PACKAGE LEAFLET

Package leaflet: Information for the user

SOLDESANIL® 0,2% ointment

Dexamethasone (as Dexamethasone sodium 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 is SOLDESANIL and what it is used for

SOLDESANIL ointment is a mild corticosteroid for cutaneous use.

Indications:
Absolute: Seborrheic dermatitis, atopic dermatitis, localized dermatitis, pruritus ani, psoriasis, dermatitis by contact, dry skin during inflammation phase.
Relative: Discoid lupus erythematosus, necrobiosis lipoidica, lichen, lichen hypertopicus (intracutaneous injections), alopecia areata (injection inside the lesion), keloid (injection inside the lesion), granuloma annulare, pretibial myxoedema, psoriasis of the palmars, plantars, elbows and knees.

2. What you need to know before you take SOLDESANIL

Do not take SOLDESANIL:
- if you are allergic to dexamethasone or any of the other ingredients of this medicine (listed in section 6).
- in severe renal disease apart from nephrosis.
- in infectious diseases.
- in bleeding tendency.
- when a vaccination is planned.

Warnings and precautions

Talk to your doctor or pharmacist before taking SOLDESANIL.

a. The long-term use should be avoided in children.

b. When a waterproof bandage is applied it should be recommended to clean the skin, in order to avoid prospective contamination.
c. The local corticosteroids should not be used longer than three weeks without re-examination from a dermatologist.
d. It may cause cataract and increase of the intraocular pressure when applied locally to the eyelids. Contact your doctor if you have blurred vision or other eye disorders.
e. Talk to your doctor if you develop swelling and weight gain in the trunk and face as these are usually the first manifestations of a syndrome called Cushing's syndrome. Suppression of adrenal function can develop after stopping long-term or intensive treatment with SOLDESANIL. Talk to your doctor before stopping treatment by yourself. These risks are particularly significant in children and patients treated with a medicinal product called ritonavir.

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

Inform your doctor if you are using ritonavir, as this may increase the levels of dexamethasone in your blood.
Acetylsalicylic acid should be used with caution concomitantly with corticosteroids in hypoprothrombinemia.
Phenytoin, phenobarbital, ephedrine and rifampicin decrease the activity of corticosteroids. Alcohol and non-steroids enhance their ulcerative action. Hypokalaemia is potentiated by potassium diuretics, whereas with digitalis there is a risk for digoxin toxicity (by hypokalaemia). Corticosteroids reduce or enhance the action of coumarin anticoagulants. With insulin or oral antidiabetics an increase in their dose is required.

pregnancy and breast-feeding

There is insufficient data on the safety of topical corticosteroids when used in pregnant women.

Therefore, the use of these medicines during pregnancy or in women with child-bearing potential requires that the benefits of the drug be weighed against the potential risks to the mother and the embryo.
Infants born to mothers who received adequate doses of corticosteroids during pregnancy should be closely monitored for signs of adrenal dysfunction.

Breast-feeding should be avoided during treatment with corticosteroids.

Driving and using machines
None known effect.

3. How to take SOLDESANIL

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

The ointment is applied to the affected area two or three times daily and for duration of time until complete healing.
Apply a thin layer of ointment and then massage slowly until the ointment is absorbed or apply to the affected area a slightly bigger quantity than the normal (layer of one millimetre) and then cover the area with a waterproof coating (plastic), afterwards bandage with gauzes and adhesive tape. This should be repeated twice or three times a day.

In severe cases it is recommended to combine the topical use of Soldesanil ointment with oral treatment with Soldesanil oral solution, drops.

Your doctor will choose your dosage based on the severity of your condition and the response to the treatment.

If you take more SOLDESANIL than you should
No cases of overdosage with topical use have been reported.
Poison Information Center Athens: (210) 7793777

If you forget to take SOLDESANIL
Do not use a double dose to make up for a forgotten dose. Just continue your regular dosing schedule and use the next dose when planned.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Fluid and electrolyte disturbances
Sodium retention
Fluid retention
Congestive heart failure in susceptible patients
Potassium loss
Hypokalemic alkalosis
Hypertension

Musculoskeletal
Muscle weakness
Steroid myopathy
Loss of muscle mass
Osteoporosis
Vertebral compression fractures
Aseptic necrosis of femoral and humeral heads
Pathologic fracture of long bones
Tendon rupture

Gastrointestinal
Peptic ulcer and possible perforation and hemorrhage
Perforation of the small and large bowel; particularly in patients with inflammatory bowel disease
Pancreatitis
Abdominal distention
Ulcerative esophagitis

Dermatologic
Impaired wound healing
Thin fragile skin
Petechiae and ecchymoses
Erythema
Increased sweating
May suppress reactions to skin tests
Burning or tingling especially in the perineal area (after IV injection)
Other cutaneous reactions, such as allergic dermatitis, urticaria, angioneurotic edema

Neurologic
Convulsions
Increased intracranial pressure with papilledema (pseudotumor cerebri) usually after treatment
Vertigo
Headache
Mental disorders

Endocrine
Menstrual irregularities: extra hair growth (especially in women), muscle weakness and asthenia, purple skin striae, increased blood pressure, irregular menstrual cycle or absent menstruation, changes in the protein and calcium levels in your body, reduced development in children and adolescents and edema and body weight gain (called 'Cushing's syndrome') (see section 2, 'Warnings and precautions')
Secondary adrenocortical and pituitary deficiency, particularly in times of stress, as in trauma, surgery, or illness.
Decreased carbohydrate tolerance
Manifestations of latent diabetes mellitus
Increased requirements for insulin or oral hypoglycemic agents in diabetics

Ophthalmic
Posterior cataracts
Increased intraocular pressure
Glaucoma
Exophthalmos
Blurred vision

Metabolic
Negative nitrogen balance due to protein catabolism

Cardiovascular
Myocardial rupture following recent myocardial infarction.

Other
Anaphylactoid or hypersensitivity reactions
Thromboembolism
Weight gain
Increased appetite
Nausea
Malaise
Hiccups

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to EOF, National Organisation for Medicines, 284 Messogion Str., GR-15562 Cholargos, Athens, Tel. no.: + 30 21 32040380/337, Fax no: + 30 21 06549585, website: http://www.eof.gr. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store SOLDESANIL

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

Do not use this medicine after the expiry date which is stated on the outer and inner package after the "Expiry date". The expiry date refers to the last day of that month.

Store below 25^0C.

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 pack and other information

What SOLDESANIL contains

- The active substance is Dexamethasone (as Dexamethasone sodium phosphate)
- The other excipients are Macrogol 400, Macrogol 4000, Cetyl alcohol.

What SOLDESANIL looks like and contents of the pack

Ointment for cutaneous use
Pack containing 1 tube of 30 g.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
DIAPIT
6 Ag. Konstantinou Str.,Athens
Tel. no. : 210 5232053, fax no. : 210 5248850

Manufacturer
DOPPEL FARMACEUTICI SRL
29106 Cortemaggiore – Piacenza,
Italy

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