

Example of Fictional Highlights of Prescribing Information (Based on Proposed Physician Labeling Rule) Translated in Consumer-Friendly Language and Formatted for Use in Consumer-Directed Advertisement

OCRACEPHALOSE [fictional drug]
Spurilous Hypothetic Chloride tablets or capsules [fictional drug]

Ocracephalose is used to treat patients with diabetes when diet and exercise alone do not lower blood sugar. Ocracephalose has only been shown to work in combination with other diabetes medications. Ocracephalose is taken by mouth as a tablet or capsule.

- **You Should Not Take OCRACEPHALOSE if . . .**

You have liver disease.

- **Warning**

Do not take Ocracephalose alone to treat your diabetic condition, that is, your elevated blood sugar. Ocracephalose must be used along with other diabetes medications.

Do not drink alcohol, including beer, wine, and liquor, because it increases your chance of getting a very low blood sugar (hypoglycemia). Hypoglycemia can also occur if you do not eat enough during the day.

Ocracephalose can affect your liver function. Tell your doctor if you notice that you are developing yellowing of the skin and whites of the eyes and easy bruising. These are symptoms of changes in your liver function.

Some patients taking Ocracephalose have become severely depressed. If you feel sad or hopeless you should tell a friend or family member immediately and call your health care provider right away! Your health care provider may ask that you stop taking Ocracephalose or recommend that you take a medication for your depression.

- **The Most Common Side Effects Are . . .**

In about 1/3 of users, Ocracephalose also causes sleepiness that generally decreases after the first 2 weeks of use. Less often, Ocracephalose causes dry mouth, vivid dreams, and sexual problems

This listing of side effects is not complete. Your health care professional can discuss with you a more complete list of side effects that may occur when taking Ocracephalose.

- **What I Should Know About Taking OCRACEPHALOSE with Other Medication . . .**

Because Ocracephalose changes the effect of some other medications when taken together, tell your health care provider if you are also taking Felidazone (domecattus chloride tablets), because your dose of Felidazone should be reduced by one-half if you are also taking Ocracephalose.

Always talk to your health care provider before starting any new medications.

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