**For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only**

MOMOZ S

## 1. Generic Name

Mometasone Furoate 0.1% & Salicylic Acid 5% Ointment

## 2. Qualitative and quantitative composition

Mometasone Furoate I.P. ….0.1% w/w

Salicylic Acid I.P…….....5.0% w/w

In a ointment base ……...q.s.

The excipients used are White Soft Paraffin, Light Liquid Paraffin, White Beeswax, Hard Paraffin and Hexylene Glycol.

## 3. Dosage form and strength

Dosage Form: Ointment

Strength: Mometasone Furoate - 0.1% w/w, Salicylic Acid - 5.0% w/w

## 4. Clinical particulars

### 4.1 Therapeutic indication

It is indicated for the treatment of plaque Psoriasis.

### 4.2 Posology and method of administration

**Dose: As directed by Physician**

*Adults, including elderly patients and Children:* A thin film of MOMOZ S.

Use of topical corticosteroids in children or on the face should be limited to the least amount compatible with an effective therapeutic regimen and duration of treatment should be no more than 5 days.

### 4.3 Contraindications

Contraindicated in patients displaying salicylate hypersensitivity, Mometasone Furoate or sensitivity to any other ingredient in the preparation**.**

It is contraindicated in facial rosacea, acne vulgaris, skin atrophy, perioral dermatitis, perianal and genital pruritis, napkin eruptions, bacterial (e.g. impetigo, pyodermas), viral (e.g. herpes simplex, herpes zoster and chickenpox verrucae vulgares, condylomata acuminata, molluscum contagiosum), parasitical and fungal (e.g. candida or dermatophyte) infections, varicella, tuberculosis, syphilis or post vaccine reactions. MOMOZ S should not be used on wounds or on skin which is ulcerated. MOMOZ S should not be used in patients who are sensitive to Salicylic Acid, Mometasone Furoate, or to other corticosteroids or to any of the excipients.

## 4.4 Special warnings and precautions for use

If irritation or sensitisation develop with the use of MOMOZ S , treatment should be withdrawn and appropriate therapy instituted.

Should an infection develop, use of an appropriate antifungal or antibacterial agent should be instituted. If a favourable response does not occur promptly, the corticosteroid should be discontinued until the infection is adequately controlled.

Systemic absorption of topical corticosteroids can produce reversible hypothalamic pituitary adrenal (HPA) axis suppression with the potential for glucocorticosteroid insufficiency after withdrawal of treatment. Manifestations of Cushing's syndrome, hyperglycemia, and glycosuria can also be produced in some patients by systemic absorption of topical corticosteroids while on treatment. Patients applying a topical steroid to a large surface area or areas under occlusion should be evaluated periodically for evidence of HPA axis suppression.

Any of the side effects that are reported following systemic use of corticosteroids, including adrenal suppression, may also occur with topical corticosteroids, especially in infants and children.

Pediatric patients may be more susceptible to systemic toxicity from equivalent doses due to their larger skin surface to body mass ratios. As the safety and efficacy of Mometasone Furoate in paediatric patients below 2 years of age have not been established, its use in this age group is not recommended.

Local and systemic toxicity is common especially following long continued use on large areas of damaged skin, in flexures and with polythene occlusion. If used in childhood, or on the face, occlusion should not be used. If used on the face, courses should be limited to 5 days and occlusion should not be used. Long term continuous therapy should be avoided in all patients irrespective of age.

Topical steroids may be hazardous in psoriasis for a number of reasons including rebound relapses following development of tolerance, risk of centralised pustular psoriasis and development of local or systemic toxicity due to impaired barrier function of the skin. If used in psoriasis careful patient supervision is important.

As with all potent topical glucocorticoids, avoid sudden discontinuation of treatment. When long term topical treatment with potent glucocorticoids is stopped, a rebound phenomenon can develop which takes the form of a dermatitis with intense redness, stinging and burning. This can be prevented by slow reduction of the treatment, for instance continue treatment on an intermittent basis before discontinuing treatment.

Glucocorticoids can change the appearance of some lesions and make it difficult to establish an adequate diagnosis and can also delay the healing.

Mometasone Furoate topical preparations are not for ophthalmic use, including the eyelids, because of the very rare risk of glaucoma simplex or subcapsular cataract.

Visual disturbance may be reported with systemic and topical (including, intranasal, inhaled and intraocular) corticosteroid use. If a patient present with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes of visual disturbances

which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

For external use only.

Avoid contact with broken or inflamed skin.

Salicylate toxicity may occur if applied to large areas of skin or to the skin of neonates.

**4.5 Drugs interactions**

There are no known interactions when used as indicated. However, topical salicylic acid may increase the absorption of other topically applied medicines. Concomitant MOMOZ S and other topical medicines on the same area of skin should therefore be avoided.

**4.6 Use in special populations (such as pregnant women, lactating women, paediatric patients, geriatric patients etc.)**

Pregnancy

During pregnancy treatment with MOMOZ S should be performed only on the physician's order. Then, however, the application on large body surface areas or over a prolonged period should be avoided. There is inadequate evidence of safety in human pregnancy. Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development including cleft palate and intrauterine growth retardation. There are no adequate and well controlled studies with Mometasone Furoate in pregnant women and therefore the risk of such effects to the human foetus is unknown. However as with all topically applied glucocorticoids, the possibility that foetal growth may be affected by glucocorticoid passage through the placental barrier should be considered. There may therefore be a very small risk of such effects in the human foetus. Like other topically applied glucocorticoids, MOMOZ S should be used in pregnant women only if the potential benefit justifies the potential risk to the mother or the foetus.

Lactation

It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. MOMOZ S should be administered to nursing mothers only after careful consideration of the benefit/risk relationship. If treatment with higher doses or long term application is indicated, breastfeeding should be discontinued.

**4.7 Effects on ability to drive and use machines**

None stated.

**4.8 Undesirable effects**

Table 1: Treatment-related adverse reactions reported with MOMOZ by body system and frequency

| Very common (≥1/10); common (≥1/100, <1/10); uncommon (≥1/1,000, <1/100); rare (≥1/10,000, <1/1,000); very rare (<1/10 000,); not known (cannot be estimated from available data) | |
|---|---|
| **Infections and infestations**<br>Not known<br>Very rare<br>**Nervous system disorders**<br>Not known<br>Very rare<br>**Skin and subcutaneous tissue disorders**<br>Not known<br>Very rare<br>**General disorders and administration site conditions**<br>Not known<br>**Eye disorders**<br>Not Known | Infection, furuncle<br>Folliculitis<br>Paraesthesia,<br>Burning sensation<br>Dermatitis contact, skin hypopigmentation, hypertrichosis, skin striae, dermatitis acneiform, skin atrophy<br>Pruritus<br>Application site pain, application site reactions<br>Vision blurred (see also section 4.4) |

Local adverse reactions reported infrequently with topical dermatologic corticosteroids include: skin dryness, irritation, dermatitis, perioral dermatitis, maceration of the skin, malaria and telangiectasia.

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Paediatric patients may demonstrate greater susceptibility to topical corticosteroid induced hypothalamic pituitary adrenal axis suppression and Cushing's syndrome than mature patients because of a larger skin surface area to body weight ratio.

Chronic corticosteroids therapy may interfere with the growth and development of children.

Possible sensitivity reactions, drying and irritation.

**4.9 Overdose**

**Mometasone furoate**

Excessive, prolonged use of topical corticosteroids can suppress hypothalamic-pituitary adrenal function resulting in secondary adrenal insufficiency which is usually reversible.

If HPA axis suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of application or to substitute a less potent steroid.

The steroid content of each container is so low as to have little or no toxic effect in the unlikely event of accidental oral ingestion.

**Salicylic Acid**

Symptoms of systemic salicylate poisoning (tinnitus, dizziness and deafness) have been reported after the application of salicylic acid to large areas of skin and for prolonged periods. Salicylism may also occur in the unlikely event of large quantities being ingested. Salicylism is unlikely to occur if Salicylic Acid Ointment BP is used as indicated.

Salicylate poisoning is usually associated with plasma concentrations >350mg/L (2.5mmol/L). Most adult deaths occur in patients whose concentrations exceed 700mg/L (5.1mmol/L). Single doses less than 100mg/kg are unlikely to cause serious poisoning.

Symptoms

Common features include vomiting, dehydration, tinnitus, vertigo, deafness, and sweating, warm extremities with bounding pulses, increased respiratory rate and hyperventilation. Some degree of acid-base disturbance is present in most cases.

A mixed respiratory alkalosis and metabolic acidosis with normal or high arterial pH (normal or reduced hydrogen ion concentration) is usual in adults and children over the age of four years. In children aged four years or less, a dominant metabolic acidosis with low arterial pH (raised hydrogen ion concentration) is common. Acidosis may increase salicylate transfer across the blood brain barrier.

Uncommon features include haematemesis, hyperpyrexia, hypoglycaemia, hypokalaemia, thrombocytopenia, increased INR/PTR, intravascular coagulation, renal failure and non-cardiac pulmonary oedema.

Central nervous system features including confusion, disorientation, coma and convulsions are less common in adults than in children.

Management

Give activated charcoal if an adult presents within one hour of ingestion of more than 250 mg/kg. The plasma salicylate concentration should be measured, although the severity of poisoning cannot be determined from this alone and the clinical and biochemical features must be taken into account. Elimination is increased by urinary alkalinisation, which is achieved by the administration of 1.26% sodium bicarbonate. The urine pH should be monitored. Correct metabolic acidosis with intravenous 8.4% sodium bicarbonate (first check serum potassium). Forced diuresis should not be used since it does not enhance salicylate excretion and may cause pulmonary oedema.

Haemodialysis is the treatment of choice for severe poisoning and should be considered in patients with plasma salicylate concentrations >700 mg/L (5.1 mmol/L), or lower concentrations associated with severe clinical or metabolic features. Patients under ten years or over 70 have increased risk of salicylate toxicity and may require dialysis at an earlier stage.

## 5. Pharmacological properties

### 5.1 Mechanism of Action

**Mometasone furoate**

Mometasone furoate exhibits marked anti-inflammatory activity and marked anti-psoriatic activity in standard animal predictive models.

**Salicylic acid**

Salicylic acid is keratolytic by lowering the pH of the skin, resulting in increased hydration of the keratin and swelling of the corneocytes. It also solubilizes the intercellular cement substance in the stratum corneum, facilitating desquamation. Salicylic acid does not change the mitotic rate of the basal keratinocytes. It is mildly antipruritic and anti-inflammatory.

### 5.2Pharmacodynamicproperties

**Mometasone Furoate**

Pharmacotherapeutic group: Mometasone, ATC code: D07AC13

Mometasone Furoate exhibits marked anti-inflammatory activity and marked anti-psoriatic activity in standard animal predictive models.

In the reported study, in the croton oil assay in mice, mometasone was equipotent to betamethasone valerate after single application and about 8 times as potent after five applications.

In guinea pigs, mometasone was approximately twice as potent as betamethasone valerate in reducing m. ovalis-induced epidermal acanthosis (i.e. anti-psoriatic activity) after 14 applications. Salicylic acid has a keratolytic action.

**Salicylic acid**

Salicylic acid has a keratolytic action.

### 5.3 Pharmacokinetic properties

**Mometasone Furoate**

Pharmacokinetic studies have indicated that systemic absorption following topical application of mometasone Furoate cream 0.1% is minimal, approximately 0.4% of the applied dose in man, the majority of which is excreted within 72 hours following application. Characterisation of metabolites was not feasible owing to the small amounts present in plasma and excreta. Salicylic acid may be percutaneously absorbed. However, there is no evidence of any systemic absorption from the use of Salicylic Acid Ointment BP.

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## 6. Nonclinical properties

### 6.1 Animal Toxicology or Pharmacology

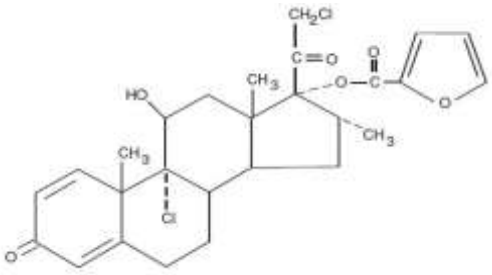
There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

## 7. Description

**Mometasone Furoate**

Mometasone furoate is a synthetic corticosteroid with anti-inflammatory activity.

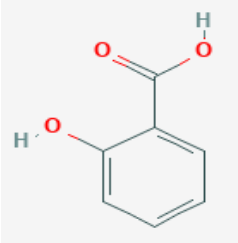
Chemically, mometasone furoate is 9α, 21-dichloro-11β-hydroxy-16α-methyl-3,20-dioxopregna-1,4-diene-3,20-dione 17-yl-furan-2-carboxylate, with the empirical formula $C_{27}H_{30}Cl_2O_6$, a molecular weight of 521.4 and the following structural formula:




Mometasone furoate is a white or almost white powder which is soluble in acetone and in dichloromethane; slightly soluble in ethanol (95%); practically insoluble in water.

**Salicylic Acid**

Salicylic acid is 2-hydroxybenzoic acid with empirical formula $C_7H_6O_3$, a molecular weight of 138.1 and following structural formula:




Salicylic acid is white or colourless, acicular crystals or a white, crystalline powder which is freely soluble in ethanol (95%) and in ether; sparingly soluble in chloroform; slightly soluble in water.

Mometasone Furoate & Salicylic Acid Ointment is white Colour, smooth ointment free from lumps. The excipients used are White Soft Paraffin, Light Liquid Paraffin, White Beeswax, Hard Paraffin and Hexylene Glycol.

## 8. Pharmaceutical particulars

### 8.1 Incompatibilities

None stated

### 8.2 Shelf-life

Do not use later than the date of expiry.

### 8.3 Packaging information

MOMOZ S is available in 15g tube.

### 8.4 Storage and handing instructions

Store at a temperature not exceeding 25ºC. Do not freeze.

## 9. Patient Counselling Information

**Package leaflet: Information for the user**

**Mometasone furoate and Salicylic Acid**

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, pharmacist or nurse.

• 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See Section 4.

What is in this leaflet?



### 9.1.What MOMOZ S is and what it is used for

MOMOZ S Cream is one of a group of medicines called topical corticosteroids. It is classified as a "potent corticosteroid". These medicines are put on the surface of the skin to reduce the redness and itchiness caused by certain skin problems.

**MOMOZ S** ointment contains two active ingredients, Mometasone Furoate and salicylic acid. Mometasone Furoate is one of a group of medicines called topical corticosteroids. It is classified as a "potent corticosteroid". These medicines are put on the surface of the skin to reduce the redness and itchiness caused by certain skin problems.

Salicylic acid softens the top layer of scales on the surface of the skin, which are caused by your skin problem. This allows the Mometasone Furoate to reach the diseased skin underneath to help heal it.

MOMOZ Sis used for the treatment of plaque Psoriasis.

**9.2 What you need to know before you use MOMOZ S**

Do not use MOMOZ S if you have any of the following:

• An allergy (hypersensitivity) to mometasone furoate, any of the other ingredients of this medicine (listed in section 6) or to other similar medicines.

• Any other skin problems as it could make them worse especially:

• Rosacea (a skin condition affecting the face)

• Acne

• Skin atrophy (thinning of the skin)

• Dermatitis around the mouth

• Genital itching

• Nappy rash

• Cold sores

• Chickenpox

• Shingles

• Warts

• ulcerated skin

• Wounds

• Other skin infections

Ask your doctor or pharmacist if you are not sure.

**Warnings and Precautions**

Contact your doctor if your psoriasis gets worse or you get raised bumps filled with pus under your skin. Contact your doctor immediately if you experience blurred vision or other visual disturbances.

If your skin becomes irritated or sensitive after using MOMOZ S, you should stop using it and tell your doctor.

If you think that you have developed an infection on your skin while using MOMOZ S, you should tell your doctor.

Side effects that may happen with inhaled or oral corticosteroids may also occur with corticosteroids used on the skin, especially in infants and children. If you use more than the correct amount of cream and/or use it for longer than is recommended, it can affect the levels of certain hormones in the body, particularly in infants and children. In adults the changes in hormone levels may lead rarely to puffiness or rounding of the face, weakness, tiredness, and dizziness when standing or sitting down.

Do not smoke or go near naked flames – risk of severe burns. Fabric (clothing, bedding, dressings etc.) that has been in contact with this product burns more easily

and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

**Children**

If more than the correct amount of cream is used and/or it is used for longer than is recommended, it can affect the child's hormones. This may lead to:

• Delayed growth and development

• A moon face or rounding of the face

**Other medicines and MOMOZ S**

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

**Pregnancy, breast-feeding and fertility**

You should tell your doctor if you are pregnant or breast-feeding, before you start using MOMOZ S.

**9.3 How to use MOMOZ S**

Always use MOMOZ S exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

**Use in children**

MOMOZ S is not recommended for children under the age of 2.

**How much to use**

Usually for adults and children aged 2 and above, a thin layer of MOMOZ S Cream should be gently rubbed into the affected area of skin once a day.

**Before using MOMOZ S**

You should always follow these instructions when using MOMOZ S:

• Do not use the cream on your face for more than 5 days.

• Do not apply the cream to children, on any part of their body, for more than 5 days.

• Do not put the cream under your child's nappy, as this makes it easier for the active drug to pass through the skin and possibly cause some unwanted effects.

• You should check with your doctor before covering the treated areas with a bandage or plaster. Treated areas on the face or in children should not be covered with a bandage or plaster.

• You should not use a large amount of cream on large areas of the body for a long time (for example every day for many weeks or months).

• Do not use in or around your eyes, including eye-lids.

If you use more MOMOZ S than you should

If you (or somebody else) accidentally swallow the cream, it should not produce any problems. However, if you are worried, you should see your doctor.

If you use the cream 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 used the cream as you were told to do and have used it too often and/or for a long time, you should tell your doctor.

**If you forget to use MOMOZ S**

If you forget to use your cream at the right time, use it as soon as you remember, then carry on as before.

**If you stop using MOMOZ S**

If you have been using MOMOZ S for a long time and your skin problem seems to have got better, you should not suddenly stop using the cream. If you do, you may find that your skin becomes red and you may notice stinging or burning. To avoid this, you should speak to your doctor who will gradually reduce how often you need to use the cream until you stop treatment altogether.

**9.4 Possible side effects**

Like all medicines, MOMOZ S can cause side effects, although not everybody gets them.

A few people may find that they suffer from some of the following side effects after using MOMOZ S:

• Allergic skin reactions

• Bacterial and secondary skin infections

• Acne

• Inflammation and/or infection of the hair follicles

• thinning of the skin

• Red marks with associated prickly heat

• Loss of skin colour

• burning

• Stinging

• itching

• tingling

• Excessive hair growth

• softening of the skin and stretch marks

• blurred vision.

• Deafness

• Hearing Disturbance

Other side effects that may occur with topical corticosteroids are dry skin, skin irritation, dermatitis, dermatitis around the mouth, and small dilated blood vessels.

**9.5 How to store MOMOZ S**

Store at a temperature not exceeding 25ºC. Do not freeze.

**9.6 Contents of the pack and other information**

**MOMOZ S** contains active ingredients as Mometasone Furoate 0.1% w/w and Salicylic Acid I.P. 5.0% w/w

The excipients used are White Soft Paraffin, Light Liquid Paraffin, White Beeswax, Hard Paraffin and Hexylene Glycol.

**10. Details of manufacturer**

Manufactured by:

Helios Pharmaceuticals (Div of P.K.T.P. Pvt. Ltd.)
Village Malpur, P.O. Bhud, Tehsil Nalagarh,
Baddi Dist. Solan (H.P.) – 173205.

**11. Details of permission or licence number with date**

Mfg Lic No. MB/05/281 issued on 01.04.2016

**12. Date of revision**

**MARKETED BY**

TORRENT PHARMACEUTICALS LTD.

**IN/ MOMOZ S 0.1% w/w, 5.0% w/w /AUG-20/01/PI**