

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

OCRACEPHALOSE® [fictional drug] **Rx**
(spurious hypothetical 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.

Revised: 12/2003