PACKAGE LEAFLET: INFORMATION FOR THE USER
Dezacor 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 Dezacor is and what it is used for

Dezacor 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 intereferes less with glucidic metabolism and has less mineralocorticosteroid effect than other corticosteroids.
Dezacor 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 Dezacor

Do not take Dezacor
- 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 Dezacor

- 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 Dezacor, 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 Dezacor

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 Dezacor might interact with them.

- Diabetes medicines: as the dose might need to be changed.
- Antibiotics (rifampicin): as they may reduce the effect of Dezacor.
- Oestrogens or oral contraceptives: as the effect of Dezacor 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 Dezacor.
- Some medicines may increase the effects of Dezacor 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

Dezacor 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. Dezacor 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.

Dezacor 22.75 mg/ml oral drops contains sorbitol (E-420) and sodium

This medicine 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 (1mmol) per mL, i.e. it is essentially sodium-free.

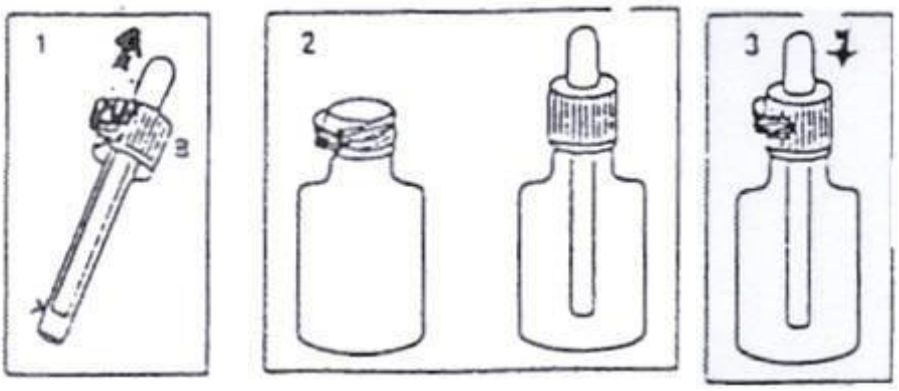
3. How to take Dezacor

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.

Instructions for correct administration

This medicine is given orally. The bottle must be shaken before use.
The drops to be administered can be diluted immediately before taking, in sugar water or in non-carbonated drinks.

Use of the bottle



1. To release the dropper from its protection, hold A and at the same time pull B upwards.
2. Unscrew the metal cap from the bottle and insert and screw on the dropper.
3. To open the bottle containing the dropper, press the stopper fully down and unscrew it at the same time.

CHILD SAFETY LOCK.

If you take more Dezacor 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 Dezacor
Do not take a double dose to make up for forgotten doses.
If you stop taking Dezacor
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Dezacor can cause side effects, although not everybody gets them.
The side-effects of Dezacor, 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 (amenorrhea)
- Musculoskeletal and connective tissue and bone disorders: muscle weakness, osteoporosis.
- Eye disorders: eye problems.
- With a frequency None known (the frequency cannot be estimated with the data available). Blurred vision.

The use of Dezacor 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.

Communication of adverse effects
If you experience any adverse effects, please consult your doctor or pharmacist, even if they are not listed in this leaflet. You can also report them directly through the Spanish Pharmacovigilance System for Medicines for Human Use: https://www.notificaram.es/. By reporting adverse effects you can help provide more information about the safety of this medicine.

5. How to store Dezacor

No special storage conditions are required.
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 CAD. 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 Dezacor 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, aluminium magnesium silicate, polysorbate 80, benzyl alcohol, sucralose, tropical flavor, citric acid monohydrate, sodium hydroxide and purified water.

What Dezacor 22.75 mg/ml oral drops looks like and contents of the pack:

Dezacor 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

Dezacor 30 mg tablets: pack containing 10 tablets of 30 mg deflazacort.
Dezacor 6 mg tablets: pack containing 20 tablets of 6 mg deflazacort.

Marketing authorisation holder and manufacturer

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

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