

PACKAGE LEAFLET: Information for the patient

MICO-SYNAL

Cream – (3% / 0.025%)

(Clioquinol / Fluocinolone acetonide)

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

In this leaflet:

1. What Mico-Synal is and what it is used for
2. What you need to know before you use Mico-Synal
3. How to use Mico-Synal
4. Possible side effects
5. How to store Mico-Synal
6. Further information

1. WHAT MICO-SYNAL IS AND WHAT IT IS USED FOR

Mico-Synal contains the active substances clioquinol and fluocinolone acetonide.

Clioquinol has antimycotic and antibacterial actions. It works by preventing the growth and multiplication of the microorganisms.

Fluocinolone is a type of medicine called a topical corticosteroid. Corticosteroids are medicines used for reducing inflammation. When fluocinolone is applied to the skin, it works by acting inside the cells to decrease the release of inflammatory substances. This reduces swelling, redness and itching.

Mico-Synal is indicated for the treatment of inflammatory dermatosis, including eczema, dermatitis, seborrhea and intertrigo, where it is present or likely to appear a secondary bacterial and / or mycotic infection.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE MICO-SYNAL

Mico-Synal should not be used:

- if you are hypersensitive (allergic) to any of the ingredients of this drug;
- if you are hypersensitive (allergic) to iodine;
- in children under 1 year of age;
- in primary skin infections, caused by bacteria, fungi, and viruses;
- in rosacea, acne, dermatitis around the mouth and nappy rash.

Take special care while using Mico-Synal

- This medicine is for external use on the skin only.
- The cream should be applied thinly only to the affected area(s).
- Avoid getting the medicine in the eyes, or in contact with the inside of the mouth or nose. Rinse with cold water if accidental contact occurs.
- Wash your hands thoroughly after applying this medicine, unless the hands are the area being treated.
- If local corticosteroids are used for long-term, on large areas of skin, raw skin, on its folds, or under airtight dressings, they may be absorbed into the body in significant quantity, which increases the risk of side effects such as skin thinning, and decrease of the production of natural hormones by the adrenal glands. For this reason, continuous, long-term use of topical steroids should be avoided wherever possible, particularly in children and on large areas of skin.
- As Mico-Synal also contains an antimicrobial, it should not normally be used for longer than a week, because longer term use may increase the chances of any microorganisms becoming resistant to the medicine. If the infection does not seem to be clearing up within a few days of using this medicine, you should consult your doctor.
- If this medicine is used on the face, wherever possible, it should not be used for longer than five days. You should not use airtight dressings to cover the area treated.

- If used in children, wherever possible, it should not be used for longer than five days, or on the face. You should not use airtight dressings to cover the area treated.
- When it is necessary to use dressings, then the affected areas should initially be cleaned carefully, then place the cream and cover with respective dressing.
- If you have been prescribed this medicine to treat psoriasis, you should have regular check-ups with your doctor. This is because although corticosteroids may be useful for psoriasis in the short-term, they can sometimes make psoriasis worse.
- The clioquinol contained in this medicine may stain clothes.

Taking other medicines

There are no known reports regarding interactions with other drugs or substances.

However, as with all medicines, it is important to tell your doctor what medicines you are already using, including those bought without a prescription and herbal products, before you start using this drug. Similarly, check with your doctor before using any new drug.

If you are using **other medicines on the same area of skin**, it is recommended that you leave several minutes between applying each product.

Pregnancy and breastfeeding

Pregnancy

This medicine should not be used during pregnancy unless considered essential by your doctor. If it is prescribed by your doctor, it should not be used on large areas of skin, underneath airtight dressings, or for prolonged periods of time. Consult your doctor for further information.

Breastfeeding

This medicine should not be used during breastfeeding unless considered essential by your doctor. If it is prescribed by your doctor, it should not be used on large areas of skin, underneath airtight dressings or for prolonged periods of time. If it is applied to the breasts, they should be washed off carefully before breast-feeding, and then the cream can be reapplied afterwards.

Driving and using machines

There are no known reports regarding the effect of this product on the ability to drive and use machines.

Important information about some of the ingredients of Mico-Synal

Mico-Synal contains:

- butylhydroxytoluene which may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes;
- methyl parahydroxybenzoate and propyl parahydroxybenzoate which may cause allergic reactions (possibly delayed);
- propylene glycol, which may cause skin irritation.

3. HOW TO USE MICO-SYNAL

Always use Mico-Synal exactly as your doctor has told you.

A small amount is applied on the affected area 1 - 2 times daily, and gently rubbed in order to penetrate well into skin lesions. After symptoms remission, reducing daily dose is recommended.

Please check with your doctor or pharmacist if you are not sure.

If you use more Mico-Synal than you should

If side effects occur, the drug should be discontinued and the appropriate therapy against unwanted side effects should be initiated.

If you forget to use Mico-Synal

If you have missed a dose, continue with the next scheduled dose. Do not use a double dose to make up for a forgotten dose.

If you stop using Mico-Synal

The disease may worsen.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Mico-Synal can cause side effects, although not everybody gets them. The following side effects are known to be associated with this medicine:

- skin irritation at the site of application, burning, itching and redness;
- allergic inflammation of the skin (contact dermatitis);
- thinning of the skin;
- changes in skin pigmentation;
- local hypertrichosis;
- stretch marks (striae);
- telangiectasia.

Prolonged use of this medicine on extensive areas of skin, on its folds, broken or raw skin, or underneath airtight dressings, may on rare occasions result in enough corticosteroid being absorbed to have side effects on other parts of the body, for example a decrease in the production of natural hormones by the adrenal glands. It may also cause the skin to become sensitive to the antimicrobial.

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

5. HOW TO STORE MICO-SYNAL

Keep out of the reach and sight of children.

Store below 25°C!

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

6. FURTHER INFORMATION

What Mico-Synal contains

The active substances are clioquinol and fluocinolone acetonide.

1 g cream contains 30 mg clioquinol and 0.25 mg fluocinolone acetonide.

The excipients are: PEG stearate/glycol stearate, light liquid paraffin, macrogolglycerol oleate, cetyl palmitate, methyl parahydroxybenzoate, propyl parahydroxybenzoate, disodium EDTA,

butylhydroxytoluene, sodium lauryl sulphate, ethyl alcohol 96 %, propylene glycol, purified water.

Content of the pack

Box with 1 tube of 15 g.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. "Skënder Vila",

Tirana, Albania.

Tel.: +355 4 23 89 602

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