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Off-Label Use of Prescription Drugs

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OFF-LABEL USE OF PRESCRIPTION DRUGS

Since the early 1960s, the Food and Drug Administration (FDA) has required that drugs used in the United States be both safe and effective. The label information -- on the container, in the package insert, in the *Physicians Desk Reference* (PDR), and in any advertising -- can indicate a drug's use only in certain "approved" doses and routes of administration for a particular condition.

The use of a drug for a disease not listed on the label, or in a dose or by a route not listed on the label, is considered to be a "nonapproved" or "unlabel" or "off-label" use of the drug. Physicians, based on their knowledge and on available current information, may use a drug for a use not indicated in the "approved" labeling if it seems reasonable or appropriate. With the rising costs of health care and the desire to curb these costs, the issue of coverage and reimbursement for the "off-label" use of drugs has become an issue.

This bibliography contains selected references to English language publications on the general concept of "off-label" uses of drugs. It includes journal articles, books and book chapters, editorials, and letters to the editor. The NLM wishes to acknowledge the assistance of Drs. Peter Rheinstein and Freddie Ann Hoffman of the Office of Health Affairs, Food and Drug Administration, in final review of this publication.

SEARCH STRATEGY

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SS 3 = (TF) ALL UNLABEL: OR UNAPPROVED OR NONAPPROVED

SS 4 = 3 AND ALL INDICATION# (TF) OR 3 AND ALL CONDITION# (TF) OR 3 AND ALL DRUG# (TF) OR 3 AND ALL DEVICE# (TF) OR 3 AND ALL REGIMEN# (TF) OR 3 AND ALL MEDICATION# (TF)

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SAMPLE CITATION

Citations in this bibliographic series are formatted according to the rules established for *Index Medicus*®*. A sample journal citation appears below.

Journal Article:

Authors *Article Title*

Klecker RJ, Cipolle RJ. Procedures for emergency or treatment use of investigational drugs. Am J Hosp Pharm 1987 May;44(5):1086-9.

Abbreviated Journal Title *Date* *Volume* *Issue* *Pages*

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*For details of the formats used for references, *see* the following publication:

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