




**Cerner Multum
CMI Testimony**

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Corporate Overview Tuesday August 05 2003

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History

- Founded 1992
- Acquired by Cerner Corporation, 1998
- Provide full complement of drug product information
- Consumer Medication Information Sheets developed and distributed since 1998
- Based in Denver, Colorado


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Today

- Approximately 100 Clients
- EMR/HIS Suppliers
 - Cerner, Eclipsys, EPIC, others
- Pharmacy Benefit Management Companies
 - Medco Health
- Pharmacy System Suppliers
 - Cerner, others
- Web Portals
- Traditional Publishers

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What steps is the private sector taking to improve the usefulness of the written information patients receive with prescription drugs and to meet the Year 2006 goal?

Cerner Multum has been providing patient education leaflets (PEL) since 1998, designed to be compliant with MedGuide 1996. The leaflets are created by pharmacists, reviewed by outside experts in clinical practice, and continuously updated using resources such as new package information and MedWatch alerts.

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Patient Education Leaflets

- Drug-specific information in English and Spanish
- Written on a 6th to 8th grade reading level
- Spanish is optimized for needs of North American Spanish speakers
- Developed in compliance with the 1996 FDA MedGuide recommendations
- Include important side effect, drug interaction, and drug administration instructions
- Includes leaflets for herbal remedies and OTC products
- Provides graphical icons to illustrate important hazards

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MI Key Features

- Full Text – comprehensive descriptions of medicines and their effects including FDA approved indications
- Subdivided into specific sections with distinct section headers

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■ **Phonetic pronunciation of the drug entity**

- Age-specific (pediatric/geriatric) information and precautions
- Renal and liver precautions
- Gender-specific precautions

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- Available in multiple print formats including web-enabled
- One to two legal size pages in length
- Detailed procedures and tools utilized to assure standard compliance with the MedGuide recommendations.

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Layout Sample

Generic Drug Name

Phonetic Pronunciation

Brand Names

What is the most important information I should know about (name of drug) ?

A summary section containing critical aspects of proper use, significant warnings, precautions, and/or contraindications, serious adverse reactions, and potential safety hazards.

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What is (name of drug)?

A section that identifies a drug product's indications for use, what class the drug is in and how the drug works.

Off-label used (FDA unapproved indications) are tagged separately to allow the institution to decide whether these should be printed). Also, a statement that "Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide".

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Who should not take (name of drug)?

Information on when the drug product should not be used (contraindications), and on conditions or circumstances that may require cautious use of the medication, dosage adjustment or special monitoring (precautions).

Information related to use of the medication during pregnancy or breast-feeding.

Specific warnings or concerns regarding use of the medication in geriatric or pediatric populations.

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How should I take (name of drug)?

Information on the proper use of the drug product, including.

A statement stressing the importance of adhering to the dosing instructions.

A statement or statements describing special instructions on how to prepare and/or administer the drug product.

A description of the recommended storage of the drug.

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What should I do if I miss a dose of (name of drug)?

A statement of what the patient should do if they miss taking a scheduled dose of the drug product.

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What should I do if I overdose?

Information on what the patient should do in case of an overdose of the drug product and the possible symptoms of an overdose.

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What should I avoid while taking (name of drug)?

Statement(s) that identify activities (such as driving or sunbathing), And drugs, foods, or other substances (such as tobacco or alcohol) that the patient should avoid, including why they should be avoided.

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What are the possible side effects of (name of drug)?

Possible serious side effects that require immediate medical attention followed by a list of those side effects

Less serious side effects that may occur, and that the patient should discuss them with their provider at a convenient time, followed by a list of those side effects

Statement that tolerance to or dependence on the drug product may occur (if applicable) Also a statement that side effects other than the ones listed may occur and patient should contact their healthcare provider with questions.

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What other drugs will interact with this drug?

Statements describing other drugs that will interact with the index drug and how this may affect the prescribed treatment.

Also a statement that drug interactions other than the ones listed may occur and patient should contact their healthcare provider with questions.

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Where can I get more information?

Example: Your pharmacist has additional information about (drug) written for health professionals that you may read.

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What does the medication look like?

Statements describing how the medication is available (over-the-counter or prescription) and common brand names for the drug.

Description of shape, color, and dose form for each strength of the medication available.

A statement such as "Formulations other than those listed may also be available. Ask your pharmacist any questions you have about this medication, especially if it is new to you."

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Date and Author

The date of the most recent revision of the Medication guide

Disclaimer

Content not intended to cover all possible uses, directions, or precautions, etc. If questions check with your health care provider.

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2. What barriers exist for the private sector to meet the Year 2006 goal, and what plans exist to overcome these barriers?

Cerner Multum has the resources of intellectual property and technology to meet the Year 2006 goal.

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Major challenges for dispensing pharmacies are

- 1) Technological resources to retrieve electronically the latest published CMI in a timely manner
- 2) Incorporation of a more lengthy CMI into the IT systems/workflow.

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3. What should the role of FDA be in assuring full implementation of the Action Plan to meet the Year 2006 goal?

FDA should encourage independent entities, e.g., publishers of healthcare information having no conflict of interest to the sale of the product, to provide unbiased, well-researched, informative and complete patient education information. Independent providers will provide a mechanism for consistent presentation and format of patient medication information for multiple therapeutic classes of drugs.

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