

THE FIRST AND ONLY ORAL THERAPY APPROVED BY THE FDA TO TREAT ROSACEA*

LEARNING ABOUT ORACEA®

Initial clearing in
just 3 to 4 weeks†

Your doctor has prescribed Oracea because its unique formulation provides safe and effective treatment. Please be aware that there are no generic equivalent medications for Oracea.

ORACEA® CAPSULES ARE DIFFERENT

At higher doses, doxycycline (a commonly used antibiotic drug) has both anti-inflammatory and antimicrobial effects. Oracea is unique because it contains a dose of doxycycline that has only the anti-inflammatory effects. Oracea doesn't work by killing bacteria, it works by controlling inflammation. This is important because:

- Rosacea is a long-term inflammatory condition, not an infection
- Oral antibiotics should be used only for known bacterial infections
- There was no increased risk of antibiotic resistance with Oracea in clinical trials

ORACEA IS EFFECTIVE

Once-daily Oracea is an oral therapy that has been shown in clinical trials to be safe and effective for people living with rosacea. Oracea treats the bumps and pimple-like blemishes of rosacea.

ORACEA IS CONVENIENT

One capsule of Oracea provides 24-hour anti-inflammatory control of your rosacea. Oracea provides highly effective rosacea control in a convenient, once-daily capsule. Generally Oracea is taken in the morning with a full glass of water. Be sure to take Oracea exactly as prescribed by your doctor.

ORACEA CAPSULES ARE SAFE AND WELL-TOLERATED

Patients treated with Oracea in clinical trials had very few side effects. Side effects reported were similar to those reported by patients receiving placebo (sugar pill), such as soreness in the nose and throat (nasopharyngitis), diarrhea, and sinus infection. Photosensitivity and yeast infections were not observed in Oracea-treated patients in clinical trials. Please read important patient information on the back of this sheet.

Important Safety Information

The dosage of Oracea differs from that of doxycycline used to treat infections. To reduce the development of resistant bacteria as well as to maintain the effectiveness of other antibacterial drugs, Oracea should be used only as prescribed by your doctor.

Do not take Oracea if you are allergic to any medicine known as a tetracycline, including doxycycline and minocycline. Oracea may cause harm to a developing fetus; do not take Oracea if you are pregnant. Do not take Oracea if you are breastfeeding. Oracea should not be given to infants and children 8 years or younger because it may cause permanent discoloration of the teeth in these age groups.

Please read important patient information on back.



(doxycycline, USP) 30 mg immediate release & 10 mg delayed release beads

*Oracea is indicated for the treatment of only inflammatory lesions (papules and pustules) of rosacea in adult patients.

†Patients treated with Oracea in clinical trials experienced initial clearing in just 3 to 4 weeks, with improvements continuing through 16 weeks of treatment.

Visit www.oracea.com to register for updates and special offers.

PATIENT INFORMATION

ORACEA® (Or-RAY-sha) (doxycycline, USP) Capsules 40 mg*

*30 mg Immediate Release & 10 mg Delayed Release beads

Read the Patient Information that comes with ORACEA before you start taking it and each time you get a refill. There may be new information. This information does not take the place of talking with your doctor about your treatment or your medical condition. If you have any questions about ORACEA, ask your doctor or pharmacist

What is ORACEA?

ORACEA is a prescription medicine to treat only the pimples or bumps on the face caused by a condition called rosacea. ORACEA may not lessen the facial redness caused by rosacea. ORACEA should not be given to infants and children 8 years or younger. It may cause stained teeth in infants and children. The yellow, gray, brown colored staining will not go away. ORACEA should not be used for the treatment of infections. ORACEA has not been studied for use longer than 9 months.

Who should not take ORACEA?

Do not take ORACEA if you are allergic to any medicine known as a tetracycline, including doxycycline and minocycline. If you are not sure, talk to your doctor or pharmacist.

What should I tell my doctor before taking ORACEA?

Tell your doctor about all your health conditions. Be sure to tell your doctor if you

- have had an allergic reaction to doxycycline or other medicines known as tetracyclines
- are pregnant or planning to become pregnant. ORACEA may harm your unborn baby.
- are breastfeeding. ORACEA passes into your breastmilk and may harm your baby.
- have kidney problems
- have liver problems
- have had surgery on your stomach
- have or had a yeast or fungus infection in your mouth or vagina.
- spend time in sunlight or artificial sunlight, such as a tanning booth or sunlamp. ORACEA may cause you to get severe sunburns [photosensitivity].

Tell your doctor about all of the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

ORACEA and other medicines can affect each other causing serious side effects. Especially tell your doctor if you take

- blood thinners (anticoagulants), such as warfarin or Coumadin®. Your doctor may need to change your anticoagulant dose.
- any medicine to treat pimples (acne) or psoriasis

ORACEA may affect the way other medicines work, and other medicines may affect how ORACEA works. Especially tell your doctor if you take

- birth control pills. Talk to your doctor about other methods of birth control because birth control pills may not work as well when you are taking ORACEA.
- antacid medicines containing calcium, magnesium or aluminum,
- products containing iron
- any medicine to treat an infection
- any medicine to treat seizures, such as barbiturates, Phenobarbital, carbamazepine, Tegretol®, phenytoin or Dilantin®

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.

How should I take ORACEA?

- Take ORACEA exactly as prescribed by your doctor. Do not change your dose unless told to do so by your doctor. Taking more than the prescribed dose may increase your chance of having side effects.
- The usual dose of ORACEA is one capsule in the morning.
- Do not take ORACEA with or right after a meal. It may not work as well. If you take ORACEA close to meal times, you should take it at least one hour before your meal or two hours after your meal.

- Take ORACEA with a full glass of water while sitting or standing. To prevent irritation to your throat, do not lay down right after taking ORACEA.
- Do not take ORACEA with or right after taking antacids or products that contain calcium, aluminum, magnesium, or iron. ORACEA may not work as well.
- If you take too much ORACEA, or overdose, stop taking ORACEA and talk to your doctor.
- If you miss a dose of ORACEA, skip that dose and take the next dose at your regular time.
- Do not take ORACEA to treat infections caused by bacteria germs or viruses.
- Your doctor may do blood tests from time to time to check for side effects of ORACEA.

What should I avoid while taking ORACEA?

- Do not spend time in sunlight or artificial sunlight, such as a tanning booth or sunlamp. You could get a severe sunburn. Use sunscreen and wear clothes that cover your skin if you have to be in sunlight.
- You should not take ORACEA if you are pregnant or breast feeding.
- You should not take ORACEA if you are a man or a woman trying to have a baby.

What are the possible side effects of ORACEA?

ORACEA may cause serious side effects. Stop taking ORACEA and talk to your doctor right away if you

- have any skin rash, redness, or unusual or severe sunburn
- have an allergic reaction, which may cause a skin rash, swelling, difficulty swallowing, or a feeling of tightness in your throat
- become pregnant
- have stomach cramps, high fever, and bloody diarrhea (pseudomembranous colitis)
- have fever, rash, joint pain, and feel tired. These may be symptoms of a problem where your body is attacking itself (autoimmune syndrome).

ORACEA may also cause

- darkening of your skin, scars, teeth, or gums
- severe headaches, dizziness, or double vision from high pressure in the fluid around the brain

Some common side effects of ORACEA are soreness in the nose and throat, diarrhea, and sinus infection. These are not all the possible side effects of ORACEA. For more information, ask your doctor or pharmacist. Tell your doctor if you have a side effect that bothers you or that does not go away.

How should I store ORACEA?

- Store ORACEA at room temperature at 59°F to 86°F (15°C to 30°C).
- Keep ORACEA in a tightly closed container.
- Keep ORACEA inside container and out of light.
- **Keep ORACEA and all medicine out of the reach of children.**

General Information about ORACEA

Do not take ORACEA for a condition for which it was not prescribed. Do not give ORACEA to other people, even if they have the same symptoms you have. It may harm them.

This leaflet gives the most important information about ORACEA. For more information, talk with your doctor or health care provider. You can also ask your doctor or pharmacist for information that is written for health professionals. More Information about ORACEA is available by contacting Galderma Laboratories, L.P. at 1-888-339-5678

What are the ingredients in ORACEA?

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.