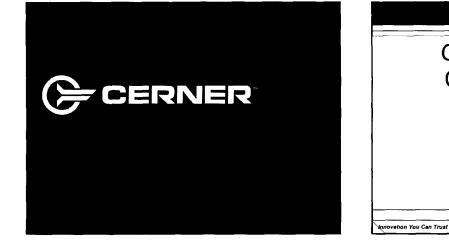
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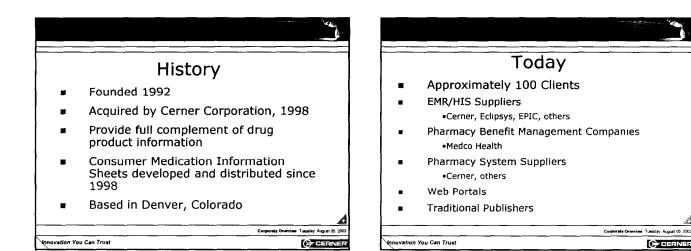


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Cerner Multum CMI Testimony

Gerry Hobson, RPh Research Manager

July 31, 2003

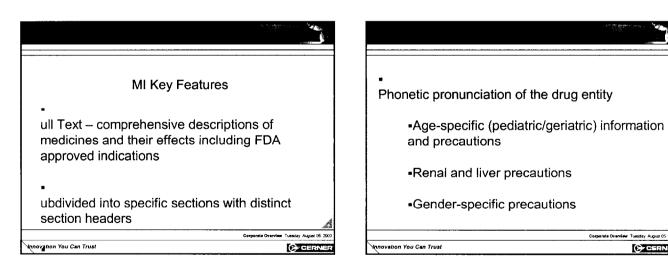


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	Patient Education Leaflets
What steps is the private sector taking to improve the usefulness of the written information patients receive with prescription drugs and to meet the Year 2006 goal?	 Drug-specific information in English and Spanish Written on a 6th to 8th grade reading level Spanish is optimized for needs of North American
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	 Spanish speakers Developed in compliance with the 1996 FDA MedGuide recommendations
outside experts in clinical practice, and continuously updated using resources such as new package information and MedWatch	 Include important side effect, drug interaction, and drug administration instructions
alerts.	 Includes leaflets for herbal remedies and OTC products
Carports Overley Tussity August 05 2003	Provides graphical icons to illustrate important bazards Compare Overland Tustor August 6
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a the second	
 Available in multiple print formats includin 	g Layout Sample Generic Drug Name
web-enabled	
 One to two legal size pages in length 	Phonetic Pronunciation
	Brand Names
 Detailed procedures and tools utilized to assure standard compliance with the 	What is the most important information I should know about (name of drug) ?
MedGuide recommendations.	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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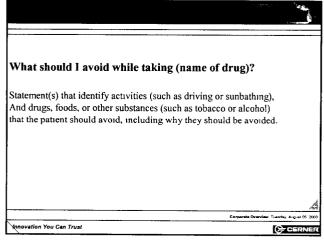
What is (name of drug)?	Who should not take (name of drug)?
A section that identifies a drug product's indications for use, what class the drug is in and how the drug works.	Information on when the drug product should not be used (contraindications), and on conditions or circumstances that may require cautious use of the medication, dosage adjustment or special monitoring (precautions).
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".	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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a dose of (name of drug)?
haveld do af the second on the law is a
hould do 1f they miss taking a ict.

What should I do if I overdose?	What sh
Information on what the patient should do in case of an overdose of the drug product and the possible symptoms of an overdose.	Statements And drugs that the pa
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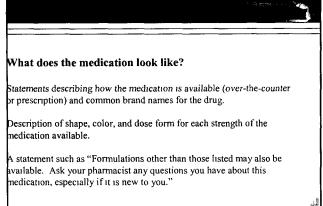


What are the possible side effects of (name of drug)?		What other drugs will interact with this drug?	
Possible serious side effects that require immediate medical attention	on		
followed by a list of those side effects		Statements describing other drugs that will interact with the ind drug and how this may affect the prescribed treatment.	lex
less serious side effects that may occur, and that the patient should		Č V I	
liscuss them with their provider at a convenient time, followed by		Also a statement that drug interactions other than the ones	
ist of those side effects		listed may occur and patient should contact their healthcare provider with questions.	
Statement that tolerance to or dependence on the drug product may		provider with questions.	
occur (if applicable) Also a statement that side effects other than			
he ones listed may occur and patient should contact their healthcar	re 🔰		
provider with questions.			
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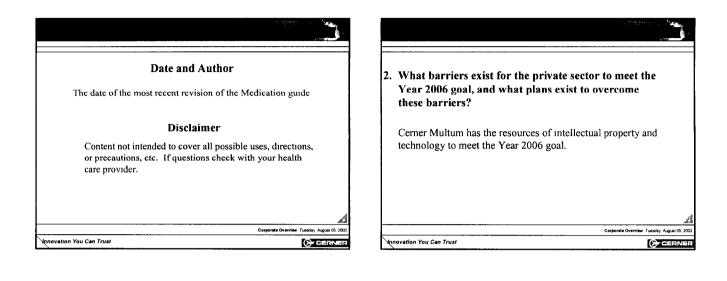
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Where can I get more information?	What does the medication look li
Example: Your pharmacıst has additıonal ınformation about (drug) written for health professionals that you may read.	Statements describing how the medication or prescription) and common brand name
	Description of shape, color, and dose for medication available.
	A statement such as "Formulations other available. Ask your pharmacist any ques medication, especially if it is new to you
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1) Te	Major challenges for dispensing pharmacies are echnological resources to retrieve electronically the atest published CMI in a timely manner	3. What should the role of FDA be in assuring full implementation of the Action Plan to meet the Year 2006 goal?
· · · ·	ncorporation of a more lengthy CMI into the IT ystems/workflow.	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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