

PharmaNet Bulletin

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Refined Severity Levels and New Clinical Effect Codes

Drug-Drug Interaction Module™ (DDIM)

Effective February 24, 2005, First DataBank is introducing the following changes to the Drug-Drug Interaction Module™ (DDIM):

- Refined description of drug interaction Severity Level 1, resulting in the reclassification of certain drug-drug interactions to Severity Level 2; and
- Four new clinical effect codes.

Refined Description of Severity Level 1

The description of Severity Level 1 will be refined to exclude drugs with interaction descriptions that contain the phrase “concurrent use should be avoided.” Drugs with interaction descriptions containing this phrase will be reassigned to Severity Level 2 (instead of Severity Level 1) and return the Clinical Effect Code AVD.

For a complete list of Drug Interaction Severity Levels and their descriptions, please see page two of this bulletin.

New Clinical Effect Codes

Four new Clinical Effect Codes will notify clinicians when information in a DDIM monograph may be especially useful in managing an interaction:

| Code | Description | Details |
|------|--|---|
| CEE | Conflicting evidence exists in the medical literature. | Indicates that some literature suggests that a combination contraindicated by the manufacturer can be used in some patients. |
| AVD | Avoid concurrent use when possible. | Indicates that the manufacturer labelling for an interaction states that “concurrent use should be avoided.” These are the interactions that have been reclassified from Severity Level 1 to Severity Level 2 effective February 24, 2005. |
| CIS | Contraindicated in some patients. | Identifies Severity Level 2 interactions that are contraindicated in some patients such as the elderly or those with renal impairment. The populations for whom the drug combination is contraindicated are identified in the DDIM monograph. |
| LBC | Labelling content conflicts between countries or products. | Identifies interactions for which labelling differs between: <ul style="list-style-type: none"> • products (e.g., labelling on one product says to “avoid” the drug combination while labelling on another product says the combination is “contraindicated”), or • countries (e.g., U.S. labelling says to “use caution” with the combination while Canadian labelling says the combination is “contraindicated”). |

Severity Levels for Drug Interactions

| Severity Level | Description | Action / Details |
|----------------|----------------------------------|--|
| 1 | Contraindicated drug combination | Drug combination is clearly contraindicated in all cases and should not be dispensed or administered to the same patient. |
| 2 | Severe interaction | <p>Action is required to reduce risk of severe adverse interaction.</p> <p>Indicates drug combinations that can produce serious consequences in most patients, but that can be monitored and/or the agent(s) titrated, significantly minimizing the risk of adverse effects.</p> <p>The drug combination may be absolutely contraindicated in some patients, but not in all patients. The information required to identify those patients in whom the combination is contraindicated is provided in the corresponding DDIM monograph. Drugs that must never be given at the same time, but can be administered on a staggered schedule, are also included in the DDIM monograph.</p> <p>Note: DDIM monographs are available through PharmaNet via additional software functionality. Contact your software vendor to determine whether or not your software provides this functionality.</p> |
| 3 | Moderate interaction | <p>Assess risk to patient and take action as needed.</p> <p>Indicates interactions of moderate severity. The clinician should assess the individual patient characteristics and take action as needed. The action required can include discontinuation of one or both agents, adjusting dosage, altering the administration schedule or performing additional patient monitoring.</p> |