Package leaflet: Information for the user

Diprofos™ Ampoule 5 mg + 2 mg/1 ml suspension for injection

betamethasone dipropionate, betamethasone disodium phosphate

Read all of this leaflet carefully before you start using 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 Diprofos is and what it is used for
2. What you need to know before you use Diprofos
3. How to use Diprofos
4. Possible side effects
5. How to store Diprofos
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1. What Diprofos is and what it is used for

Diprofos 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.

Diprofos is used in inflammatory conditions requiring systemic corticosteroid treatment, in particular:
- arthritis, bursitis, sciatica, lumbago or other disorders of bone or deep tissue
- allergic conditions such as asthma, hay fever, bronchitis, allergies to medicine, bites or insect bites
- skin conditions such as inflammation, itching, hives, hair loss, psoriasis, scarring or cystic acne
- other conditions diagnosed by your doctor.

2. What you need to know before you use Diprofos

Do not use Diprofos:
- if you are allergic to the active substances or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic to other corticosteroids.
- if you have a fungal infection - please tell your doctor before using Diprofos. Your doctor may want to treat the infection before you use Diprofos.

Warnings and precautions

Talk to your doctor or pharmacist before using Diprofos. Tell your doctor before using this medicine:
- if you are diabetic
- if you have thyroid problems
- if you have liver problems
- if you have epilepsy or seizures
- if you have eye problems
- if you have a viral or bacterial infection
- if you have kidney problems
- if you have stomach or intestinal problems
- if you have high blood pressure or heart problems
- if you have muscle weakness or loss of calcium
- if you have a history of psychiatric illness
- if you need to be vaccinated.

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.

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.

Other medicines and Diprofos

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular, please tell your doctor or pharmacist if you are taking any of the following:
- 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 Diprofos.

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 Diprofos.

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Some medicines may increase the effects of Diprofos 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 Diprofos if he/she plans to have you undergo certain laboratory tests.

Diprofos with food, drink and alcohol

Do not drink alcohol while using Diprofos, as this could cause problems with your stomach or intestine.

Pregnancy, breast-feeding and fertility

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 Diprofos 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.

Ask your doctor or pharmacist before taking any medicine.

Driving and using machines

In general, Diprofos does not affect coordination or the ability to react. However, in cases of high dosage 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.

Diprofos contains benzyl alcohol (9 mg/ml) – which may cause toxic reactions and anaphylactoid reactions in infants and children up to 3 years. Do not administer to premature babies or newborns at term.

Diprofos contains methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) – which may cause allergic reactions (possibly delayed) and exceptionally, difficulty breathing.

3. How to use Diprofos

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Diprofos is a suspension for injection. It must be shaken before use. The injection is usually done by your doctor or a health professional. Your doctor will determine the dose depending on your needs.

The injection can be intramuscular, intra-articular, periarticular, intralesional, intradermal or administered in the synovial bursa. It can also be injected into soft tissues.

Diprofos cannot be used for intravenous or subcutaneous administration.

If you use more Diprofos than you should

Your doctor will regularly check that you are receiving the correct dose.

If you have received too much Diprofos, immediately contact your doctor, pharmacist.

If you forget to use Diprofos

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

If you stop using Diprofos

Do not abruptly stop using Diprofos. The dose should be reduced slowly by your doctor.

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.

The side effects associated with corticosteroids, including Diprofos, depend on the dose and duration of treatment.

You can develop the following side effects during treatment with Diprofos:
- 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.

Reporting of side effects

If you get any side effects, tell your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

By reporting side effects, you are helping to provide more information on the safety of the medicine.

5. How to store Diprofos

Keep this medicine out of the sight and reach of children.

Diprofos Ampoule:
Stored not above 30°C. Protect from light and freezing
Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the carton and other information

What Diprofos contains
- The active substances are 6,43 mg/ml betamethasone dipropionate (equivalent to 5 mg of betamethasone) and 2,63 mg/ml betamethasone disodium phosphate (equivalent to 2 mg of betamethasone).
- The other ingredients are: disodium phosphate dihydrate*, sodium chloride, disodium edetate, polysorbate 80, benzyl alcohol, methyl parahydroxybenzoate, propyl parahydroxybenzoate, sodium carboxymethylcellulose, macrogols, hydrochloric acid, water for injections, nitrogen.
  *Anhydrous form for Diprofos Disposable Syringe.

What Diprofos looks like and contents of the pack

Diprofos Ampoule:
Boxes containing 1 ampoule of 2 ml

Not all pack sizes may be marketed.

Marketing Authorization Holder and Manufacturer

Marketing authorization holder:
MSD Belgium BVBA/SPRL,
Clos du Lynx 5,
B-1200 Bruxelles,
Belgium

Manufacturer and Batch releaser:
Schering-Plough Labo NV,
Industriepark 30,
B-2220 Heist-op-den-Berg,
Belgium

Medicinal product subject to medical prescription.
This leaflet was last revised in 03/2018.

(THIS IS A MEDICAMENT)
-Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
-Follow strictly the doctor's prescription, the method of use, and the instructions of the pharmacist who sold the medicament.
-The doctor and the pharmacist are experts in medicine, its benefits and risks.
-Do not by yourself interrupt the period of treatment prescribed for you.
-Do not repeat the same prescription without consulting your doctor.

Keep medicament out of reach of children

Council of Arab Health Ministers
Union of Arab Pharmacists