PACKAGE LEAFLET: INFORMATION FOR THE USER

Multodrin ointment

Active substances: Dexamethasone, diphenhydramine hydrochloride

Read all of this patient information leaflet carefully before you start using this medicine because it contains important information.
- Retain this patient information 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 can harm other people, even if they have the same symptoms as you. If you note any side effects, ask your doctor or pharmacist This includes any possible side effects not listed in this patient information leaflet. See section 4.

What is in this patient information leaflet

1. What Multodrin is and what it is used for

Multodrin is an anti-allergic, anti-inflammatory and antipruritic (anti-itch) ointment for cutaneous use.

Mode of action

Multodrin contains the glucocorticoid dexamethasone and the antihistamine diphenhydramine hydrochloride as its active substances. This active substance combination demonstrates a fast acting anti-allergic, anti-inflammatory and itching-suppressant effect. This results in the alleviation of pain. A reduction or prevention of the swelling of the skin also occurs.

Multodrin is easily applied to the skin and the active ingredients are evenly distributed. The ointment base is non-irritant and practically grease-free. The effect onsets just a short time after the ointment is applied.

Areas of application:

For external treatment of inflammatory skin diseases that respond to corticoids, such as:
- eczemas
- itching

- non-infected insect bites with severe oedema formation
- first degree burns, including sunburn
- frostbite
- skin damage following irradiation

2. What you need to know before you use Multodrin

Do not use Multodrin
- if you are allergic to dexamethasone hydrochloride or any of the other ingredients of this medicine listed in section 6.,
- in new-borns and children up to the age of 2
- if you suffer from one of the following diseases:
  Perioral dermatitis (small blister rash on the face, especially around the mouth and the eyes),
- Rosacea (skin inflammation particularly affecting the facial area),
- skin tuberculosis,
- skin infection by syphilis
- skin reactions following viral infections (smallpox, chicken pox, measles) and smallpox vaccinations.
- on open wounds, mucosa, large-area changes to the skin like inflamed or damaged skin, especially in patients experiencing blistering of the skin.

Warnings and precautions
Talk to your doctor or pharmacist before using Multodrin.
Particular care should be taken when using Multodrin
- if areas of skin treated are exposed to sunlight for prolonged periods, as this could trigger possible photosensitivity reactions,
- if there is no improvement in your condition or the symptoms deteriorate, you must consult a doctor in every case,
- if you suffer from a fungal infection of the skin, you should either take Multodrin together with an appropriate medicine for treating the fungal infection, or only commence using it after the infection has been controlled through suitable methods,
- if Multodrin is applied over a prolonged period of time across an extensive skin area, especially on mucosa, or on small children and older people, because the increased intake of active substances may result in the occurrence of side effects,
- wash hands after the application, Multodrin must not be allowed to come into contact with the eyes,
- particular care should be taken using diphenhydramine if there is an existing condition of sleep apnoea (respiratory difficulties during sleep),
- talk to your doctor if you experience swelling and weight gain on the trunk and the face, as these are usually the first signs of the so-called Cushing's syndrome. Suppression of the adrenal function can occur after discontinuation of a long-term or intensive treatment with Multodrin. Talk to your doctor before you take the decision to discontinue the treatment. These risks are particularly noticeable in children and patients treated with a medicine which contains Ritonavir,
- if blurred vision or other visual disturbances occur, consult your doctor

Application of other medicines with Multodrin

Tell your doctor or a pharmacist if you are are using, have recently used or might use any other medicines.
Tell your doctor if you take Ritonavir as this can lead to the level of dexamethasone in your blood being raised.
Multodrin should not be applied simultaneously with other medicines containing diphenhydramine or glucocorticoids.

Application of Multodrin with foods and drinks
No interactions have been observed.

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 using this medicinal product.

Multodrin may not be used in the first three months of pregnancy.
During the remainder of the pregnancy, Multodrin should only be used after a careful balancing of benefit/risk by the doctor and after the dose was determined on an individual basis. Wide area application is to be avoided, especially on inflamed or damaged skin.

Multodrin may not be used while breast-feeding, because dexamethasone and diphenhydramine are excreted in the mother's milk.

Driving and using machines
Multodrin generally does not affect the ability to drive or operate machines
However, an influence on the ability to drive and use machines cannot be fully ruled out in case of an individual increased level of sensitivity.

3. How to use Multodrin

Always use this medicine exactly as described in this patient information leaflet or exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
Multodrin should be applied as a thin film to the affected area of skin.
Adults, adolescent and children should repeat this procedure 3-4 times daily.

Maximum daily doses

Adults with a body weight over 60 kg:
It is recommended not to exceed the daily dose of 20 g Multodrin (corresponding to 300 mg diphenhydramine hydrochloride). 20 g corresponds to 2/3 of one 30 g tube.

Adolescents aged 12 to 18 years old (weighing more than 30 kg) cannot exceed the maximum daily dose set out in the following table. The maximum daily dose depends on the body weight:

Body weight	Maximum daily dose		
	Ointment strand length	corresponds to an amount of Multodrin	
50 kg	80 cm	17 g	corresponds approximately to

			one tube of 15 g or ½ tube of 30 g
40 kg	64 cm	13.5 g	a little less than one tube of 15 g or ½ tube of 30 g
30 kg	48 cm	10.2 g	2/3 of the tube of 15 g or 1/3 of the tube of 30g

Children from 2-12 years (less than 30 kg) must not exceed the maximum daily dose set out in the following table.
The maximum daily dose depends on the body weight; the ointment strand length is used to estimate the maximum daily dose.

Body weight	Maximum daily dose	
	Ointment strand length	corresponds to an amount of Multodrin
20 kg	32 cm	6.75 g
10 kg	16 cm	3.35 g
5 kg	8 cm	1.70 g

You should apply the medicine only as long as is absolutely necessary, and in the lowest possible dose. The period of application depends on the severity of the disease. If there is no improvement in your condition following two weeks of uninterrupted use, you should consult a doctor in every case.

In children, a treatment break should be observed for a minimum 2 weeks after treatment of 2-3 weeks, so that the skin can regenerate.

If you use more Multodrin than you should
No cases of Multodrin overdose have been reported to date.
If you have accidentally ingested Multodrin, please consult a doctor without delay.

If you forget to use Multodrin
Do not apply more ointment if you have forgotten the previous application.

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

4. Possible side effects

Like all medicinal products, this medicinal product can cause side effects, although not everybody gets them.

Rare side effects: may affect up to 1 in every 1000 patients

- Hypersensitivity reactions to constituents of the preparation, redness, itching, swelling as well as increased photosensitivity (avoid direct sunlight!)

- Prolonged application and particularly the application of Multodrin under a thick dressing can result in contact dermatitis (allergic contact eczema), cutaneous atrophy (thinning of the skin), superficial vasodilation and perioral dermatitis (skin inflammation of the skin around the mouth). Furthermore, abnormal skin pigmentation and secondary infections may occur.
- In rare individual cases, after extensive application of Multodrin, side effects of the whole organism may occur, such as dryness of the mouth, headaches, fatigue and especially in children, agitation (restlessness, cramps). In this case, discontinue the treatment and contact your doctor immediately. Possible glucocorticoid side effects on the entire organism may be observed following prolongedlarge-area or high-dose application.

Very rare side effects: may affect up to 1 in every 10000 patients
Urination disorders

Side effects with unknown frequency (frequency not assessable based on the available data)
- Blurred vision
- Hormone problems:

Growth of additional body hair (especially in women), muscle weakness and shrinkage, steroid acne (medicine-induced acne form), reddish bluish stretch marks of the skin, increased blood pressure, irregular or absent period, changes in protein and calcium levels in the body, growth inhibition in children as well as swelling and weight gain of the body and face (so-called "Cushing's syndrome") (see Section 2, "Warnings and precautions").

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 patient information leaflet.
You can also report side effects directly via the national reporting system:

Bundesamt für Sicherheit im Gesundheitswesen-Austrian Federal Office for Safety in Health Care
Traisengasse 5
1200 VIENNA
AUSTRIA
Fax: + 43 (0) 50 555 36207
Website: http://www.basg.gv.at/

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Multodrin

Keep the medicinal product out of the reach of children.

Do not store over 25 °C.
Shelf life after first opening: 6 months

You should not use the medicine beyond the <<*Use by.*>> expiry date on the tube. The expiry date refers to the last day of the month.

Do not throw away medicine via waste water or household waste. Ask your pharmacist how the medicine is to be disposed of, if you are not using it any more. You thus make a contribution to environmental protection.

6. Contents of the pack and other information

What Multodrin contains
- The active ingredients are: Dexamethasone, diphenhydramine hydrochloride
- The other ingredients are: Macrogol 600, Gelot 64, benzyl alcohol, citric acid, water for injection purposes, sodium hydroxide solution and hydrochloric acid solution for pH value setting.

What Multodrin looks like and contents of the pack
Creamy, white, completely non-irritant ointment is easy to rub in and spread on the skin.

Pack sizes: tubes with 15 g and 30 g in a folding carton.

Marketing Authorisation Holder and Manufacturer
Pharm. Fabrik Montavit Ges.m.b.H.
A-6067 Absam
Tel: +43 5223 57926 0
Fax: +43 5223 52294
e-mail: pharma@montavit.com

Authorisation no.: 13.232

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