One ORACEA Capsule (40 mg) should be taken once daily in the morning on an empty stomach. Efficacy of ORACEA beyond 16 weeks and safety beyond 9 months have not been established.

Indications and Usage:

- ORACEA is indicated for the treatment of moderate to severe rosacea.
- It is not intended for use in allergic reactions to ORACEA or its excipients.

Ingredients:

- Hypromellose, iron oxide red, iron oxide yellow, methacrylic acid copolymer, Polysorbate 80, sugar spheres, talc, titanium dioxide, and triethyl citrate.

General Information:

- Keep ORACEA inside container and out of light.
- ORACEA may cause serious side effects, including:
  - Bleeding
  - Stomach pain or upset
  - Ulcers

Dosage and Administration:

- Take ORACEA exactly as directed. Increasing doses beyond 40 mg every morning may increase the likelihood that bacteria will develop resistance and will not be treatable by other tetracycline antibiotics.

Adverse Reactions:

- Adverse reactions in clinical trials of ORACEA include:
  - Nausea
  - Diarrhea
  - Vomiting

Drug Interactions:

- ORACEA and other medicines can affect each other causing serious side effects.
- Erythromycin may increase the blood levels of ORACEA, which could increase side effects.
- ORACEA 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.

Contraindications:

- Who should not take ORACEA:
  - Pregnant women
  - Nursing mothers
  - Individuals with known drug allergies to ORACEA or its excipients

Warnings and Precautions:

- Photosensitivity can occur with ORACEA; patients should minimize or avoid exposure to natural or artificial sunlight (tanning beds or UVA/B treatment) while using doxycycline. If patients need to be outdoors while using doxycycline, they should wear loose-fitting, long-sleeved clothing and wide-brimmed hats and use a broad spectrum sunscreen with a high SPF.
- Bulging fontanels have been associated with the use of tetracyclines in infants. While both of these conditions and related symptoms usually resolve after discontinuation of the drug, Caution is advised and close observation is recommended.

Dosage Forms and Strengths:

- The dosage of ORACEA differs from that of doxycycline used to treat infections. Exceeding the recommended dosage may result in an increased incidence of side effects including the potential for doxycycline resistance.

Clinical Pharmacology:

- Absorption of doxycycline is minimally affected by food.
- Drug accumulation in patients with renal impairment occurs and may be reduced by dose modification.
- Doxycycline demonstrates linear kinetics following oral and intravenous administration.
- Distribution:
  - The volume of distribution of doxycycline is 250 to 500 liters.
  - The drug is widely distributed in body fluids and tissues.

Pediatric Use:

- No clinical studies have been conducted in children younger than 8 years.
- There are no adequate and well-controlled studies in pregnant women.

Special Populations:

- Distribution:
  - Distribution of doxycycline may be increased in patients with renal impairment.
  - Patients with hepatic impairment may have increased serum levels of doxycycline.

Adverse Reactions in Clinical Trials of ORACEA:

- Common adverse reactions include:
  - Nausea
  - Diarrhea
  - Vomiting
  - Dyspepsia

Drug/Laboratory Test Interactions:

- Aspartate aminotransferase Increase
- Bilirubin Increase
- Glucose Increase

Special Considerations:

- Caution is advised in patients with severe hepatic impairment.
- Monitoring of patients for evidence of systemic drug accumulation is advisable.
- Caution is advised in patients with a history of allergy to penicillins.
- Caution is advised in patients with a history of photosensitivity.

Immunologic Reactions:

- Immune system reactions including a lupus-like syndrome, hepatitis, and inflammation of blood or lymph vessels have occurred with tetracycline therapy.

Bulging fontanels have been associated with the use of tetracyclines in infants. While both of these conditions and related symptoms usually resolve after discontinuation of the drug, close observation is recommended.