

PACKAGE LEAFLET: Information for the user

Triamcinolon Tinkture

Solution for cutaneous application – (2 mg + 20 mg) / 1 g

(Triamcinolone acetonide, Salicylic acid)

Read all of this leaflet carefully before you start using this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects becomes worse or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. What Triamcinolon Tinkture is and what it is used for
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1. WHAT TRIAMCINOLON TINKTURE IS AND WHAT IT IS USED FOR

The active ingredients of Triamcinolon Tinkture are triamcinolone acetonide and salicylic acid. Triamcinolone acetonide is a corticosteroid. It reduces the actions of chemicals in the body that cause inflammation, redness, and swelling. Topical triamcinolone is used to treat the inflammation caused by a number of conditions such as allergic reactions, eczema, and psoriasis. Salicylic acid has keratolytic activity.

Triamcinolon Tinkture is indicated for the management of acute and chronic hyperkeratotic dermatoses, including lesions of the scalp and other hairy areas,

responsive to corticosteroid and salicylic acid therapy which can include contact eczema, eczematous dermatitis, seborrheic dermatitis, atopic dermatitis (neurodermatitis), lichen chronicus simplex, mycosis interdigitalis, psoriasis vulgaris.

2. BEFORE YOU USE TRIAMCINOLON TINKTURE

Do not use Triamcinolon Tinkture:

- if you are pregnant;
- if you are hypersensitive (allergic) to triamcinolone acetonide, salicylic acid and salicylates or to any of the other ingredients of the medication;
- in ear canal;
- if you have a fungal infection;
- if you have tuberculous lesions, topical or systemic viral infections (i.e., vaccinia, varicella, herpes simplex) or exudative dermatitis;
- if you have rosacea (acne rosacea), perioral dermatitis, acne vulgaris;
- in children under 6 years.

Because of the salicylic acid content, Triamcinolon tinkture should not be used for a prolonged time (more than 4 weeks) or in large surface areas of the body (over 10%).

Take special care with Triamcinolon Tinkture:

Be sure to inform your doctor of all your medical conditions before you begin using this medication.

Before using triamcinolone acetonide, tell your doctor or pharmacist if you are allergic to it, or to other corticosteroids (e.g., hydrocortisone, prednisone); or if you have any other allergies. Before using this medication, tell your doctor or pharmacist your medical history, especially of: poor blood circulation, immune system problems.

Though very unlikely, it is possible this medication will be absorbed into your bloodstream. This may have undesirable consequences that may require additional corticosteroid treatment. This is especially true for children, those who have used this drug for an extended time, and those who have serious medical problems such as serious infections, injuries, or surgeries. This precaution applies for up to one year after you stop using this drug. Caution is advised when using this drug in children because

they may be more sensitive to the effects of too much steroid medication. This medication may affect growth in infants and children if used for prolonged periods. Monitor your child's height and rate of growth periodically.

If this medication is used under an occlusive dressing (those that don't breathe), particularly over extensive areas, enough medication may be absorbed into the bloodstream to cause serious side effects. Do not use dressings that don't breathe unless directed to do so from your doctor.

If it is used for a long time and in large surface areas of the body, salicylic acid may be absorbed, and it may cause serious side effects in patients with renal impairment.

Avoid contact with the eyes and mucous membranes.

This preparation is inflammable and appropriate precautions should be taken.

Taking other medicines

Systemic absorption of triamcinolone acetonide may cause interactions with analgesics, anticoagulants, antiepileptics, antibacterials, antifungals, antitubercular drugs, immunosuppressants, antineoplastic (triamcinolone acetonide increases the toxicity of methotrexate), leukotriene antagonists, neuromuscular blockers, sex hormones, sympathomimetics, diuretics (water pills), hypoglycaemic agents (including insulin), anti-hypertensive drugs, digitalis glycosides, human growth hormone, vaccines and toxoids.

An interaction between medications does not always mean that you must stop taking one of them. If you are taking / using any of the other medications (including non-prescription, herbal, and supplement products), talk to your doctor or pharmacist. Depending on your specific circumstances, your doctor may want you to change your therapy or suggest ways of managing any interactions. Since caffeine, alcohol, the nicotine from cigarettes can affect the action of many medications, you should let your prescriber know if you use them.

Pregnancy

You should not use Triamcinolone Tincture if you are pregnant. Inform immediately your doctor to advise whether to stop or change the therapy.

Breast-feeding

It is not known if topical triamcinolone acetonide and salicylic acid pass into breastmilk. If you are a breast-feeding mother and are using this medication, it may affect your baby. The contact of the child with the treated areas should be avoided.

Talk to your doctor if you should continue breast-feeding.

Pediatric use

This preparation is not recommended for children under 6 years of age.

Use of this medication over large surface areas or for prolonged periods in children and adolescents could result in sufficient systemic absorption to produce systemic effects.

When applied to those between 6 and 12 years of age, this medication should be limited to the lowest amount for the shortest duration compatible with an effective therapeutic regimen. These patients should be closely monitored for signs and symptoms of systemic effects.

Driving and using machines

There are no data showing that this medicinal product has influence on the ability to drive and use machines.

3. HOW TO USE TRIAMCINOLON TINKTURE

Use this medication exactly as it was prescribed for you.

For cutaneous application.

If not otherwise prescribed by the doctor, Triamcinolon tincture is used with drops 1 – 2 times a day in the affected areas. The total daily dose should not exceed 10 ml. After the application, let the tincture dry till the skin does not shine anymore.

In all the indications, the treatment should be continued until total recovery. Treatment duration should not exceed 4 weeks.

If you use more Triamcinolon Tinkture than you should

Seek emergent medical attention if you think you have used too much of this medicine, or if anyone has accidentally swallowed it. An overdose of topical triamcinolone applied to the skin is not expected to produce life-threatening symptoms.

If you forget to use Triamcinolon Tinkture

If you forget to use one dose, use the next dose in its usual time. Do not use a double dose to make up a forgotten dose.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

This medication is generally well tolerated. There have been reports of burning, dryness, pruritus, capillary fragility.

The following local adverse reactions are reported infrequently with topical corticosteroids, but may occur more frequently with the use of occlusive dressings (reactions are listed in an approximate decreasing order of occurrence): burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of skin, secondary infection, skin atrophy, striae, and miliaria.

Some local reddening of the skin, desquamation, dermatitis, pruritus, and smarting at the site of application may result from salicylic acid. Hypersensitivity to salicylic acid may occur.

Manifestations of adrenal suppression in children and adolescents include linear growth retardation, delayed weight gain, low plasma cortisol levels, and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema.

Signs and symptoms of salicylism include nausea, vomiting, dizziness, loss of hearing, tinnitus, lethargy, hyperpnea, diarrhea, psychic disturbances.

Local irritation and dryness due to alcohol can occur.

If any of the side effects gets serious, or if you notice side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE TRIAMCINOLON TINKTURE

Keep out of the reach and sight of children.

Do not use this medication after the expiry date which is stated on the package.

Do not store above 25°C.

After each use, the vial should be well closed.

6. FURTHER INFORMATION

What Triamcinolon Tinkture contains

The **active substances** are triamcinolone acetonide and salicylic acid.

1 g solution corresponding to 1.14 ml contains 2 mg triamcinolone acetonide and 20 mg salicylic acid.

The **other ingredients** are ethanol 96%, purified water.

Contents of the pack

Box with one plastic vial 20 ml.

Marketing authorisation holder and manufacturer:

PROFARMA Sh.a.

Rruga "Myslym Keta"

Tel.: 00355 4 23 89 602

Tirana - ALBANIA

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