

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Monovo 1 mg/g ointment

Mometasone furoate

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 Monovo is and what it is used for
2. What you need to know before you use Monovo
3. How to use Monovo
4. Possible side effects
5. How to store Monovo
6. Contents of the pack and other information

1. WHAT MONOVO IS AND WHAT IT IS USED FOR

Monovo contains the active substance mometasone furoate, which belongs to a group of medicines called topical corticosteroids (or steroids).

Topical corticosteroids can be divided into four degrees of strength or potency: mild, moderate, potent and very potent. Monovo is classified as a “potent corticosteroid”.

In adults, adolescents and children, aged 6 years and older, Monovo is used to reduce symptoms caused by certain inflammatory skin disorders such as psoriasis (excluding widespread plaque psoriasis) and atopic dermatitis. This preparation is generally used to treat very dry, scaly and cracked skin complaints. It is not a cure for your condition, but should help to relieve your symptoms.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE MONOVO

Do not use Monovo

- if you, or your child are allergic to mometasone furoate, or other corticosteroids or any of the other ingredients of this medicine (listed in section 6),
- on any other skin problems as it could make them worse especially:
 - rosacea (a skin condition affecting the face)
 - acne
 - dermatitis around the mouth (perioral dermatitis)
 - perianal and genital itching
 - nappy rash
 - bacterial infections such as impetigo, viral infections such as cold sores, shingles, and chickenpox (varicella), fungal infections such as athlete’s foot (red, itchy, flaky skin on the feet), or thrush (an infection affecting the vagina that can cause discharge and itching)

- bacterial infections such as tuberculosis (infection of the lung) or syphilis (a sexually transmitted disease)
- if you have recently had a reaction to a vaccination (e.g. for flu)
- on the eyelids

Warnings and precautions

Talk to your doctor or pharmacist before using Monovo.

- Monovo should not be put on the eyelids.
- Take care not to get any ointment in the eye. However if this should occur rinse thoroughly with clean water. If eye irritation remains please see your doctor.
- The ointment should not be applied to broken skin and mucous membranes.
- Do not use the ointment on your face without close supervision of your doctor.
- If irritation or sensitisation develops with the use of Monovo, you should tell your doctor immediately.
- When this medication is used on psoriasis, it may make the conditions worse (e.g. a pustular form of the disease may occur). You should let your doctor review your progress at regular intervals, as such treatment needs careful supervision.
- Contact your doctor if you experience blurred vision or other visual disturbances.

Children (under 6 years of age)

Monovo ointment should not be used in children under 6 years of age.

Other medicines and Monovo

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. This includes medicines obtained without a prescription and any other remedies or dietary supplements such as vitamins.

Ask your doctor for advice before taking any medicine.

- **Do not** use latex products (e.g. condom, diaphragms) together with Monovo in the genital or anal area, as the safety of these products may be impaired.

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 taking this medicine. If your doctor does prescribe the ointment to you during pregnancy or while you are breast-feeding, you should avoid using large doses and the use should be limited to a short period.
- **Do not** apply Monovo to the breast area whilst breast-feeding.

Monovo contains propylene glycol monopalmitostearate and emulsifying cetostearyl alcohol.

Propylene glycol monopalmitostearate may cause skin irritation. Emulsifying cetostearyl alcohol may cause local skin reactions (e.g. contact dermatitis).

3. HOW TO USE MONOVO

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Your doctor should review your treatment at regular intervals.

Adults, including the elderly, adolescents and children 6 years of age and older:

- A thin layer of ointment should be gently applied to the affected areas of skin once daily.
- You only need to use a small amount of this preparation. If you have been prescribed the ointment, one fingertip unit (a line from the tip of an adult index finger to the first crease) is enough to cover an area

twice the size of an adult hand. Never apply more than this quantity or more often than advised by your doctor or pharmacist.

Adults, including the elderly:

- You should not use the ointment on large areas of the body (over 20% of body surface area) or for a long time (for example every day for over three weeks).
- Unless directed by your doctor, do not apply a bandage or dressing to the area being treated. This will increase absorption of the preparation and increase possible side effects.

Children (6 years of age and older):

- **Do not** use the ointment for children over 6 years of age on any part of their body without close supervision of the doctor.
- **Do not** apply the ointment to more than 10% of the child's body surface area.
- **Do not** use in skin folds and under airtight dressings.
- **Do not** use for more than 3 weeks.

Method of administration

Monovo ointment is for cutaneous use (use on the skin).

This medicinal product is for external use only.

If you used more Monovo than you should

- If you (or somebody else) accidentally swallow the ointment, it should not produce any undesirable effects. However, if you are worried, you should see your doctor or pharmacist.
- If you use the ointment more often than you should, or on large areas of the body, it can affect some of your hormones. In children, this may affect their growth and development.
- If you have not followed the dosage instructions or your doctor's advice and have used the ointment too frequently and/or for a long time, you should tell your doctor or pharmacist.

If you forget to use Monovo

- If you forget to apply the ointment at the scheduled time, do it as soon as you remember and then carry on as before.
- **Do not** apply twice as much or use twice in one day to make up for a missed application.

If you stop using Monovo

- Do not stop treatment suddenly if you have used it for a long time since this may be harmful.
- Treatment should be stopped gradually, as advised 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. If your symptoms do not begin to improve after using this medicine as instructed by your doctor or if they get worse, check with your doctor.

Side effects in children and adults that have been reported with the use of topical corticosteroids include:

Common: may affect up to 1 in 10 people

These include mild to moderate burning sensations at the application site, tingling/stinging, itching, bacterial infections, abnormal sensations on the skin (paraesthesia), skin boils (furunculosis), and thinning of the skin (skin atrophy).

Uncommon: may affect up to 1 in 100 people

These include irregular skin marks or stripes (striae), skin irritation, unusual hair growth (hypertrichosis), changes in skin colour, dermatitis around the mouth (perioral dermatitis), softening and whitening of the skin (maceration), allergic contact dermatitis, pus-filled blisters on facial skin (papulous rosacea-like dermatitis), inflammation (including acne type reactions), purple or dark blue discoloration of the skin (ecchymoses), heat rash (miliaria), dryness, sensitisation, inflammation of skin follicles (folliculitis) and secondary infection.

Very rare: may affect up to 1 in 10,000 people

Dilated blood vessels on the skin or spider veins.

Not known: frequency cannot be estimated from the available data

Blurred vision.

Increased usage, treatment of large areas of skin, long term use and use under a dressing may increase the risk of side effects.

Corticosteroids may affect the normal production of steroids in the body. This is more likely to happen if high doses are being used over a long period of time.

Children in particular, treated with corticosteroid ointments and creams can absorb product through the skin and this can lead to a disorder called Cushing's syndrome which includes many symptoms, such as a fat, round face and weakness. Children on long term treatment may grow more slowly than others. Your doctor will help prevent this happening by prescribing the lowest dose of steroid at which your symptoms are well-controlled.

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 via the HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.hpra.ie, e-mail: medsafety@hpra.ie.

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

5. HOW TO STORE MONOVO

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 carton and the tube after "EXP". The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Discard the opened tube with any remaining ointment after 6 months.

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. FURTHER INFORMATION**What Monovo contains**

- The active substance is mometasone furoate.

One gram of ointment contains 1 mg of mometasone furoate (0.1% mometasone furoate).

- The other ingredients are:

White soft paraffin, liquid paraffin, 2-methylpentane-2,4-diol, emulsifying cetostearyl alcohol (type A contains disodium/potassium hydrogen phosphate for pH adjustment), propylene glycol monopalmitostearate, white beeswax, purified water, anhydrous citric acid, sodium citrate.

What Monovo looks like and contents of the pack

Monovo is an off-white, transparent ointment. The ointment is filled in aluminium tubes fitted with a white plastic screw cap in a cardboard carton.

Pack sizes: Tubes with 10 g, 15 g, 20 g, 25 g, 30 g, 35 g, 50 g, 60 g, 70 g, 90 g and 100 g of ointment.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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This medicinal product is authorised in the Member States of the EEA under the following names:

Country	Trade names
Austria	Monovo 1 mg/g Salbe
Germany	Monovo 1 mg/g Salbe
Ireland	Monovo 1 mg/g Ointment
Italy	Frondava 1 mg/g Unguento
Luxembourg	Monovo 1 mg/g Salbe
Poland	Ivoxel
Portugal	Ivoxel 1 mg/g Pomade
Spain	Monovo 1 mg/g Pomada
The Netherlands	Monovo 1 mg/g Zalf
United Kingdom	Mometasone furoate 0.1% w/w Ointment

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