Example of Fictional Highlights of Prescribing Information  
(Based on Proposed Physician Labeling Rule)

OCRACEPHALOSE® [fictional drug]  
(Rx spurilous hypothetic chloride) Tablets or Capsules for oral use [fictional drug]

-----------------------RECENT LABELING CHANGES--------------------------
Warnings/Precautions, Depression (5.3)

------------------------INDICATIONS AND USAGE---------------------------
• Adjunct therapy with a sulfonylurea to lower blood glucose in patients with Type 2 diabetes whose hyperglycemia cannot be controlled by diet and exercise (1.1)

----------------------DOSAGE AND ADMINISTRATION-----------------------
• Initial dose is 100 mg once every morning and may be titrated up to 300 mg (2.1)

----------------------------------HOW SUPPLIED-------------------------------------
• Tablets: 100 mg (3)  
• Capsules: 100 mg (3)

-------------------------------CONTRAINDICATIONS------------------------------
• Hepatic impairment (4)

------------------------WARNINGS/PRECAUTIONS---------------------------
• Hepatic dysfunction leading to acute liver failure may occur, typically within 3 months of initiation (5.2)  
• Evaluate liver function prior to initiating Ocracephalose and monitor weekly for 3 months. Discontinue if LFTs increase > 3 times upper limit of normal (5.2)  
• Severe depression with suicidal ideation occurred in 2% of patients. Discontinue Ocracephalose or initiate antidepressant therapy if depression occurs (5.3)  
• Hypoglycemia can occur with insufficient caloric intake and use of alcohol (5.5, 6.2)  

Most Common Adverse Reactions (> 5%) (8)
• somnolence, dry mouth, nightmares, and sexual disorders

To report SUSPECTED SERIOUS ADRs, call (manufacturer) at (phone #) or FDA's MedWatch at 1-800-FDA-1088

------------------------DRUG INTERACTIONS-----------------------------
• Domecattus reduce domecattus dose by one-half (5.4, 6.1)
• Alcohol: increases incidence of hypoglycemia (6.2)

------------------------USE IN SPECIFIC POPULATIONS---------------------
• Hepatic impairment: Contraindicated in patients with hepatic impairment (4, 7.6)

---See P for PATIENT COUNSELING INFORMATION and ---
Ocracephalose’s approved patient labeling

These highlights do not include all the information needed to prescribe Ocracephalose safely and effectively. See Ocracephalose’s comprehensive prescribing information provided below.

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