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Drugs and Lactation Database (LactMed) - Record Format

Generic Name:

The United States Adopted Name (USAN) of the active portion of the drug is listed. The specific salt (e.g., hydrochloride, sulfate) is usually not included, but the information should be considered to apply to all forms of the active drug unless noted otherwise. Database records usually refer to only one drug, but drugs which are marketed as both racemates and specific isomers are covered in the same record unless there is a good reason to list them separately. For botanical products, the most frequently used common name of the product is given. Numerous synonyms are embedded in LactMed records that allow searches on these names to link to the record.

Scientific Name:

The genus and species name of botanical products is listed here. This field is not used for other types of products.

Summary of Use During Lactation:

This section summarizes important points found in the body of the record. When conflicting data or recommendations are given in published case reports and reviews, the alternative viewpoints are presented with citations to the papers in which they are presented.

Drug Levels:

Some records have a brief description of the drug's metabolism and issues involved in measuring and interpreting drug levels, such as the presence of active metabolites or interference by concurrent drug therapy.

<*Maternal Levels.*> Studies that measured drug concentrations in the breastmilk of humans are summarized. Study results are usually presented in chronological order. Whenever possible, the stage of lactation and time postpartum reported in the paper are presented. Drug concentrations are usually given in mg/L, which might be different from those used in the original paper; very low concentrations might be listed in other units (e.g., ng/L). Data from studies that report molar concentrations are converted to mg/L when the moiety being measured is clear. When a study finds no detectable amount of drug in the milk, the lower limit of the assay is given in parentheses when it is stated in the paper.

When possible, the weight-adjusted (i.e., mg/kg) percentage of the maternal dosage (relative infant dose, RID) ingested by a fully breastfed infant is given from the papers above, provided it was calculated using accepted

methods. These include using milk-to-plasma (M/P) ratios calculated from the areas under the milk and plasma (or serum) concentration curves rather than random time points, and use of the standard infant intake of 150 mL/kg/day of milk. Where only case reports exist, a range of values might be given or a composite number might be calculated from several case reports and studies. Occasionally, the weight-adjusted percentage of the maternal dosage (RID) is calculated using an estimate of 60 kg for the maternal weight when the maternal weight is not stated. If an infant dosage is known, a percentage of the usual infant dosage is given. Estimates from the literature are referenced accordingly. Estimates by the author of the LactMed record explain the calculation method, but provide no specific literature citation for the calculated value.

For most drugs, a weight-adjusted percentage of the maternal dosage (RID) of 10% or less is considered relatively safe; caution is required for drugs excreted in dosages of 10 to 25% of the maternal dosage; and, those few drugs excreted in dosages over 25% of the maternal dosage are considered unacceptable.[1][2] However, if the infant is receiving mixed feeding, the percentages reported for fully breastfed infants should be adjusted downward in proportion to the percentage of intake of breastmilk before assessing the acceptability of the drug during breastfeeding. For drugs with unusually high or low clearance rates (short or long half-lives) the ranges might also need to be adjusted.

<*Infant Levels.*> This section contains serum or urine concentrations of the drug measured in breastfed infants. These data come from literature reports and are referenced accordingly.

Effects In Breastfed Infants:

This section reports all known side effects reported in the scientific literature with an assessment of the likelihood that the event was caused by the medication using the Naranjo adverse drug reaction assessment methodology.[3] In this system, an adverse reaction can be rated as "definite", "probable", "possible", or "unlikely" to have been caused by the medication in question. Virtually all reported adverse effects from medications in mother's milk are probable or possible. Unlikely reactions are usually not included unless they have been widely purported to be drug related. For grammatical purposes, the words "probably" and "possibly" are often used to designate the Naranjo categories of "probable" and "possible", respectively.

Few studies rigorously document the safety of maternal drug use during lactation, but if they exist, they are described here. Where documentation indicates some degree of safety during breastfeeding, or refutes or mitigates case reports of infant toxicity, these publications are described. When possible, the number of infants exposed to the drug in breastmilk without adverse reactions is enumerated.

Effects on Lactation and Breastmilk:

In this section, all known possible effects of the drug on lactation are listed. Information may be extrapolated from reports or studies on drugs with similar pharmacology that would be expected to have the same effect on lactation (e.g., dopaminergic drugs). In these cases, the drug that has actually caused the effect is stated. Because the mother and infant interact as a unit to regulate milk supply, plausible indirect effects of drugs that may affect the infant's ability to nurse adequately (e.g., sedation) or affect lactation (e.g., breast binding) are mentioned. Cases of gynecomastia and galactorrhea are reported in this section when relevant. Drug effects on serum prolactin are included in this section. These drugs might not have been reported to cause effects on lactation, but it is possible that they could affect lactation under some circumstances. In addition, any drug effects on the normal components of breastmilk are reported in this section.

Alternative Drugs to Consider:

This section lists drugs marketed in the United States that have uses similar to the drug under discussion and that have a record included in the LactMed database. The list of drugs may not be comprehensive and alternate drugs for uncommon uses may not be included. If the drug has more than one common use, the alternate drugs may be grouped according to the condition being treated. The clinician should consult the information provided

on the alternate drugs and other prescribing information before deciding on the best course of therapy for a specific patient. Alternative substances for dietary supplements are usually not provided.

References:

This is a bibliography of all articles cited in the record. Each citation in the list is hypertext linked to the record of that article in PubMed if such record exists. If an article is not listed in PubMed, a hyperlink to the article using the digital object identifier (doi) is provided if it is available. This allows the reader to read the abstract or link to the full text document as their availability permits.

CAS Registry Number:

The Chemical Abstracts Service Registry Number of the parent compound (i.e., not the salt form) is listed. This field is searchable in LactMed.

Drug Class:

The drug class or classes to which the drug belongs are listed alphabetically. Classes are named using terminology identical to or consistent with MeSH headings for that class in order to ensure proper mapping by existing NLM algorithms. Searching this field in LactMed will provide a list of all drugs in a particular drug class in the database.

LactMed Record Number:

An internal NLM number that identifies the record.

Last Revision Date:

This field designates the date of the last revision to this record. The first 4 characters designate the year, the next 2 designate the month and the last 2 designate the day of the month. This field is not searchable.

References

1. Bennett PN, ed. Drugs and human lactation, 2nd ed. Amsterdam. Elsevier. 1996.
2. Bennett PN, Notarianni LJ. Risk from drugs in breast milk: an analysis by relative dose. Br J Clin Pharmacol. 1996;42:673–4. P. Abstract.
3. Naranjo CA, Busto U, et al. A method for estimating the probability of adverse drug reactions. Clin Pharmacol Ther. 1981;30:239–45. PubMed PMID: 7249508.