

## Package leaflet: Information for the patient

Efracea 40 mg, capsules with modified release, hard doxycycline

Read the entire 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.
- Do you have any questions? Contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed only for you. It may harm them, even if their symptoms are the same as yours.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor or pharmacist.

### Contents of this leaflet

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#### 1. What is Efracea and what is it used for?

Efracea is a medicine that contains the active substance doxycycline. It is used in adults to reduce the pimples and red bumps on the face caused by a condition called rosacea.

#### 2. When should you not use this medicine or be extra careful with it?

##### When should you not use this medicine?

- You are allergic to a medicine in the tetracycline group, including doxycycline or minocycline, or to any of the substances in this medicine. You can find these substances in section 6.
- If you are pregnant, Efracea should not be used from the 4<sup>th</sup> month, as it can harm the unborn child. If you think or hear that you are pregnant while using Efracea, contact your doctor immediately.
- If you are also using retinoids that need to be taken orally (these are medicines such as isotretinoin used for the treatment of certain skin conditions like severe acne) (see the section 'Are you taking any other medicines?').
- If you have a condition where there is a lack of acid in the stomach (achlorhydria) or if you have had surgery in the upper part of the intestines (duodenum or small intestine).

Efracea should not be taken by infants or children under 12 years, as it can cause permanent discoloration of the teeth or problems with tooth development.

##### When should you be extra careful with this medicine?

Efracea should not be used to treat infections caused by bacteria.

Contact your doctor or pharmacist before using this medicine: - if you have a liver condition

- if you have a history of susceptibility to candidiasis overgrowth or currently have an oral or vaginal yeast or fungal infection
- if you have a muscle disease called myasthenia gravis
- if you have colitis
- if you have esophageal irritation or ulcer
- if you have the type of rosacea that affects the eyes
- if you expose your skin to strong sunlight or artificial sunlight, as more severe burning sometimes occurs in some people taking doxycycline. You should consider using a sunscreen or sunblock to reduce the risk of burning and you should stop using Efracea if your skin becomes burned.
- If your doctor has told you that you cannot tolerate certain sugars.

Efracea can cause permanent discoloration of the teeth.

Tell your doctor or pharmacist if you experience any of the following while being treated with Efracea:

- Experience severe, persistent, or bloody diarrhea during or after using Efracea. Inform your doctor immediately as it may be necessary to discontinue treatment. This could be a sign of an intestinal inflammation (pseudomembranous colitis) that can occur as a result of antibiotic treatment.

Take Efracea exactly as prescribed by your doctor. If you take more than the prescribed dose, the chance of intestinal bacteria becoming resistant to Efracea may increase.

Are you using any other medicines?

Are you using any other medicines besides Efracea, or have you done so recently, or is there a possibility that you will use other medicines in the near future? If so, tell your doctor or pharmacist.

Efracea and certain other medicines sometimes do not work well when taken together. Tell your doctor about any medicines you are taking or plan to take while using Efracea.

- Efracea should not be used at the same time as the medicine isotretinoin, due to the risk of increased pressure in the brain. Isotretinoin is prescribed to patients with severe acne.
- Do not take antacids, multivitamins, or other products containing calcium (such as milk and dairy products and calcium-containing fruit juices), aluminum, magnesium (such as quinapril tablets, taken for high blood pressure), iron or bismuth, or cholestyramine, activated charcoal, or sucralfate until 2 to 3 hours after taking Efracea. These medicines can reduce the effectiveness of Efracea if taken at the same time.
- Other treatments for stomach/intestinal ulcers or excessive stomach acid can also reduce the effectiveness of Efracea and should not be taken until at least 2 hours after Efracea.
- If you are using blood thinners, your doctor may need to adjust the dose of your blood thinner.
- If you are on certain diabetes treatments, your doctor may need to check if the dose of the diabetes treatment needs to be changed.
- Efracea can make certain antibiotics, such as penicillins, less effective.
- Barbiturates (sleeping pills or short-term painkillers), rifampicin (tuberculosis), carbamazepine (epilepsy), diphenylhydantoin and phenytoin (seizures), primidone

(anticonvulsant), or cyclosporine (organ transplantation) can shorten the time Efracea remains effective in your body.

- Efracea together with the general anesthetic methoxyflurane can cause serious kidney damage.

What should you pay attention to with food and drink?

Always take Efracea with plenty of water to swallow the capsule, as this reduces the risk of irritation or ulcer in the throat or esophagus.

Do not take milk or dairy products at the same time as Efracea because these products contain calcium which can reduce the effectiveness of Efracea. Wait 2 to 3 hours after your daily dose of Efracea before consuming dairy products.

Pregnancy and breastfeeding

Efracea must not be used during pregnancy as it can cause permanent discoloration of the unborn child's teeth.

Efracea should not be used for extended periods by breastfeeding mothers as it can cause tooth discoloration and reduced bone growth in the infant.

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medicine.

Driving and using machines

Efracea has no or negligible influence on the ability to drive and use machines.

Efracea contains sugar (sucrose) and Allura Red AC aluminum lake (E129).

If your doctor has told you that you cannot tolerate certain sugars, contact your doctor before taking this medicine.

The ink with which the capsule is printed contains Allura Red AC aluminum lake (E129). This can cause allergic reactions.

### 3. How to use this medicine?

Always use this medicine exactly as your doctor or pharmacist has told you. If you are unsure about the correct use, contact your doctor or pharmacist.

The recommended dosage is 1 capsule of Efracea daily in the morning on an empty stomach, preferably at least one hour before or two hours after a meal. Swallow the capsule whole and do not chew it.

You should take Efracea with a full glass of water while sitting or standing to prevent throat irritation.

Have you used too much of this medicine?

If you take an overdose of Efracea, there is a risk of damage to the liver, kidneys, or pancreas.

If you take more Efracea capsules than you should, ask your doctor for advice immediately.

For Belgium: If you have used or taken too much Efracea, contact your doctor, pharmacist, or the Poison Control Center (070/245.245) immediately.

Have you forgotten to use this medicine?

Do not take a double dose to make up for a forgotten capsule.

If you stop using this medicine

You should continue taking Efracea until your doctor tells you to stop.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

#### 4. Possible side effects

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

Contact your doctor as soon as possible if any of the following side effects occur:

The Jarisch-Herxheimer reaction, which causes fever, chills, headache, muscle pain, and skin rash, usually resulting in limitations. This reaction occurs shortly after starting Efracea treatment for spirochete infections such as Lyme disease.

#### Common side effects

The following side effects are common (in 1-10 out of 100 users) during treatment with Efracea:

Inflammation of the nose and throat

Inflammation of the sinuses

Fungal infection

Feelings of anxiety

Sinus headache

High or increased blood pressure

Diarrhea

Pain in the upper part of the abdomen

Dry mouth

Back pain

Pain

Changes in some blood values (amount of sugar in the blood or liver function tests).

Side effects with unknown frequency (cannot be determined from the available data)

The following side effects may occur during treatment with Efracea:

Increased pressure in the brain

Headache

#### Rare side effects

The following side effects are rare (in 1-10 out of 10,000 users) during treatment with the group of medicines to which Efracea belongs (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 around the heart  
Nausea, vomiting, diarrhea, anorexia  
Liver damage  
Skin rash or hives  
Abnormal skin reaction to sunlight  
Increased urea levels in the blood

#### Very rare side effects

The following side effects are very rare (in less than 1 in 10,000 users) during treatment with the group of medicines to which Efracea belongs (tetracyclines):

Allergic reaction causing swelling of eyes, lips, and tongue\*  
Yeast infection around the anus or genitals  
Damage to the red blood cells (hemolytic anemia)  
Brown-black microscopic discoloration of thyroid tissue has been reported with prolonged use of tetracyclines. Thyroid function is normal.  
Increased pressure in the brain in infants  
Inflammation of the tongue  
Problems with swallowing  
Inflammation of the intestines  
Inflammation or ulcer of the esophagus  
Inflammation of the skin causing flakiness  
Deterioration of the immune system, a condition known as systemic lupus erythematosus (SLE)

Side effects with unknown frequency (cannot be determined from the available data)

The following side effects occur during treatment with the group of medicines to which Efracea belongs (tetracyclines):

Detachment of the nail from the nail bed after sun exposure

Tell your doctor immediately or go to the emergency room if you experience side effects such as:

Swollen face, lips, tongue, and throat, breathing difficulties, hives or itchy skin and eyes, or rapid heartbeat (palpitations) and feeling faint. These side effects may be symptoms of a severe allergic (hypersensitivity) reaction.

#### Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects, you can help us obtain more information about the safety of this medicine.

Belgium  
Federal Agency for Medicines and Health Products  
Vigilance Department  
EUROSTATION II  
Victor Hortaplein, 40/40  
B-1060 Brussels  
Website: [www.fagg.be](http://www.fagg.be)  
e-mail: [patientinfo@fagg-afmps.be](mailto:patientinfo@fagg-afmps.be)

Netherlands  
Netherlands Pharmacovigilance Centre Lareb  
Website: [www.lareb.nl](http://www.lareb.nl)

## 5. How to store this medicine?

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. It can be found on the outer packaging and the blister after "Exp". It includes a month and a year. The last day of that month is the expiry date.

Store in the original packaging to protect from light.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. They will then be destroyed responsibly and will not enter the environment.

## 6. Contents of the packaging and other information

What substances are in this medicine?

- The active substance is doxycycline. Each capsule contains 40 mg doxycycline (as monohydrate).
- The other substances in this medicine 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 aluminum lake, Allura Red AC aluminum lake (E129), brilliant blue FCF aluminum lake, D & C yellow no. 10 aluminum lake. For information on sugar (sucrose) and Allura red AC aluminum lake (E129): see the end of section 2.

What does Efracea look like and what is in a package? Efracea is a hard capsule with controlled release.

The capsules are beige in color, marked with "GLD 40".

Efracea is available in packages of 14, 28, and 56 capsules (not all package sizes may be marketed).

Method of delivery: on medical prescription.

Marketing authorization holder and manufacturer Marketing authorization holder Galderma Benelux B.V.  
Gravinnen van Nassauboulevard 91  
4811 BN Breda  
Netherlands

The manufacturer responsible for batch release is  
Catalent UK Packaging Limited, Lancaster Way, Wingates Industrial Estate, Westhoughton,  
Bolton, Lancashire BL5 3XX, United Kingdom

PATHEON France, 40 boulevard de Champaret, 38300 BOURGOIN JALLIEU, France

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

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

Marketing authorization number

In the Netherlands: RVG 33759

In Belgium: BE391133

This medicine is registered in EEA member states under the following names:

Denmark, Greece, Spain, Finland, Iceland, Sweden, Norway - ORACEA 40 mg modified-release capsule, hard

Germany, Austria - ORAYCEA 40 mg modified-release capsule, hard

Belgium, France, Netherlands, United Kingdom, Ireland, Italy, Poland, Portugal, Luxembourg - EFRACEA 40 mg modified-release capsule, hard

This leaflet was last approved in October 2019.