the proposed rule described criteria for *usefulness* to permit evaluation of whether the information met the target goals.[2]

- On August 6, 1996, as FDA was reviewing the public comments on the 1995 proposed rule, Public Law 104-180 was enacted.[3]

This law adopted goals and time frames consistent with the 1995 proposed rule. The legislation also established a voluntary private-sector process through which a committee of interested stakeholders would develop a long-range comprehensive action plan to achieve the goals specified in the statute. The law also required the Secretary of the U. S. Department of Health and Human Services to evaluate the private sector's progress toward meeting the goals in the law and, if the goals were not met, to seek public comment on other initiatives to meet the goals. The law prohibited FDA from taking further regulatory steps specifying a uniform content or format for written information voluntarily provided to consumers about prescription drugs if private-sector initiatives met the goals of the plan within the specified time frames.

- In 1996, after Public Law 104-180 was enacted, a Steering Committee was created.

The Steering Committee, consisting of healthcare professionals, consumer organizations, voluntary health agencies, pharmaceutical manufacturers, prescription drug wholesalers, drug information database companies, CMI developers, and others, developed a report entitled *Action Plan for the Provision of Useful Prescription Medicine Information* (the Action Plan).[4] The Action Plan delineated *criteria* for evaluating whether a particular piece of written medication information is useful to consumers. The Action Plan endorsed the elements specified in Public Law 104-180 for defining the usefulness of medication information. Specifically, the Action Plan stated materials should be:

- scientifically accurate
- unbiased in content and tone
- sufficiently specific and comprehensive

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[2] FDA also specified that the usefulness of written patient information would be evaluated based on scientific accuracy, consistency with a standard format, nonpromotional tone and content, specificity, comprehensiveness, understandable language, and legibility.

[3] Public Law 104-180, Title VI, Sec 601 Effective Medication Guides, 110 Stat 1593 (1996).

[4] Steering Committee for the Collaborative Development of a Long-Range Action Plan for the Provision of Useful Prescription Medicine Information, unpublished report submitted to The Honorable Donna E. Shalala, Secretary of the U. S. Department of Health and Human Services, December 1996, available on the Internet at http://www.fda.gov/cder/offices/ods/keystone.pdf. Secretary Shalala accepted the Action Plan by letter dated January 13, 1997.

- presented in an understandable and legible format that is readily comprehensible to consumers
- timely and up-to-date
- useful, that is, enables the consumer to use the medicine properly and appropriately, receive the maximum benefit, and avoid harm

- In 1998, FDA contracted with the National Association of Boards of Pharmacy (NABP) to conduct a CMI assessment to determine progress toward meeting the stated goals of Public Law 104-180.

The NABP performed a pilot study to test the usefulness of the CMI being developed. The NABP also conducted a national study to assess the extent to which the year 2000 goals specified in the law had been achieved. The results of the study were announced in 2002. On average, 89 percent of the patients in the study received some form of written medication information. However, the average *usefulness* of the information was only about 50 percent.[5]

- On July 17, 2002, the FDA Drug Safety and Risk Management Advisory Committee (Advisory Committee) met to review the study results and public comments.

The Advisory Committee recommended that FDA take a more active role in advising and encouraging the private sector to meet the next target goal set for year 2006.[6]

In response to that recommendation, the Agency met with various groups, held a public meeting in 2003 (see www.fda.gov/cder/offices/ods/writtenPrescripinfo.htm), and was asked to provide clarification on how the Action Plan should be interpreted and implemented. This guidance is part of FDA's efforts to assist developers of CMI. This guidance provides recommendations to developers of CMI regarding how best to evaluate current CMI and develop future CMI to help ensure that all CMI meets the usefulness criteria provided in the Action Plan. FDA views the *criteria* and *components* described in the Action Plan as the minimum appropriate characteristics of *useful* CMI. Throughout this guidance, in providing recommendations about the Action Plan criteria, FDA uses the wording of the Action Plan as much as possible.

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[5] Svarstad, B.L. and J.K. Mount, *Evaluation of Written Prescription Information Provided in Community Pharmacies, 2001*, final report to the U.S. Department of Health and Human Services and the Food and Drug Administration, December 2001, available on the Internet at http://www.fda.gov/cder/reports/prescriptioninfo/default.htm.

[6] A transcript of FDA's Drug Safety and Risk Management Advisory Committee meeting on July 17, 2002, is available on the Internet at http://www.fda.gov/ohrms/dockets/ac/02/transcripts/3874T1.htm.

III. APPLYING THE ACTION PLAN CRITERIA FOR CMI

A. General Considerations

As discussed above, by 2006, 95 percent of people who receive new prescriptions should receive useful written patient information with their prescriptions. To determine whether CMI developers have met that goal, FDA will evaluate CMI against the Action Plan's criteria for usefulness. This guidance is intended to assist developers of CMI in meeting the 2006 goal by providing specific recommendations for implementing the Action Plan criteria.

CMI that adheres to the Action Plan criteria, as accepted by the Secretary, for a specific prescription drug will be considered *useful* when (1) information in generalized CMI about the use of or indication for use of the drug is consistent with the most recent version of the manufacturer's professional labeling or package insert (PI) (see 21 CFR 201.56 and 201.57)[7,8] and (2) it includes the components suggested in the Action Plan and substantially conforms to the formatting suggestions made in the Action Plan. Specifically, written CMI should be:

- scientifically accurate
- unbiased in content and tone
- sufficiently specific and comprehensive
- presented in an understandable and legible format that is readily comprehensible to consumers
- timely and up-to-date
- useful

Critical criteria, components, and formatting suggestions are in Chapter 3 (*Guidelines for Useful Prescription Medication Information*) and Appendix G (*Specific Language and Format Guidelines, with Samples*) of the Action Plan. This guidance provides FDA's recommendations to the private sector for implementing the Action Plan criteria.

The eight categories listed in the following table were developed by an expert panel, subcontracted by NABP for FDA's evaluation of CMI in 2001, by combining the Action Plan criteria and components. FDA believes that this list provides the factors for determining whether written medication information is useful under the Action Plan. Written information that

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[7] FDA-approved drug products and labeling can be found on the Internet at http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm. However, this Web site does not list all FDA-approved products and labeling. We are working to make all approved labeling available soon.

[8] Consistent with the Action Plan and acceptance by the Secretary, information beyond the FDA-approved labeling, such as patient-specific indications for use from scientific literature or provided by the prescriber, is appropriate in customized patient information. FDA recommends that the source of such information be included in CMI.

substantially satisfies each Action Plan criterion listed in the table will be deemed *useful* and will count toward the quantitative goals of Section 601 of Title VI of Public Law 104-180.

Action Plan Criteria for Defining Useful Information

Criterion	Description
1	Drug names, indications for use, and how to monitor for improvement
2	Contraindications and what to do if they apply
3	Specific directions about how to use and store the medicine, and overdose information
4	Specific precautions and warnings about the medicine
5	Symptoms of serious or frequent possible adverse reactions and what to do
6	Certain general information, including encouraging patients to communicate with healthcare professionals, and disclaimer statements
7	Information that is scientifically accurate, unbiased in tone and content, and up-to-date
8	Information in an understandable and legible format that is readily comprehensible to consumers

B. Specific Recommendations for Each Action Plan Criterion

Criterion 1: Drug Name, Indications for Use, and How to Monitor for Improvement

We recommend that the following information be included in the CMI to satisfy Criterion 1:

- Established or proper name and brand name (e.g., the trademark or proprietary name) of the drug. FDA recommends also including the phonetic spelling of the brand name,[9] or the established name if a brand name does not exist.

- All FDA-approved indications listed in the PI for the medication. Information on unapproved indications should only be included in CMI customized for individual patients.

[9] The Action Plan contained an error in reference to established name and brand name. All marketed products have an established name (also known as the generic name), while not all products have a brand name. Therefore, if a brand name does not exist, the phonetic spelling of the established name would be used.

- Information regarding how to monitor the effectiveness of the treatment by correctly interpreting physical reactions to the medicine, if this information is in the PI. This would include, for example, informing patients about when to call their healthcare provider if they do not notice signs of improvement.

Criterion 2: Contraindications and What to Do If They Apply

We recommend that the following information be included in the CMI to satisfy Criterion 2:

- Information about circumstances in which the medication should not be used for its labeled indication. Include all contraindications listed in the PI.

- Directions about what to do if any of the contraindications apply to the patient, such as contacting the healthcare provider before taking the medicine or discussing with him or her situations that would warrant discontinuing use of the medication. Include a general statement such as, *Talk to your healthcare provider before taking this medicine if you have any of these conditions*.

- Information on any contraindication that could result in serious injury or death if it is disregarded.

- A statement of precaution about any circumstances (such as past or current medical conditions or use of other medications, vitamins, or supplements) in which the use of the medication could lead to serious injury or death.

Criterion 3: Specific Directions About How to Use and Store the Medicine and Information About Overdose

We recommend that the following elements be addressed to satisfy Criterion 3:

- The CMI should be considered a stand-alone document in meeting this criterion. The label and packaging of the dispensed medication may also contain such information (e.g., name, strength, dosage, brief directions for use), but should not be considered as part of CMI.

- The Action Plan recommends that information regarding the "usual dosing instructions" be included. To avoid confusion between the usual dosing instructions and the prescribed dose, FDA suggests that the CMI refer the patient to the prescription label for specific dosing instructions. A statement should be included in the CMI stressing that it is important to follow the dosing instructions provided by the patient's healthcare provider, which is usually found on the prescription label for the medicine.

- If detailed instructions describing how to administer the medication (instructions for use) are included in the manufacturer's patient labeling for the product (for example, instructions for inhalers, injections, and patches), include a statement to alert the patient to read the instructions for use contained in the package.

- State the route of administration. Examples of information about the route of administration are *skin use only* if a patch and *do not swallow* if a suppository.

- If specified in the PI, include information on how to use the medication, such as whether to take it with or without food or water, times of day to take the medication, and any other instructions, for example, statements such as (1) *Do not chew*, (2) *Do not split or crush*, and (3) *Do not lie down for 30 minutes after taking this medicine*.

- Describe what patients can do if they miss a scheduled dose, if this information is in the PI.

- State what to do in case of an overdose. If overdose is a significant issue for a particular medication, include text describing signs of overdose so that patients can recognize the symptoms. In all cases, we recommend that symptoms of overdose be directly followed by instructions for what to do should these signs or symptoms occur, such as calling a poison control center, the doctor, or other emergency telephone number.

- Include storage instructions.

Criterion 4: Specific Precautions and Warnings

If the PI contains any boxed warnings that relate to important knowledge the consumer should have or actions the consumer should take, we recommend that a prominently displayed statement which is consistent with or derived from the boxed warnings be included in the CMI. FDA believes that most boxed warnings have information that is relevant to the consumer.

We recommend that the CMI include all information stated in the PI regarding what precautions the patient should take while using the drug to avoid serious situations. For example, the following information should be included, if relevant to the medication:

- Drugs to avoid because of drug-drug interactions. FDA notes that some drugs have few labeled drug-drug interactions, while other drugs list numerous interactions. We do not recommend that CMI list every possible interaction. We do recommend, at minimum, including all drugs listed in the *Contraindications* section of the PI, and we encourage including interactions listed in the *Warnings* and *Precautions* sections of the PI. If there are interactions in the PI that will not be included in CMI, we recommend that a consumer-friendly statement appear in CMI explaining that the list is not complete, telling patients that other medicines they are taking may interact with the product, and encouraging patients to keep a list of all the medicines they take to share it with their doctor or pharmacist. We also recommend that if specific drugs are listed as interactions in CMI, both generic and trade names be included.

- Foods and other substances (e.g., dietary supplements) to avoid because of the potential for interactions. Since the Action Plan was written, there has been increased awareness

of dietary supplement interactions with medications. If such interactions are included in the PI, include them in the CMI in the same way as drug and food interactions.

- A description of the risks, if any, to the patient of developing a tolerance to or dependence on the drug product. Such risks would be described in the PI. Any signs and symptoms of tolerance or dependence should be stated in terms that the patient would be able to understand to recognize them.

- Patient activities and behavior to avoid. Examples of such activities include smoking tobacco, drinking alcohol, being exposed to the sun, or driving a vehicle or operating dangerous machinery.

- Any risks to the mother and the fetus or the infant from use of the drug during pregnancy, labor, or breast-feeding. If the risks are unknown, include a statement such as, *Talk to your doctor if you are pregnant or breast-feeding.*

- Specific risks to identifiable patient populations, such as children, elderly patients, people with compromised immune systems, or people with impaired kidney or liver functioning, if such information is in the PI. Provide enough information for the consumer to understand the importance of the hazard described.

Criterion 5: Symptoms of Serious or Frequent Possible Adverse Reactions and What to Do

Under the Action Plan, CMI is not expected to contain a full listing of all possible side effects. Because the most serious potential adverse reactions will most likely appear in the *Warnings* and *Precautions* sections of the PI, we recommend that this information also be included in CMI. In addition, we recommend that CMI include a list of the symptoms of the most frequently occurring (common) adverse reactions.

We recommend including a statement telling patients that the side effects given are not a complete list and instructing them to ask their doctor or pharmacist for more information.

Criterion 6: Certain General Information, Including Encouraging Patients to Communicate with Healthcare Professionals, and Disclaimers

We recommend that certain general information be contained in all CMI:

- A statement that the medicine should only be used by the patient for whom it is prescribed and should not be given to other people.

- The name of the publisher of the CMI.

- The date that the CMI was published or the date of the most recent revision or review for adequacy and accuracy of content.

- A disclaimer stating that the CMI is a summary and does not contain all possible information about the medicine.

- A statement encouraging discussion with a healthcare professional about the prescription medicine. A statement that the healthcare professional who prescribed the medicine has additional information about the medicine as well as about the patient's specific health needs, and that the healthcare professional can provide this information to the patient and answer the patient's questions. An example of a statement that covers both recommendations could be: *This leaflet summarizes the most important information about <insert medication name>. If you would like more information, talk with your doctor*.

Criterion 7: Information That Is Scientifically Accurate, Unbiased in Tone and Content, and Up-to-Date

Scientific accuracy is an essential characteristic of CMI. The entire CMI will be assessed for scientific accuracy and bias. The information in the CMI about the use of or indication for use of the drug should be consistent with or derived from the PI, unless the CMI is customized for a specific patient. FDA-approved indications could also be listed with the customized information.

The text of the CMI should be unbiased in content and tone and should meet the accepted standards of scientific literature. That is, the text should be explanatory; neutral; without comparative adjectives, untruthful claims about the benefit of a product, or hyperbole; and distinguished from any promotional or other information provided to the patient.

CMI should not promote a specific brand, manufacturer, or distributor for the purpose of economic gain.

Criterion 8: Information in an Understandable and Legible Format That Is Readily Comprehensible to Consumers

To be useful, CMI should be written in wording that is understandable. To meet the Action Plan criterion of being understandable, we suggest that CMI be provided at the sixth to eighth grade reading level. We encourage using plain language and looking at the message from the reader's point of view.

CMI should adhere to the criteria, components, and formatting suggestions in Chapter 3 (*Guidelines for Useful Prescription Medication Information*) and Appendix G (*Specific Language and Format Guidelines, with Samples*) of the Action Plan, which "reflect widely recognized standards used by designers and publishers of written information to ensure that the materials are legible and readable." We recommend that CMI be designed to ensure the prominence of important information. It is helpful to use formats that distinguish between the degree of seriousness of cautions or warnings. Information should be written clearly and concisely, and complex terms should be avoided. Polysyllabic words could be replaced by shorter, simpler words (e.g., *harmful* rather than *detrimental*), even if it takes several words to get across a concept that can be expressed in a single, more complex term.

We recommend the following formatting:

- Use 10-point or larger type size.
- Do not use ornate typefaces and italics. Choose a bolder type over a thin version of the same style.
- Use upper- and lower-case lettering, not all capitals.
- Use bold-face type or a box to call attention to important information, rather than highlighting or underlining.
- Provide adequate space between letters, lines, and paragraphs. We suggest that text generally have no more than –3 *kerning* (space between letters). With 10-point type, 12-point *leading* (space between lines) is recommended (at least 2.2 millimeters). Provide adequate space between paragraphs and space above and below headings.
- Do not use a line length that is too long. In 10-point or 12-point type, optimal line length is approximately 40 letters long.
- Select text color and paper that give a strong contrast. Black, dark blue, or brown ink on white or pale yellow uncoated paper provides the best contrast. We suggest that other combinations be avoided.
- Use short paragraphs and bullets where possible.

C. Summary

The components of useful information identified in the Action Plan are meant to be useful "as a total package." We suggest that the information be provided in the following order:

1. Personalized information in a box (if customized for individual patients)
2. Established name and brand name
3. What the medicine is used for
4. Do not take this medicine if you are…
5. How to take the medicine
6. Side effects include …
7. General information

This list is not the only appropriate headings or order in which the headings should appear. Moreover, information pertaining to each Action Plan criterion need not be organized under the above-specified individual headings; they can be combined as appropriate.

The Appendix contains examples of CMI that follow the recommendations in this guidance. These examples are not to be construed as required formats. Since many formats are consistent

with the recommendations for usefulness, three possible formats for the same drug are illustrated.

APPENDIX

Prescription Medicine Information

Cefaclor for Oral Suspension [sef-ah-klor]

Why is Cefaclor for Oral Suspension prescribed?
Cefaclor is used to treat infections caused by certain bacteria. These infections include middle ear, bladder, and skin infections, as well as strep throat and pneumonia. Cefaclor works by killing certain bacteria or preventing them from growing.

Cefaclor is in a class of medicines known as cephalosporin antibiotics.
These medicines are sometimes prescribed for uses other than those listed in this leaflet. If you have any questions please call your healthcare provider.

Before Taking Your Medicine

Do not take Cefaclor if you are allergic to any cephalosporin antibiotics. Allergic reactions to Cefaclor can cause death.

Talk with your healthcare provider if you have any of the following conditions. This medicine may not be right for you, if you:

- have diabetes. Cefaclor can interfere with the urine test you may be using to test for sugar.
- have kidney disease.
- have colitis or other stomach or intestine problems.
- are allergic to penicillin or other antibiotic medicines.
- are pregnant or nursing.

While You Are Taking Your Medicine

Take Cefaclor exactly as prescribed. Continue taking Cefaclor even if you feel better. If you stop taking Cefaclor too soon, the bacteria can grow back and you may get sick again with the same infection.

- Take Cefaclor by mouth, with or without food.
- If you miss taking a dose of Cefaclor, take it as soon as you remember.
- If it is almost time for your next dose, skip the missed dose and take your next dose as scheduled.
- Do not take double your prescribed dose.
- If you think that someone may have taken more than the prescribed dose of this medicine, call your poison control center or emergency room right away.
- **Shake the bottle well each time before taking this medicine.**
- Keep Cefaclor for Oral Suspension in the refrigerator. Throw away any unused Cefaclor after the expiration date.

Prescription Medicine Information

Possible side effects

The most common side effects are mild upset stomach, diarrhea, and rash. Call your healthcare provider if these side effects bother you or do not go away.

Call your healthcare provider right away if the following side effects occur:

- swelling of the throat or trouble breathing
- hives, itching, and rash
- severe or bloody diarrhea
- stomach area pain
- tiredness or faintness (that lasts after taking this medicine for 24 hours)
- fever (that lasts after taking this medicine for 24 hours)
- joint aches or stiffness (that lasts after taking this medicine for 24 hours)

General Information

- This medicine was prescribed for your condition.
- Do not use it for another condition or give the medicine to others.

This leaflet provides a summary of information about Cefaclor and does not contain all possible information about this medicine. If you have any questions or concerns, or want more information about Cefaclor, call your healthcare provider or pharmacist. Your pharmacist also has a longer leaflet about Cefaclor that is written for health professionals that you can ask to read.

[Name of publisher and date of most recent publication or revision]

Prescription Medicine Information

Questions and Answers About
Cefaclor for Oral Suspension [sef-ah-klor]

What is Cefaclor for Oral Suspension?

Cefaclor is used to treat infections caused by certain bacteria. These infections include middle ear, bladder, and skin infections, as well as strep throat and pneumonia. Cefaclor works by killing certain bacteria or preventing them from growing. Cefaclor is in a class of medicines known as cephalosporin antibiotics. These medicines are sometimes prescribed for uses other than those listed in this leaflet. If you have any questions please call your healthcare provider.

Who should not take Cefaclor for Oral Suspension?

Do not take Cefaclor if you are allergic to other cephalosporin-class antibiotics. Allergic reactions to Cefaclor can cause death.

Talk with your healthcare provider if you have any of the following conditions. This medicine may not be right for you, if you:

- have kidney disease
- have colitis or other stomach or intestine problems
- are pregnant or breastfeeding
- are a diabetic and are checking your urine for sugar (Cefaclor can interfere with the urine test you may be using)

How should I take Cefaclor for Oral Suspension?

- Follow your healthcare provider's advice about how to take Cefaclor. **Continue taking Cefaclor even if you feel better. Be sure to take all of the medicine for the length of time prescribed for you.** If you stop taking your medicine too soon, the bacteria can grow back and you may get sick again with the same infection.
- Take Cefaclor by mouth, with or without food.
- Shake your bottle well every time before taking the medicine.
- If you miss taking a dose of Cefaclor, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose and take your medicine as scheduled. Do not take double your prescribed dose.
- If you think that someone may have taken more than the prescribed dose of this medicine, call your poison control center or emergency room right away.

Prescription Medicine Information

What are the possible side effects of Cefaclor for Oral Suspension?

The most common side effects are mild upset stomach, diarrhea, and rash. Call your healthcare provider if these side effects bother you or do not go away.

Call your healthcare provider right away if the following side effects occur:

- swelling of the throat or trouble breathing
- hives, itching, and rash
- severe or bloody diarrhea
- stomach area pain
- tiredness or faintness (that lasts after taking this medicine for 24 hours)
- fever (that lasts after taking this medicine for 24 hours)
- joint aches or stiffness (that lasts after taking this medicine for 24 hours)

How should I store Cefaclor for Oral Suspension?

- **Keep Cefaclor for Oral Suspension in the refrigerator.**
- Throw away any unused Cefaclor after the expiration date.

This medicine was prescribed for your particular condition. Do not use it for another condition or give the medicine to others.

This leaflet provides a summary of information about Cefaclor and does not contain all possible information about this drug. If you have any questions or concerns, or want more information about Cefaclor, call your healthcare provider or pharmacist. Your pharmacist also has a longer leaflet about Cefaclor that is written for health professionals that you can ask to read.

[Name of publisher and date of most recent publication or revision]

Prescription Drug Information

Cefaclor for Oral Suspension

Summary

Cefaclor (pronounced sef-ah-klor) is used to treat infections caused by certain bacteria. You should not take Cefaclor if you are allergic to similar antibiotics. Allergic reactions to Cefaclor can cause death. If you have trouble breathing, swelling of the throat, rash, severe diarrhea, or stomach area pain, call your healthcare provider right away or get medical help.
Take Cefaclor for the length of time prescribed by your healthcare provider, even if you feel better.
Shake your bottle well every time before taking Cefaclor.

Uses

Cefaclor is used to treat infections caused by certain bacteria. These infections include middle ear, bladder, and skin infections, as well as strep throat and pneumonia. Cefaclor works by killing certain bacteria or preventing them from growing.

Cefaclor is in a class of medicines known as cephalosporin antibiotics. These medicines are sometimes prescribed for uses other than those listed in this leaflet. If you have any questions please call your doctor or other prescriber.

General Cautions

- **Do not take Cefaclor if you are allergic to other cephalosporin-class antibiotics**. Allergic reactions to Cefaclor can cause death.

This medicine may not be for you. Check with your healthcare provider if you:

- have diabetes. Cefaclor can interfere with the urine test you may be using to test for sugar.
- have kidney disease.
- have colitis or other stomach or intestine problems.
- are pregnant or are breast-feeding.
- are allergic to penicillin or other antibiotic medicines.

Proper Use

- Follow your healthcare provider's advice about how to take Cefaclor. Continue taking Cefaclor even if you feel better. Be sure to take all of the medicine prescribed for you. If you stop taking your medicine too soon, the bacteria can grow back and you may get sick again with the same infection.

Prescription Drug Information

- **Shake your bottle well every time before taking this medicine.**
- If you miss taking a dose of Cefaclor, take it as soon as you remember. However, if it is almost time for your next dose, skip the missed dose and take your medicine as scheduled. Do not take double your prescribed dose.

Possible Side Effects

The most common side effects are mild upset stomach, diarrhea, and rash. Call your healthcare provider if these side effects continue or bother you.

Call your healthcare provider right away if the following side effects occur:

- Swelling of the throat or trouble breathing
- Hives, itching, and rash
- Severe or bloody diarrhea
- Stomach pain
- Tiredness or faintness (that lasts after taking this medicine for 24 hours)
- Fever (that lasts after taking this medicine for 24 hours)
- Joint aches or stiffness (that lasts after taking this medicine for 24 hours)

Storage

- **Keep Cefaclor for Oral Suspension in the refrigerator.**
- Throw away any unused portion after the expiration date.

Each teaspoon (5 mL) of Cefaclor for Oral Suspension contains 125, 250, or 375 mg of Cefaclor monohydrate and is pink in color.

If you think that someone may have taken more than the prescribed dose of this medicine, call your local poison control center or emergency room right away. This medicine was prescribed for your condition. Do not use it for another condition or give it to others.

This leaflet provides a summary of information about Cefaclor. If you have any questions or concerns, or want more information about Cefaclor, call your healthcare provider or pharmacist. Your pharmacist also has a longer leaflet about Cefaclor that is written for health professionals that you can ask to read.

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