EFRacea® 40 mg modified release hard capsules

Package leaflet: Information for the patient
Efracea 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 your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Efracea is and what it is used for

Efracea 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 Efracea

Do not take Efracea
- 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 Efracea 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 Efracea, 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 Efracea).
- 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).

Efracea must not be taken by infants or children under the age of 12, because it may cause permanent discolouration of the teeth or problems with tooth development.

Warnings and precautions
Efracea must not be used to treat infections caused by bacteria.
Talk to your doctor or pharmacist before taking Efracea 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 a sunscreen or sunblock to reduce the risk of sunburn and you should stop using Efracea if your skin becomes sunburned.
- you have been told by your doctor that you have an intolerance to some sugars

Efracea may cause permanent discolouration of the teeth.
During your treatment with Efracea talk to your doctor or pharmacist if:
- you develop severe or prolonged or bloody diarrhoea during or after using Efracea 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 Efraea exactly as prescriped by your doctor. Taking more than your prescribed dose may increase the chance that intestinal bacteria will become resistant to Efracea.

Other medicines and Efracea
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
Efracea 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 Efracea .
- Efracea 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 Efracea. These medicines may reduce the effectiveness of Efracea if taken at the same time.
- Other treatments for ulcers or heartburn may also reduce the effectiveness of Efracea and should not be taken until at least 2 hours after Efracea.
- 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.
- Efracea 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 Efracea stays active in your system.
- Using Efracea with the general anaesthetic methoxyfluorane may cause serious harm to the kidneys.

Efracea with food and drink
Always take Efracea 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 Efracea since these products contain calcium which may reduce the effectiveness of Efracea. Leave 2 to 3 hours after your daily dose of Efracea before drinking or eating dairy products.

Pregnancy and breast-feeding
Efracea must not be used during pregnancy since it may cause permanent discolouration of the teeth in the unborn child.
Efracea should not be used for long periods by breastfeeding mothers since it may cause tooth discolouration 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
Efracea has no or negligible influence on the ability to drive and use machines.
Efracea 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 Efracea

Always take 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 Efracea 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 Efracea with a full glass of water whilst sitting or standing to avoid any irritation to the throat.

If you take more Efracea than you should

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 immediately for advice.

If you forget to take Efracea

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

If you stop taking Efracea

You should continue to take Efracea 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.

Common side effects

The following side effects may occur commonly (affects 1 to 10 users in 100) during treatment with Efracea:

- 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 treatment with Efracea:

- 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 Efracea 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 Efracea 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 discolouration 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 Efracea belongs (the tetracyclines):

- Loosening of the nail from the nail bed after exposure to the sun

* 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 (see details below). By reporting side effects, you can help provide more information on the safety of this medicine.

United Kingdom

Yellow Card Scheme
www.mhra.gov.uk/yellowcard

Ireland

FREEPOST: HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2;
Tel: +353 1 6764971; Fax: +353 1 6762517.
Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

5. How to store Efracea

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 no longer used. These measures will help to protect the environment.

6. Contents of the pack and other information

What Efracea 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, hypromellose, 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 Efracea looks like and contents of the pack

Efracea is a modified-release hard capsule.
The capsules are beige in colour and bear the marking "GLD 40".
Efracea 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:
Galderma (UK) Ltd
Meridien House
69-71 Clarendon Road
Watford
Herts.
WD17 1DS
UK

Product Licence Number: PL 10590/0056 (UK) & PA 590/25/1 (IRE)
The manufacturer responsible for batch release is:
Catalent UK Packaging Limited, Lancaster Way, Wingates Industrial Estate, Westhoughton, Bolton, Lancashire, BL5 3XX, UK
Or
Laboratoires GALDERMA, Zone Industrielle Montdésir, 74540 Alby sur Chéran, France

This medicinal product is authorised in the Member States of the EEA under the following names:

CZ, DK, EL, ES, FI, IS, SE, NO - *ORACEA* 40 mg modified release hard capsules
DE, AT - *ORAYCEA* 40 mg modified release hard capsules
BE, HU, FR, NL, UK, IE, IT, PL, PT, SK, LU - Efracea 40 mg modified release hard capsules

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GALDERMA