



澳門特別行政區政府
Governo da Região Administrativa Especial de Macau
藥物監督管理局
Instituto para a Supervisão e Administração Farmacêutica

五洲藥物產品出入口及批發商號
台啓

來函編號
Sua referência

來函日期
Sua comunicação de

發函編號
Nossa referência
1888/VPRA/ISAF/2023

澳門郵政信箱 3092號
C. Postal 3092 - Macau
03/11/2023

事由：確認 DEFAL TABLETS 6MG 藥物訊息
Assunto

茲確認藥物 DEFAL TABLETS 6MG (澳門藥物登記編號 MAC-01003)
已獲本局核准的產品外包裝及說明書資料，如附件所示。

耑此，順頌
台祺

藥物監督管理局副局長

李世恩



澳門特別行政區政府
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 藥物監督管理局
 Instituto para a Supervisão e Administração Farmacêutica

頁編號 2/5
 Pág. n.º
 公函編號 1888/VPR/MSAF/2023
 Of. n.º
 日期 03 / 11 / 2023
 Data

附件：外包裝

Composition: Each tablet contains:
 Deflazacort 6 mg, Corn starch, lactose and other excipients q.s.
 Keep out of sight and reach of children. | Medicinal product: subject to medical
 prescription. | Store below 30°C. | Read the inner leaflet before use.
 FAES FARMIA, S.A., Máximo Aguado, 14. 48940 Leioa (Bizkaia) - SPAIN | ESPAGNE



Defal[®] 6 mg
 Deflazacort 6 mg

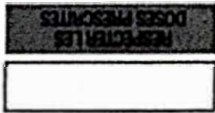
ORAL WAY



20 Tablets

Reg. AEMPS (SPAIN): 57817

CT AN03581
 58x20x130 mm



Composition: Chaque comprimé contient:
 Déflazacort 6 mg, Amidon de maïs, lactose et autres excipients q.s.
 Tenir hors de la vue et de la portée des enfants. | Médicament soumis à prescription
 médicale. | Conserver à une température inférieure à 30°C. | Lire la notice avant utilisation.

20 Comprimés

Defal[®] 6 mg
 Déflazacort 6 mg

VOIE ORALE



BATCH/LOT 3183
 EXP/PER 03-2026





附件：說明書

PACKAGE LEAFLET: INFORMATION FOR THE USER
 Defal 6 mg tablets Deflazacort

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 medicinal product 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 Defal is and what it is used for
2. What you need to know before you take Defal
3. How to take Defal
4. Possible side effects
5. How to store Defal
6. Further information

1. What Defal is and what it is used for

Defal is a medicine from a group of medicines known as corticosteroids, which have anti-inflammatory and anti-allergic properties. Its safety profile is different as it interferes less with glucidic metabolism and has less mineralocorticosteroid effect than other corticosteroids.

Defal is indicated for the treatment of:

- Rheumatic and collagen diseases.
- Skin diseases.
- Allergic diseases: bronchial asthma that does not respond to conventional treatment.
- Respiratory apparatus diseases.
- Eye diseases.
- Blood diseases.
- Digestive system diseases.
- Kidney diseases.
- Liver diseases.

2. What you need to know before you take Defal

Do not take Defal

- If you are allergic (hypersensitive) to deflazacort or any of the other ingredients of this medicine (refer to section 6).
- If you suffer from stomach ulcer.
- If you suffer from bacterial (active tuberculosis) or viral infections (herpes simplex eye disease, herpes zoster, chicken pox) or generalized infections caused by fungi.
- If you are about to be, or have recently been, vaccinated.

Defal 6 mg tablets contains lactose

This medicine contains lactose. If your doctor has indicated that you suffer from intolerance to certain sugars, ask them before taking this medicine.

3. How to take Defal

Always take this medicine exactly as per your doctor's instructions.

Check with your doctor or pharmacist if you are not sure. This medicine is administered by oral route.

Your doctor will tell you how many tablets you need to take and how often. The dose is individual for each patient and may be changed by the doctor depending on how you respond to treatment.

If you take more Defal than you should

In the event of overdose or accidental ingestion, call the Toxicology Information Service, stating the medicine and the amount taken and immediately go to a hospital to receive appropriate treatment.

If you forget to take Defal

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

If you stop taking Defal

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

4. Possible side effects

Like all medicines, Defal can cause side effects, although not everybody gets them. The side-effects of Defal, which have mainly been observed during long-term treatment, are as follows:

- Gastrointestinal disorders: gastrointestinal ulcer.
- Nervous system disorders: headache, dizziness, restlessness, sleep disorders.
- Skin and subcutaneous tissue disorders: healing problems, skin damage.
- Cardiac and vascular disorders: increased blood pressure (hypertension), water retention in tissues (oedema).
- Endocrine disorders: weight gain, worsening of diabetes mellitus, disappearance of menstruation (amenorrhoea).
- Musculoskeletal and connective tissue and bone disorders: muscle weakness, osteoporosis.
- Eye disorders: eye problems.
- With a frequency None known (the frequency can not be estimated with the data available): Blurred vision.





附件：說明書

Warnings and precautions

Take special care with Defal

- Tell your doctor if you are suffering from
 - heart disease
 - congestive heart failure,
 - high blood pressure,
 - thromboembolic diseases (those caused by blood clots),
 - diseases of the oesophagus, stomach or intestine,
 - diabetes mellitus,
 - emotional disorders, psychosis, epilepsy,
 - high intraocular tension (glaucoma),
 - hypothyroidism (failure of the thyroid gland),
 - cirrhosis (severe liver damage).
 - The dose of corticosteroids must be adjusted in special situations (surgery, infections and others); therefore the doctor must know whether you have suffered from any disease.
 - In children, the prolonged use of this medicine may stop their growth and development.
 - After long-term treatment with Defal, the dose must be reduced gradually. Do not stop taking this medicine without talking to your doctor first.
 - Contact your doctor if you experience blurred vision or other visual disturbances.
- Talk to your doctor before taking this medicine.

Use in athletes

Patients must be warned that this medicine contains deflazacort, which can produce a positive antidoping test result.

Other medicines and Defal

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without prescription.

In particular, tell your doctor or pharmacist if you are taking any of the medicines listed below, as Defal might interact with them.

- Diabetes medicines: as the dose might need to be changed.
- Antibiotics (rifampicin): as they may reduce the effect of Defal.
- Oestrogens or oral contraceptives: as the effect of Defal may be increased.
- Medicines that cause muscle relaxation: as the relaxant effect may be prolonged.
- Anticholinesterase medicines used in myasthenia gravis.
- Vaccines and toxoids: as corticosteroids decrease the immune response.
- Medicines for epilepsy and those used in psychiatric treatments (theophyllin, phenobarbital): as they may decrease the effect of Defal.
- Some medicines may increase the effects of Defal 6 mg tablets and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

The use of Defal along with other medicines that cause muscle relaxation, especially when high doses are administered for long periods of time, may produce severe muscle disorders. If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. How to store Defal

Store below 30°C.
 Keep out of the sight and reach of children.
 Do not use this medicine after the expiry date which is stated on the container after EXP. The expiry date refers to the last day of that month.
 Do not throw away any medicines via wastewater or household waste. Place the containers and medicines you no longer need in the recycling point at the pharmacy. If you are unsure, ask your pharmacist how to throw away packages and medicines you no longer need. These measures will help protect the environment.

6. Further information

What Defal 6 mg tablets contains

The active substance is deflazacort. Each tablet contains 6 mg of deflazacort.
 The other ingredients are lactose monohydrate, corn starch, microcrystalline cellulose and magnesiumstearate.

What Defal 6 mg tablets looks like and contents of the pack:

Round, white, uncoated tablets with a cross on one face and the number 6 on the other.
 The tablet can be divided into equal parts.
 Defal 6 mg tablets is packaged in a PVC-aluminium blister and is supplied in packs containing 20 tablets.

Other presentations

Defal 30 mg tablets: pack containing 10 tablets of 30 mg deflazacort.
 Defal 22.75 mg/ml oral drops, suspension; bottle containing 13 ml of suspension and a dropper.
 Not all presentations or pack sizes are marketed or registered.

Marketing authorisation holder and manufacturer

FAES FARMA, S.A.
 Máximo Aguirre, 14
 48940 Leiza - SPAIN
 Tel: 0034 944 818 300

This leaflet was last revised in: November 1999



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附件：說明書

Pregnancy and breast-feeding

Defal must not be used during the first three months of pregnancy unless the doctor considers that the benefits outweigh the potential risk.

IMPORTANT INFORMATION FOR WOMEN:

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. The use of medicines during pregnancy can be dangerous for the embryo or foetus and must be monitored by your doctor. Defal passes into breast milk, therefore its use during breastfeeding is not recommended.

Driving and using machines

Although no information is available, until the response to treatment is satisfactory, you are advised not to perform tasks that require special attention, such as driving vehicles, using potentially dangerous machinery, etc.



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成藥登記證書

CERTIFICADO DE REGISTO DE ESPECIALIDADE FARMACÊUTICA

茲證明下列成藥已在澳門特別行政區登記，有關資料如下：

Certifico que a especialidade farmacêutica, abaixo identificada, se encontra registada na Região Administrativa Especial de Macau, de acordo com as seguintes especificações:

- (1)商品名稱 : DEFAL TABLETS 6MG MAC- 01003
Nome comercial : _____
- (2)成份及含量 : Deflazacort 6mg
Composição e dose : _____
- (3)劑型 F.Farm : 片劑 comprimido (4)每一包裝數量 Apresentação : 20's
- (5)申請登記人 : 五洲藥物產品出入口及批發商號
Requerente do registo : Firma de Importação, Exportação e Venda por Grosso de Produtos Farmacêuticos Wuzhou
- (6)核准登記人 : 藥物監督管理局副局長 (7)批示日期 : 22/09/2022
Registo autorizado por : Vice-presidente do ISAF Data do despacho : _____
- (8)登記有效期 : 2027年09月22日
Validade do registo : 22 / 09 / 2027

日期 : 2022 年 09 月 22 日

Data : 22 / 09 / 2022

藥物監督管理局局長
P' O Presidente do ISAF



李世恩 代行

Lei Sai Ian

按照九月十九日第五九/九零/M 號法令第七條第四款之規定發出
(Emitido ao abrigo do nº4 do artigo 7º do Decreto Lei Nº59/90/M, de 19 de Setembro)



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茲確認藥物 DEFAL TABLETS 6MG(澳門藥物登記編號 MAC-01003)
的申請登記人、產品准照持有人及製造商的訊息如下：

申請登記人 : 五洲藥物產品出入口及批發商號

申請登記人地址 : 澳門電廠巷 22 號亨達大廈地下 AJ 座

產品准照持有人 : FAES FARMA S.A.

產品准照持有人地址 : Maximo Aguirre, 14.
48940 Lamiaco-Lejona (Vizcaya)
España/Spain

製造商 : FAES FARMA S.A.

製造商地址 : Maximo Aguirre, 14.
48940 Lamiaco-Lejona (Vizcaya)
España/Spain

此，順頌
台祺

藥物監督管理局副局長

李世恩

註：根據產品准照持有人所提供的資料，題述產品之產品准照持有人及製造商地址與其外包裝所載的 Maximo Aguirre, 14 48940 Leioa (Bizkaia) SPAIN-ESPAGNE 及說明書所載的 Maximo Aguirre, 14 48940 Leioa-SPAIN 為同一地址。