Package leaflet: Information for the patient

Oracea 40 mg modified release hard capsules
doxycycline

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to you doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What <Invented name> is and what it is used for
2. What you need to know before you take <Invented name>
3. How to take <Invented name>
4. Possible side effects
5. How to store <Invented name>
6. Contents of the pack and other information

1. What <Invented name> is and what it is used for

<Invented name> is a medicine containing the active substance doxycycline. It is used in adults to reduce the pimples or red bumps on the face caused by a condition called rosacea.

2. What you need to know before you take <Invented name>

DO NOT TAKE <Invented name> - OR - TELL YOUR DOCTOR BEFORE TAKING <Invented name>
- if you are allergic (hypersensitive) to any medicinal product in the tetracycline family, including doxycycline or minocycline, or to any of the other ingredients of this medicine (listed in section 6.)
- if you are pregnant <Invented name> should not be used from the 4th month of pregnancy because it may harm the unborn child. If you suspect or learn that you are pregnant whilst taking <Invented name>, contact your doctor immediately.
- in combination with retinoids (drugs used in the treatment of certain skin disorders such as severe acne) administered by the oral route (see section Other medicines and <Invented name>).
- if you have a condition causing absence of acid in the stomach (achlorhydria) or if you have had surgery on the upper part of the gut (called the duodenum).
- if you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking <Invented name> or other tetracyclines.

<Invented name> must not be taken by infants or children under the age of 12, because it may cause permanent discoloration of the teeth or problems with tooth development.

Warnings and precautions

<Invented name> must not be used to treat infections caused by bacteria.

Talk to your doctor or pharmacist before taking <Invented name> if:
- you have liver disease
- you have a history of predisposition to candidiasis overgrowth or are currently experiencing an oral or vaginal yeast or fungal infection
- you suffer from the muscle disease called myasthenia gravis
- you suffer from colitis
- you suffer from oesophageal irritation or ulceration
- you have the type of rosacea which affects the eyes
- you expose your skin to strong sunlight or artificial sunlight, because more severe sunburn may occur in some people taking doxycycline. You should consider using sunscreen or sunblock to reduce the risk of sunburn and you should stop using <Invented name> if your skin becomes sunburned.
- you have been told by your doctor that you have an intolerance to some sugars

<Invented name> may cause permanent discoloration of the teeth. That permanent discoloration may occur when used during tooth development, and it is more common with long-term use, although it has also been observed after repeated short-term courses.

During your treatment with <Invented name> talk to your doctor or pharmacist if:
- you develop severe or prolonged or bloody diarrhoea during or after using <Invented name> tell your doctor immediately since it may be necessary to interrupt the treatment. This may be a sign of bowel inflammation (pseudomembranous colitis) which can occur following treatment with antibiotics.

Take <Invented name> exactly as prescribed by your doctor. Taking more than your prescribed dose may increase the chance that intestinal bacteria will become resistant to <Invented name>.

Tell your doctor straight away if you get serious skin reactions when taking this medicine, such as fixed drug eruption, skin rash with blistering or peeling, mouth or genital ulcers often with flu-like symptoms (these may be signs of Stevens-Johnson Syndrome (SJS), Toxic Epidermal Necrolysis (TEN) or Drug Rash with Eosinophilia and Systemic Symptoms (DRESS)). If this happens, stop taking the medicine and tell your doctor immediately.

Take special care with <Invented name>:
This medicine can cause serious skin reactions. Stop using <Invented name> and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Other medicines and <Invented name>
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

<Invented name> and certain other medications may not work properly when taken together. Tell your doctor about medications that you are taking or plan to take whilst you are taking <Invented name>.
- <Invented name> should not be used at the same time as the medicine isotretinoin because of the risk of increased pressure in the brain. Isotretinoin is prescribed to patients with a severe case of acne.
- Do not take antacids**,** multi-vitamins or other products that contain calcium (such as milk and dairy products and calcium-containing fruit juices), aluminium, magnesium (including quinapril tablets, which are taken for high blood pressure), iron or bismuth, or cholestyramine,

activated charcoal or sucralfate until 2 to 3 hours after taking <Invented name>. These medicines may reduce the effectiveness of <Invented name> if taken at the same time.
- Other treatments for ulcers or heartburn may also reduce the effectiveness of <Invented name> and should not be taken until at least 2 hours after <Invented name>.
- If you are taking blood thinners, your doctor may need to make changes to the dose of your blood thinner.
- If you are taking certain treatments for diabetes, your doctor may need to check whether the dose of the diabetes treatment has to be changed.
- <Invented name> may make certain antibiotics, including penicillins, less effective.
- Taking barbiturates (sleeping pills or short-term pain-killers), rifampicin (tuberculosis), carbamazepine (epilepsy), diphenylhydantoin and phenytoin (seizures of the brain), primidone (anti-convulsant) or cyclosporin (organ transplant) may reduce the time that <Invented name> stays active in your system.
- Using <Invented name> with the general anaesthetic methoxyfluorane may cause serious harm to the kidneys.

<Invented name> with food and drink
Always take <Invented name> with an adequate amount of water to wash down the capsule, since this reduces the risk of irritation or ulcer in the throat or gullet.

Do not take milk or dairy products at the same time as <Invented name> since these products contain calcium which may reduce the effectiveness of Efracea. Leave 2 to 3 hours after your daily dose of <Invented name> before drinking or eating dairy products.

Pregnancy and breast-feeding
<Invented name> must not be used during pregnancy since it may cause permanent discoloration of the teeth in the unborn child.

<Invented name> should not be used for long periods by breastfeeding mothers since it may cause tooth discoloration and reduced bone growth in the suckling child.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines
<Invented name> has no or negligible influence on the ability to drive and use machines.

<Invented name> contains sugar (sucrose) and allura red AC aluminium lake (E129). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
The ink used to print on the capsule contains Allura red AC aluminium lake (E129) which may cause allergic reactions.

3. How to take <Invented name>

Always take <Invented name> this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is one capsule of <Invented name> each day in the morning, on an empty stomach, preferably at least one hour prior to or two hours after the meal. Swallow the capsule whole

and do not chew it.
You should take <Invented name> with a full glass of water whilst sitting or standing to avoid any irritation to the throat.

If you take more <Invented name> than you should
If you take an overdose of <Invented name>, there is a risk of damage to the liver, kidneys or pancreas. If you take more <Invented name> capsules than you should, ask your doctor immediately for advice.

If you forget to take <Invented name>
Do not take a double dose to make up for a forgotten capsule.

If you stop taking <Invented name>
You should continue to take <Invented name> until your doctor tells you to stop.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop using <invented name> and seek medical attention immediately if you notice any of the following symptoms of serious skin reactions (unknown frequency (cannot be estimated from the available data)) :

- reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome (SJS)/ toxic epidermal necrolysis (TEN))
- Widespread rash, high body temperature, and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).
- Fixed drug eruption.

If any of the side effects listed below occur, contact your doctor as soon as possible:

- The Jarisch-Herxheimer reaction which causes fever, chills, headache, muscle pain, and skin rash that is usually self-limiting. This occurs shortly after starting doxycycline treatment for infections with spirochete such as Lyme disease.

Common side effects
The following side effects may occur commonly (affects 1 to 10 users in 100) during treatment with <Invented name>:

- Inflammation of the nose and throat
- Inflammation of the sinuses
- Fungal infection
- Anxiety
- Sinus headache
- High or increased blood pressure
- Diarrhoea
- Pain in the upper part of the abdomen
- Dry mouth
- Back pain
- Pain
- Changes in some blood tests (amount of glucose in blood or tests of liver function).

Side effects of unknown frequency (cannot be estimated from the available data). The following side effects may occur during the treatment with <Invented name>:

- Increased pressure in the brain
- Headache

Rare side effects

The following side effects may occur rarely (affects 1 to 10 users in 10,000) during treatment with the class of medicines to which <Invented name> belongs (the tetracyclines):

- Allergic (hypersensitivity) reaction throughout the body*
- Changes in the number or type of certain blood cells
- Increased pressure in the brain
- Inflammation of the membrane surrounding the heart
- Nausea, vomiting, diarrhoea, anorexia
- Liver damage
- Skin rashes or hives
- Abnormal reaction of the skin to sunlight
- Increased level of urea in the blood

Very rare side effects

The following side effects may occur very rarely (affects less than 1 user in 10,000) during treatment with the class of medicines to which <Invented name> belongs (the tetracyclines):

- Allergic reaction causing swelling of the eyes, lips or tongue*
- Yeast infection around the anus or genitals
- Damage to red blood cells (haemolytic anaemia)
- Brown-black microscopic discoloration of thyroid tissue has been reported with long-term use of tetracyclines. Thyroid function is normal.
- Increased pressure in the brain in infants
- Inflammation of the tongue
- Difficulty in swallowing
- Inflammation of the intestine
- Inflammation or ulceration of the gullet
- Inflammation of the skin causing flakiness
- Worsening of the immune system disease known as systemic lupus erythematosus (SLE)

Side effects of unknown frequency (cannot be estimated from the available data)

The following side effects may occur during treatment with the class of medicines to which <Invented name> belongs (the tetracyclines). Sometimes, these side effects could occur during treatment with <Invented name>:

- Loosening of the nail from the nail bed after exposure to the sun
- Skin inflammation with peeling (scaling) and/or any severe skin reactions which may cause you to feel very unwell.
- Skin rash that occurs as a recurring reddish or dark spot in the same place after repeated use of doxycycline and may cause itching or burning (fixed drug eruption).

*Tell your doctor immediately or go to casualty if you suffer side effects such as swollen face, lips, tongue and throat, difficulty in breathing, hives or itchy skin and eyes, or rapid heartbeat (palpitations) and feeling faint. These effects may be symptoms of a severe allergic (hypersensitivity) reaction.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in

Appendix V. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store <Invented name>

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the outer pack and blister after EXP. The expiry date refers to the last day of that month.

Store in the original package in order to protect from light.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What <Invented name> contains

- The active substance is doxycycline. Each capsule contains 40 mg doxycycline (as monohydrate).
- The other ingredients are:

hypromellose, methacrylic acid-ethyl acrylate copolymer (1:1), triethyl citrate, talc, titanium dioxide, macrogol 400, yellow iron oxide, red iron oxide, polysorbate 80, sugar spheres (maize starch, sucrose).
Capsules: gelatin, black iron oxide, red iron oxide, yellow iron oxide, titanium dioxide
Printing ink: shellac, propylene glycol, black iron oxide, indigo carmine aluminium lake, allura red AC aluminium lake (E129), brilliant blue FCF aluminium lake, D & C yellow no. 10 aluminium lake.
See end of section 2 for information on sugar (sucrose) and allura red AC aluminium lake (E129).

What <Invented name> looks like and contents of the pack

<Invented name> is a modified-release hard capsule.
The capsules are beige in colour and bear the marking “GLD 40”.
<Invented name> is available in packs containing 56, 28, or 14 capsules (not all pack sizes may be marketed).

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
{Name and address}
<{tel}>
<{fax}>
<{e-mail}>

The manufacturer responsible for batch release is:

Patheon France, 40 boulevard de Champaret
38300 BOURGOIN JALLIEU
France

Or

Laboratoires GALDERMA, Zone Industrielle Montdésir
74540 Alby sur Chéran, France

Or

Galderma Laboratorium GmbH, Toulouser Allee 23a
40211 Düsseldorf, Germany

This medicinal product is authorized in the Member States of the EEA under the following names:
DK, EL, ES, FI, IS, SE, NO – ORACEA 40 mg modified release hard capsules
DE, AT - ORAYCEA 40 mg modified release hard capsules
BE, FR, NL, UK, IE, IT, PL, PT, LU – EFRACEA 40 mg modified release hard capsules

This leaflet was last revised in 2026-10-21