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	澳門郵政信箱3092號 C. Postal 3092 - Macau
		1886/VPRA/ISAF/2023	03/11/2023

事由：
Assunto **確認 DEFAL ORAL DROPS SUSPENSION 22.75MG/ML 藥物訊息**

茲確認藥物 DEFAL ORAL DROPS SUSPENSION 22.75MG/ML(澳門藥物登記編號 MAC-01002)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

電話 Tel：(853)-2852 4708 圖文傳真 Fax：(853)-2852 4016 電子郵件 E-mail：info@isaf.gov.mo

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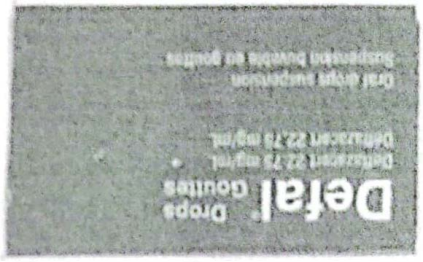
附件：外包装

IT-B/901691
58x33x98 mm



Composition:
Chaque 1 mL (22 gouttes) contient Déflazacort 22,75 mg, sorbitol (E-420), sodium et autres excipients.

Tenir hors de la vue et de la portée des enfants.
Uniquement sur ordonnance.
Conserver à une température inférieure à 30°C.
Lire la notice avant utilisation.

VOIE ORALE

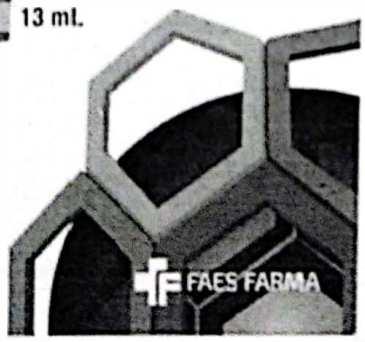
Defal® Gouttes

Déflazacort 22,75 mg/mL

Suspension buvable en gouttes

13 mL

Agiter avant d'utiliser
Shake before use



Composition:
Each 1 mL (22 drops) contains: Deflazacort 22.75 mg, sorbitol (E-420), sodium and other excipients.

Keep out of the sight and reach of children.
Prescription only.
Store below 30°C.
Read the inner leaflet before use.

8 436024 613575

Reg.AEMPS/SPAIN/61049

FAES FARMA, S.A.
Máximo Aguirre, 14
48940 Leioa (Bizkaia)
SPAIN - ESPAGNE

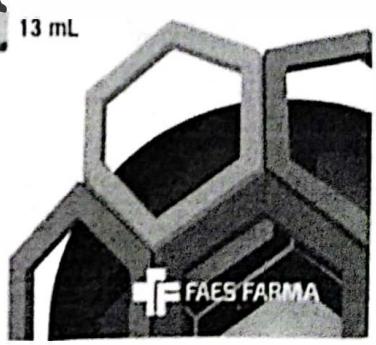
ORAL WAY

Defal® Drops

Deflazacort 22.75 mg/mL

Oral drops suspension

13 mL



BATCH/LOT 3131
EXP/PER 09-2023

澳門特別行政區政府
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附件：說明書

PACKAGE LEAFLET: INFORMATION FOR THE USER

Defal 22.75 mg/mL, oral drops suspension. 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.

What is in this leaflet:

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.

Warnings and precautions

Take special care with Defal

- Tell your doctor if you are suffering from any 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, glaucoma, hypothyroidism (failure of the thyroid gland) and/or cirrhosis.
- 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.

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 (amenorrhea).
- 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.

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 22.75 mg/mL oral drops contains

The active substance is deflazacort. Each mL of suspension contains 22.75 mg of deflazacort or each drop of suspension contains 1 mg of deflazacort.
Other ingredients: sorbitol solution 70%, sodium carboxymethyl cellulose, aluminum magnesium silicate, polysorbate 80, benzyl alcohol, sucralose, tropical flavour, citric acid monohydrate, sodium hydroxide and purified water.

What Defal 22.75 mg/mL oral drops looks like and contents of the pack:

Defal drops is an homogeneous and whitish suspension. This medicine is available in amber glass bottles of 20 mL with an aluminum cap. The bottle contains 13 mL of suspension. A glass dropper is also included.

Other presentations

Defal 30 mg tablets: pack containing 10 tablets of 30 mg deflazacort.
Defal 6 mg tablets: pack containing 20 tablets of 6 mg deflazacort.
Not all presentations or pack sizes are marketed or registered.

Marketing authorisation holder and manufacturer

FAES FARMA, S.A.
Máximo Agurre, 14
48940 Leioa – SPAIN
Tel: 0034 944 818 300

This leaflet was last revised in: June 2010

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附件：說明書

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 (phenytoin, phenobarbital): as they may decrease the effect of Defal.
- Some medicines may increase the effects of Defal oral drops and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

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.

Defal 22.75 mg/mL oral drops contains sorbitol (E-240) and sodium
This medicinal product contains sorbitol. If your doctor has indicated that you suffer from intolerance to certain sugars, ask her/him before taking this medicine.
This medicinal product contains less than 23 mg of sodium (1 mmol) per mL, i.e. it is essentially sodium-free.

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 establish the daily dose. 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,

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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 ORAL DROPS SUSPENSION 22.75MG/ML MAC- 01002
Nome comercial :
(2)成份及含量 : Deflazacort 22.75mg/mL
Composição e dose :
(3)劑型 F.Farm : 懸液劑 Suspensão (4)每一包裝數量 Apresentação : 13mL
(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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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	澳門郵政信箱3092號 C. Postal 3092 - Macau
		1885/VPRA/ISAF/2023	03/11/2023

事由：**確認 DEFAL ORAL DROPS SUSPENSION 22.75MG/ML 藥物訊息**
Assunto

茲確認藥物 DEFAL ORAL DROPS SUSPENSION 22.75MG/ML(澳門藥物登記編號 MAC-01002)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

耑此，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 Máximo Aguirre, 14 48940 Leioa (Bizkaia) SPAIN-ESPAGNE 及說明書所載的 Máximo Aguirre, 14 48940 Leioa-SPAIN 為同一地址。

電話 Tel：(853)-2852 4708 圖文傳真 Fax：(853)-2852 4016 電子郵件 E-mail：info@isaf.gov.mo