MOMETASONE FUROATE

MOMECORT®

1 mg/g Cream
1 mg/g Ointment

Anti-inflammatory / Antipruritic
FOR EXTERNAL USE ONLY

FORMULATION
Each gram cream/ointment contains: Mometasone furoate ……..……. 1 mg (0.1%)

PRODUCT DESCRIPTIONS
Mometasone furoate cream is a white, homogeneous, smooth, and non-gritty cream with a characteristic odor.
Mometasone furoate ointment is a translucent, homogeneous, smooth, and non-gritty ointment with a characteristic odor.

WHAT IS IN THE MEDICINE?
Mometasone furoate belongs to a group of medicines called topical corticosteroids, which are used on the skin to relieve inflammation (e.g., swelling, redness) and itch caused by certain skin problems. Mometasone furoate cream and ointment are classified as a medium potency topical corticosteroids.

STRENGTH OF THE MEDICINES
See Formulations.

WHAT ARE THE MEDICINES USED FOR?
For the relief of inflammation and itch caused by skin conditions such as psoriasis (itchy, scaly, pink patches that develop on the elbows, knees, scalp, and other parts of the body), atopic dermatitis (or eczema, a skin disorder that involves scaly and itchy rashes), and contact dermatitis (red, sore or inflamed skin after direct contact with a substance that causes a reaction).

HOW MUCH AND HOW OFTEN SHOULD YOU USE THESE MEDICINES?
Mometasone furoate cream is suitable for thin skin or moist lesions.
Mometasone furoate ointment is suitable for thick skin or dry, scaling lesions.

Directions for Use: Rub a thin layer of mometasone cream or ointment to affected areas of the skin once a day, or as directed by a doctor.
- Do not use on the face for longer than 5 days.
- Do not use for longer than 5 days in children, unless directed by a doctor.
- Do not use for longer than 7 days in adults, unless directed by a doctor.

WHEN SHOULD YOU NOT USE THESE MEDICINES?
- If you are allergic to mometasone furoate or other corticosteroids, or to any ingredient in the product.

- Do not use this medicine if you have:
  - Rosacea (skin redness on the face)
  - Acne vulgaris
  - Skin atrophy (thinning of the skin),
  - Inflammation around the mouth
  - Tuberculosis
  - Ulcerated skin or wounds
  - Genital itching
  - Diaper rash
  - A viral infection (cold sores, chickenpox, shingles, warts)
  - A fungal skin infection (thrush, tinea or ringworm)
  - Other skin infections

- Do not use on children younger than 2 years old.

UNDESIRABLE EFFECTS
Mometasone furoate is generally well tolerated on the skin. However, skin reactions such as burning, tingling or stinging sensations, itching, skin thinning, application-site reactions, inflamed hair follicles, and pimple-like reactions may occur.

Other skin reactions reported rarely include skin redness, skin irritation, dry skin, excessive hair growth, loss of skin color, tiny red bumps around the mouth, macerated skin, stretch marks, dilated blood vessels on the skin, boils, abscess, increased lesion size, pimples, prickly heat, formation of papules (solid, raised spots on the skin) or pustules (small collection of pus in the top layer of skin), secondary infection, worsening of allergy, and worsening of disease.

Absorption of topical corticosteroids increases when corticosteroids are used on large areas of skin, for longer period of time, with occlusive dressings/bandages, when used in infants and children, or when very potent agents are used. Conditions such as reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, Cushing's syndrome, high blood sugar, and glucose in the urine have occurred with the use of topical corticosteroids.

Infants and children may be more at risk to corticosteroid-induced HPA axis suppression and Cushing's syndrome than adults because of a larger skin surface area to body weight ratio. Chronic treatment with corticosteroids may also interfere with growth and development of children.

WHAT OTHER MEDICINE OR FOOD SHOULD BE AVOIDED WHILE USING THESE MEDICINES?
No harmful interactions have been reported with topical mometasone furoate.

WHAT SHOULD YOU DO IF YOU MISS A DOSE?
Just apply the missed dose and then continue with your regular dosing schedule.

Do not double the dose.

HOW SHOULD YOU KEEP THESE MEDICINES?
Keep the products out of sight and reach of children.

Store at temperatures not exceeding 30°C.
Keep containers tightly closed.

Do not freeze.

SIGNS AND SYMPTOMS OF OVERDOSAGE
When topical corticosteroids are used excessively for a longer period of time, they can suppress HPA function resulting in secondary adrenal insufficiency which is usually reversible. The use of appropriate symptomatic treatment is recommended. Electrolyte imbalance should be treated, if needed.

In case of long-term toxicity, corticosteroid therapy should be withdrawn gradually.

WHAT TO DO IF YOU HAVE USED MORE THAN THE RECOMMENDED DOSAGE
If you have used more than the recommended dosage, or in case of accidental swallowing, consult a doctor.

CARE THAT SHOULD BE TAKEN WHEN USING THESE MEDICINES
- **For external use on the skin only.**
- Avoid contact with the eyes, eyelids or skin near the eyes because of the risk of corticosteroid-induced glaucoma (damaged optic nerves) and increased fluid pressure in the eye, especially with prolonged use.
- Do not use on the face, underarms or groin area unless directed by a doctor.
- Do not cover the treated area with occlusive dressing or bandage, unless directed by a doctor.
- Do not use on the diaper area since diapers or plastic pants may act as occlusive dressing.
- If an infection occurs, an antifungal or antibacterial medicine should be used as recommended by a doctor. If a favorable response does not occur promptly, corticosteroid use should be discontinued until the infection is under control.
- Corticosteroids can change the appearance of some lesions and make it difficult to establish an adequate diagnosis and can also delay the healing of the lesions.
- Patients should be evaluated periodically for evidence of HPA axis suppression if topical corticosteroids are applied to large areas of the body or when used under occlusive dressing.
- Adrenal suppression and any of the side effects that have been reported with systemic corticosteroids may also occur with topical corticosteroids, particularly in infants and children.
- Patients should be carefully monitored when topical corticosteroids are used in the treatment of psoriasis because worsening of the disease or development of pustular psoriasis (a type of psoriasis seen as defined, raised bumps on the skin that are filled with pus) may occur during therapy or when the drug is suddenly discontinued.
- Mometasone cream and ointment both contain propylene glycol which may cause skin irritation. Mometasone ointment contains stearyl alcohol which may cause local skin reactions (e.g., contact dermatitis).
- Do not use after the expiry date on the label.

WHEN SHOULD YOU CONSULT YOUR DOCTOR?
Consult your doctor before use if:
- You are pregnant or breastfeeding
- You have used this medicine before
- You are using other corticosteroids
- You are using other medicines on your skin
- Condition worsens or does not improve within 7 days

If undesirable effects such as skin irritation are experienced, stop use and consult a doctor.

AVAILABILITY
MOMETASONE FUROATE (Momecort®) 1mg/g Cream in aluminum collapsible tube of 5g.
MOMETASONE FUROATE (Momecort®) 1mg/g Ointment in aluminum collapsible tube of 5g.

DATE OF REVISION OF PATIENT INFORMATION LEAFLET (PIL): May 2013

Manufactured by Asian Antibiotics, Inc.
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