PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS REGULATIONS (PREPARATIONS) 1986

This medicine is marketed upon physician's prescription only

DIPROSPAN® INJECTION

Suspension for Injection

Each ml of **DIPROSPAN INJECTION** contains:
Betamethasone dipropionate equivalent to 5 mg Betamethasone.
Betamethasone sodium phosphate equivalent to 2 mg Betamethasone.

For a list of inactive ingredients see section 6 "Further information". See also section 2.8 "Important information about some of the ingredients of the medicine".

Read the entire leaflet carefully before you start using this medicine.

- This leaflet contains concise information about the medicine. If you have any further questions, refer to the doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

1. WHAT DIPROSPAN IS INTENDED FOR?

Produces anti-inflammatory, anti-rheumatic and anti-allergic action and is indicated for systemic and local therapy of acute and chronic corticosteroid-responsive disorders.

THERAPEUTIC GROUP: DIPROSPAN belongs to a group of medicines called 'corticosteroids'. These medicines help relieve parts of the body affected by inflammation. They work by reducing swelling, redness, itching, and allergic reactions. They are used to treat a number of problems.

2. BEFORE USING DIPROSPAN

2.1 Do not use DIPROSPAN if:

- You are sensitive (allergic) to betamethasone dipropionate or betamethasone sodium phosphate or any of the other ingredients that this medicine contains. For a list of inactive ingredients, see section 6 "Further information".
- You are allergic to other corticosteroids.
- You have a fungal infection - please tell your doctor before using **DIPROSPAN**. Your doctor may want to treat the infection before you use **DIPROSPAN**.

2.2 Special warnings regarding use of DIPROSPAN

Before starting treatment with DIPROSPAN, tell your doctor if you:

- are diabetic
- have thyroid problems
- have liver problems
- have epilepsy or seizures
- have eye problems
- have a viral or bacterial infection
- have kidney problems
- have stomach or intestinal problems
- have high blood pressure or heart problems
- have muscle weakness or loss of calcium
- have a history of psychiatric illness
- need to be vaccinated

- have pheochromocytoma (a tumour of the adrenal gland).

Contact your doctor if you experience blurred vision or other visual disturbances.

Serious neurologic events, some resulting in death, have been reported with epidural injection of corticosteroids. Specific events reported include, but are not limited to, spinal cord infarction, paraplegia, quadriplegia, cortical blindness, and stroke. These serious neurologic events have been reported with and without use of fluoroscopy. The safety and effectiveness of epidural administration of corticosteroids have not been established, and corticosteroids are not approved for this use.

2.3 Children and adolescents
As corticosteroids can disturb the growth of infants and children, it is important for your doctor to monitor their growth and development carefully in case of prolonged treatment.

2.4 Interactions with other medicines
If you are taking, or have recently taken other medicines, including non-prescription medicines, and nutritional supplements, tell the doctor or pharmacist. Especially if you are taking:
- anti-epileptic medicines,
- antibiotics,
- hormonal medicines,
- medicines for the heart or blood problems, such as diuretics.

This is because it may be necessary to change the dose of certain medicines while you are using **DIPROSPAN**.

Please also tell your doctor or pharmacist if you are taking any of the following medicines:
- Anti-inflammatory medicines.

Because it is possible that your stomach or intestine will not function properly if you take these medicines while using **DIPROSPAN**.

Some medicines may increase the effects of **DIPROSPAN** and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

Remember to tell your doctor that you are using **DIPROSPAN** if he/she plans to have you undergo certain laboratory tests.

2.5 Taking DIPROSPAN with alcohol
Do not drink alcohol while using **DIPROSPAN**, as this could cause problems with your stomach or intestine.

2.6 Pregnancy and breast-feeding
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.

Indeed it is not known if **DIPROSPAN** can be used safely during pregnancy and lactation.
In case of treatment with corticosteroids during pregnancy, both the mother and the child should be carefully monitored during labor and after birth.

Newborn babies of mothers who received **DIPROSPAN** near the end of pregnancy may have low blood sugar levels after birth.

Ask your doctor or pharmacist before taking any medicine.

2.7 Driving and using machines
In general, **DIPROSPAN** does not affect coordination or the ability to react. However, in cases of high doses or prolonged treatment, some patients may experience an exaggerated sense of well-being (euphoria), or drowsiness or vision problems, which may affect their ability to drive a vehicle.

2.8 Important information about some of the ingredients of the medicine
DIPROSPAN contains 9 mg benzyl alcohol in each ml.
Benzyl alcohol may cause allergic reactions. Benzyl alcohol has been linked with the risk of severe side effects including breathing problems (called “gasping syndrome”) in young children. Do not give to your newborn baby (up to 4 weeks old), unless recommended by your doctor. Do not use for more than a week in young children (less than 3 years old), unless advised by your doctor or pharmacist.

Ask your doctor or pharmacist for advice if you are pregnant or breast feeding, or if you have a liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called “metabolic acidosis”).

DIPROSPAN contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per ml, that is to say essentially ”sodium-free”.

DIPROSPAN contains methyl parahydroxybenzoate and propyl parahydroxybenzoate – which may cause allergic reactions (possibly delayed) and exceptionally, difficulty breathing.

3. HOW SHOULD YOU USE DIPROSPAN?
Always use **DIPROSPAN** exactly according to the doctor’s instructions. You should check with the doctor or pharmacist if you are not sure regarding the dosage and treatment regimen.
The dosage and treatment regimen will be determined by the doctor only.

DIPROSPAN is a suspension for injection. It must be shaken before use. The injection is usually done by your doctor or a healthcare professional.
The injection can be intramuscular, intra-articular, periarticular, intralesional, intradermal or intrabursal. It can also be injected into soft tissues.
DIPROSPAN cannot be used for intravenous or subcutaneous administration.
Do not exceed the recommended dose.

If you have accidentally taken a higher dose than you should
Your doctor will regularly check that you are receiving the correct dose.
If you have received too much **DIPROSPAN**, immediately contact your doctor.
If you have taken an overdose, or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or hospital emergency room and bring the package of the medicine with you.

If you have forgotten to take DIPROSPAN
Do not take a double dose to make up for a forgotten dose.
Adhere to the treatment regimen as recommended by the doctor.
Even if there is an improvement in your health, do not discontinue use of this medicine before consulting your doctor.

If you stop taking DIPROSPAN
Do not abruptly stop using **DIPROSPAN**. The dose should be reduced slowly by your doctor.

Do not take medicines in the dark! Check the label and the dose <u>each time</u> you take your medicine. Wear glasses if you need them.
If you have further questions regarding the use of the medicine, consult with your doctor or a pharmacist.

4. SIDE EFFECTS

As with any medicine, **DIPROSPAN** may cause side effects, in some users.
Do not be alarmed by reading the list of side effects. You may not suffer from any of them.
The side effects associated with corticosteroids, including **DIPROSPAN**, depend on the dose and duration of treatment.
You can develop the following side effects during treatment with **DIPROSPAN**:

- changes in your heart rate, increase in blood pressure
- muscle weakness, muscle pain, loss of calcium
- water retention
- thinning of the skin, ecchymoses (bruising), facial flushing, slow wound healing, hypersensitivity reactions, increased sweating, hives
- certain disorders of the stomach or intestine such as ulcers, hiccups
- seizures, exaggerated feeling of well-being (euphoria), difficulty sleeping (insomnia), dizziness, headache, mood fluctuation, severe depression, excessive irritability, psychotic reactions, particularly in patients with a history of psychiatric disorders
- eye disorders, e.g., cataract, glaucoma or protrusion of the eyeball from its usual place
- blurred vision
- moon face (facial swelling), acne, menstrual and libido disorders, increased requirements for insulin or oral antidiabetic medicines in patients with diabetes, symptoms of latent diabetes mellitus
- slower growth of the fetus or child
- weight gain
- inhibition of skin tests
- masking of the symptoms of infection, activation of a latent infection
- decreased resistance to infection, especially when caused by mycobacteria, tuberculosis, *Candida albicans* or viruses.

If a side effect appears, if any of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health by using the link "Adverse Drug Reactions Report" at the home page of the Ministry of Health's web site (www.health.gov.il) which refers to the online side effects reporting form, or by using the link: https://sideeffects.health.gov.il/

5. HOW TO STORE DIPROSPAN?

- Avoid Poisoning! This medicine and any other medicine must be stored in a safe place out of the reach and sight of children and/or infants, in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the pack. The expiry date refers to the last day of the indicated month.
- **Storage conditions:** Store **DIPROSPAN** between 2°C-25°C. Do not freeze.
- Medicines should not be disposed of via wastewater or household waste. Ask the pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.

6. FURTHER INFORMATION

In addition to the active ingredients, **DIPROSPAN** also contains:
Macrogols, benzyl alcohol, sodium chloride, sodium carboxymethylcellulose, disodium hydrogen phosphate dihydrate, methyl parahydroxybenzoate, polysorbate 80, propyl parahydroxybenzoate, disodium edetate, hydrochlorid acid, nitrogen, water for injections.

What DIPROSPAN looks like and contents of the pack

DIPROSPAN suspension for injection is a clear, colourless, slightly viscous liquid containing easily re-suspendable white to off-white particles, free from foreign matter.
Pack sizes: box containing 1 ampoule of 1 ml; box containing 1 ampoule of 2 ml.
Not all pack sizes may be marketed.

License holder and address:
Organon Pharma Israel Ltd., 1 Atir Yeda, Kfar Saba

Manufacturer:
Organon LLC, NJ USA

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Drug registration no. listed in the official registry of the Ministry of Health: 047.07.24139