Important Safety Information

**Indication:** ORACEA® (doxycycline, USP) 40 mg* Capsules are indicated for the treatment of only inflammatory lesions (papules and pustules) of rosacea in adult patients. ORACEA Capsules do not lessen the facial redness caused by rosacea.

**Adverse Events:** In controlled clinical studies, the most commonly reported adverse events (2%) in patients treated with ORACEA Capsules were nasopharyngitis, sinusitis, diarrhea, hypertension and aspartate aminotransferase increase.

**Warnings/Precautions:** ORACEA Capsules should not be used to treat or prevent infections. ORACEA Capsules should not be taken by patients who have a known hypersensitivity to doxycycline or other tetracyclines. ORACEA Capsules should not be taken during pregnancy, by nursing mothers, or during tooth development (up to the age of 8 years). Although photosensitivity was not observed in clinical trials, ORACEA Capsules patients should minimize or avoid exposure to natural or artificial sunlight. The efficacy of ORACEA Capsules treatment beyond 16 weeks and safety beyond 9 months have not been established.

*30 mg immediate release & 10 mg delayed release beads
You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

**Cannot be used in combination with Galderma CareConnect.**

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Galderma Laboratories, L.P.,
14501 N. Freeway Fort Worth, TX 76177
USMP/ORA/0034/0720  08/20

FOR MORE INFORMATION,
PLEASE SEE THE ORACEA CAPSULE
BRIEF SUMMARY INSIDE
Important Safety Information

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Galderma Laboratories, L.P.,
14501 N. Freeway Fort Worth, TX 76177
USMP/ora/0034/0720 08/20
IMPORTANT INFORMATION ABOUT
Oracea® (doxycycline, USP) 40 mg* Capsules
*30 mg Immediate Release & 10 mg Delayed Release Beads

BRIEF SUMMARY
This summary contains important information about ORACEA (Or-RAY-sha) Capsules. It is not meant to take the place of your doctor’s instructions. Read this information carefully before you start taking ORACEA Capsules. Ask your doctor or pharmacist if you do not understand any of this information or if you want to know more about ORACEA Capsules. For full Prescribing Information and Patient Information please see the package insert.

WHAT IS ORACEA CAPSULES?
ORACEA Capsules are a tetracycline class medicine. ORACEA Capsules are a prescription medicine to treat only the pimples or bumps (papules and pustules) caused by a condition called rosacea. ORACEA Capsules do not lessen redness caused by rosacea. ORACEA Capsules should not be used for the treatment or prevention of infections. It is not known if ORACEA Capsules are effective for use longer than 16 weeks, safe for use longer than 9 months, or safe and effective in children. ORACEA Capsules should not be used in infants and children less than 8 years of age because it may cause stained teeth in infants and children.

WHO SHOULD NOT TAKE ORACEA CAPSULES?
Do not take ORACEA Capsules if you are allergic to doxycycline or other medicines in the tetracycline class. Ask your doctor or pharmacist for a list of these medicines if you are not sure.

WHAT SHOULD I TELL MY DOCTOR BEFORE TAKING ORACEA CAPSULES?
Before you take ORACEA Capsules tell your doctor if you:
• have kidney problems.
• have liver problems.
• have diarrhea or watery stools.
• have vision problems.
• have had surgery on your stomach (gastric surgery).
• have or had a yeast or fungal infection in your mouth or vagina.
• have any other medical condition.
• are pregnant or planning to become pregnant. ORACEA Capsules may harm your unborn baby. Taking ORACEA Capsules while you are pregnant may cause serious side effects on the growth of bone and teeth of your baby. Stop taking ORACEA Capsules and call your doctor right away if you become pregnant while taking ORACEA Capsules.
• are breastfeeding or plan to breastfeed. ORACEA Capsules can pass into your breast milk and may harm your baby. Talk to your doctor about the best way to feed your baby if you take ORACEA Capsules. You and your doctor should decide if you will take ORACEA Capsules or breastfeed. You should not do both.

You should not take ORACEA Capsules if you are male with a female sexual partner who plans to become pregnant at any time while you are being treated with ORACEA Capsules.

Tell your doctor about all of the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. ORACEA Capsules and other medicines can affect each other causing serious side effects.

Especially tell your doctor if you take:
• birth control pills. ORACEA Capsules may reduce the effectiveness of birth control pills. Talk to your doctor about what types of birth control you can use to prevent pregnancy while taking ORACEA Capsules.
• a blood thinner medicine
• a penicillin (antibacterial medicine).
• proton pump inhibitors or antacids that contain aluminum, calcium, or magnesium.
• products containing iron or bismuth subsalicylate.
• a medicine taken by mouth that contains isotretinoin or acitretin.
• a medicine to treat seizures, such as carbamazepine or phenytoin.

Ask your doctor or pharmacist for a full list of your medicines, if you are not sure. Know the medicines you take. Keep a list of your medicines and show it to your doctor and pharmacist when you get a new medicine.

WHAT ARE THE POSSIBLE SIDE EFFECTS OF ORACEA CAPSULES?
ORACEA Capsules may cause serious side effects, including:
• Harm to an unborn baby. See “What should I tell my doctor before taking ORACEA Capsules?”
• Permanent teeth discoloration. ORACEA Capsules may permanently turn a baby or child’s teeth yellow-grey-brown during tooth development. ORACEA Capsules should not be used during tooth development. Tooth development happens in the last half of pregnancy, and from birth to 8 years of age. See “What should I tell my doctor before taking ORACEA Capsules?”
• Intestine infection (pseudomembranous colitis). Pseudomembranous colitis can happen with most antibiotics, including ORACEA Capsules. Call your doctor right away if you get diarrhea or bloody stools.
• Immune system reactions including a lupus-like syndrome, hepatitis, and inflammation of blood or lymph vessels (vasculitis). Stop taking ORACEA Capsules and tell your doctor right away if you get joint pain, fever, rash or body weakness.
• Discoloration (hyperpigmentation). ORACEA Capsules can cause darkening of your skin, scabs, teeth, gums, nails, and whites of your eyes.
• Benign intracranial hypertension, also called pseudotumor cerebri. This is a condition where there is high pressure in the fluid around the brain. The swelling may lead to vision changes and permanent vision loss. Stop taking ORACEA Capsules and tell your doctor right away if you have blurred vision, vision loss, or unusual headaches.

The most common side effects of ORACEA Capsules include:
• soreness in the nose and throat, diarrhea, sinus infection, stomach (abdominal) bloating or pain, fungus infection, high blood pressure (hypertension), flu-like symptoms, and change in certain blood tests.

Tell your doctor if you have any side effect that bothers you or does not go away. These are not all the possible side effects of ORACEA Capsules. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. You may also report side effects to GALDERMA LABORATORIES, L.P. at 1-866-735-4137.

HOW SHOULD I TAKE ORACEA CAPSULES?
• Take ORACEA Capsules exactly as prescribed by your doctor. Taking more than your prescribed dose may increase your chance of side effects, including the chance that bacteria will become resistant to ORACEA Capsules.
• Take ORACEA Capsules 1 time a day in the morning on an empty stomach.
• You should take ORACEA Capsules at least one hour before or two hours after a meal.
• Take ORACEA Capsules with enough fluid to completely swallow the capsule and to lower your risk of getting irritation or ulcer in your esophagus. Your esophagus is the tube that connects your mouth to your stomach.
• If you took too much ORACEA Capsules, call your doctor right away.
• Your doctor may do blood tests during treatment with ORACEA Capsules to check for side effects.

WHAT SHOULD I AVOID WHILE TAKING ORACEA CAPSULES?
• Avoid sunlight or artificial sunlight, such as a tanning booth or sunlamp. You could get severe sunburn. Use sunscreen and wear clothes that cover your skin while out in sunlight.

HOW SHOULD I STORE ORACEA CAPSULES?
• Store ORACEA Capsules at room temperature between 59°F to 86°F (15°C to 30°C).
• Keep ORACEA Capsules in a tightly closed container.
• Keep ORACEA Capsules inside container and out of light.

Keep ORACEA Capsules and all medicine out of the reach of children.

GENERAL INFORMATION ABOUT ORACEA CAPSULES
Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not take ORACEA Capsules for a condition for which it was not prescribed. Do not give ORACEA Capsules to other people, even if they have the same symptoms you have. It may harm them.

This Brief Summary summarizes the most important information about ORACEA Capsules. If you would like more information, talk with your doctor. You can also ask your doctor or pharmacist for information that is written for health professionals.

WHAT ARE THE INGREDIENTS IN ORACEA CAPSULES?
Active ingredient: doxycycline. Inactive ingredients: hypromellose, iron oxide red, iron oxide yellow, methacrylic acid copolymer, polyethylene glycol, Polysorbate 80, sugar spheres, talc, titanium dioxide, and triethyl citrate.

WHERE SHOULD I GO FOR MORE INFORMATION ABOUT ORACEA CAPSULES?
• Talk to your doctor or pharmacist.
• Go to www.oracea.com or call 1-866-735-4137

GALDERMA LABORATORIES, L.P., Fort Worth, Texas 76177 USA
Revised: August 2013
IMPORTANT INFORMATION ABOUT
Oracea® (doxycycline, USP) 40 mg* Capsules
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• a penicillin (antibacterial medicine).
• proton pump inhibitors or antacids that contain aluminum, calcium, or magnesium.
• products containing iron or bismuth subsalicylate.
• a medicine taken by mouth that contains isotretinoin or acitretin.
• a medicine to treat seizures, such as carbamazepine or phenytoin.
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