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

MOMOZ T

1. Generic Name

Mometasone Furoate with Terbinafine Hydrochloride Cream

2. Qualitative and quantitative composition

Mometasone Furoate I.P...……. 0.1% w/w

Terbinafine Hydrochloride I.P……. 1.0 % w/w

In a cream base……. q.s.

The excipients used are Propylene Glycol, Cetosteryl Alcohol, Cetomacrogol 1000, Petroleum Jelly White, Liquid Paraffin, Butylated Hydroxy Toluene, EDTA Sodium, Sodium Dihydrogen Phosphate Dihydrate, Benzyl Alcohol and Purified Water.

3. Dosage form and strength

Dosage Form: Cream

Strength: Mometasone Furoate - 0.1% w/w, Terbinafine Hydrochloride - 1.0 % w/w.

4. Clinical particulars

4.1 Therapeutic indication

For the treatment of Topical fungal infection associated with inflammation & pruritis.

4.2 Posology and method of administration

Directions for use: As directed by Physician.

For external use only.

4.3 Contraindications

- Hypersensitivity to the active substances Terbinafine Hydrochloride, Mometasone Furoate or to other corticosteroids or to any of the excipients.
- 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.
- On wounds or on skin which is ulcerated. MOMOZ T should not be used in patients who are sensitive to Mometasone Furoate or or to any of the excipients.

4.4 Special warnings and precautions for use

Mometasone Furoate

If irritation or sensitisation develop with the use of Mometasone Furoate, treatment should be withdrawn and appropriate therapy instituted.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

Terbinafine Hydrochloride

Terbinafine may be irritating to the eyes. Contact with the eyes should be avoided. In case of accidental contact with the eyes, rinse eyes thoroughly with running water. Momoz T cream should be kept out of the reach of children.

In the event of allergic reaction, the cream should be removed and the treatment interrupted.

Candidiasis: It is not recommended to use acid pH soap. This provides favourable growth conditions for *Candida* spp.

Instruct patients not to 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.

Excipients

This medicine contains benzyl alcohol in each gram of cream. Benzyl alcohol may cause allergic reactions and mild local irritation. This medicine also contains cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis).

4.5 Drugs interactions

No drug interactions are known with the topical forms of terbinafine and/or mometasone.

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

Mometasone Furoate

Pregnancy

During pregnancy treatment with Mometasone Furoate 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, Mometasone Furoate 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. Mometasone Furoate 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.

Terbinafine Hydrochloride

Pregnancy

There is no clinical experience reported with Terbinafine in pregnant women. Reported foetal toxicity studies conducted in animals suggest no adverse effects. Terbinafine should not be used during pregnancy unless clearly necessary.

Breast-feeding

Terbinafine is excreted into breast-milk. After topical use, only a low systemic exposure is expected. Terbinafine should not be used during breast-feeding. In addition, infants must not be allowed to come into contact with any treated skin, including the breast.

Fertility

No effects of terbinafine on fertility have been seen in reported animal studies.

4.7 Effects on ability to drive and use machines

MOMOZ T has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Mometasone Furoate

Table 1: Treatment-related adverse reactions reported with MOMOZ T 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	
Not known	Infection, furuncle
Very rare	Folliculitis
Nervous System disorders	
Not known	Paraesthesia
Very rare	Burning sensation
Skin and subcutaneous tissue disorders	

Not known	Dermatitis contact, skin hypopigmentation, hypertrichosis, skin strrae, dermatitis acneiform, skin atrophy
Very rare	Pruritus
General disorders and administration site conditions	
Not known	Application site pain, application site reactions
Eye disorders	
Not known	Vision blurred

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

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.

Terbinafine Hydrochloride

Local symptoms such as pruritus, skin exfoliation, application site pain, application site irritation, pigmentation disorder, skin burning sensation, erythema, scab, etc. may occur at the site of application.

These harmless symptoms must be distinguished from hypersensitivity reactions including rash, which are reported in sporadic cases and require discontinuation of therapy.

In case of accidental contact with the eyes terbinafine may be irritating to the eyes.

In rare cases the underlying fungal infection may be aggravated.

Adverse reactions are listed below by system organ class and the frequency. Frequencies are defined as: *very common* (≥1/10), *common* (≥1/100 to <1/10), *uncommon* (≥1/1,000 to <1/100), *rare* (≥1/10,000 to <1/1,000), *very rare* (<1/10,000), not known (cannot be estimated from the available data). Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness.

Immune system disorders	
Not known:	Hypersensitivity*
Eye disorders	

Rare:	Eye irritation
Skin and subcutaneous tissue disorders	
Common:	Skin exfoliation, pruritus
Uncommon:	Skin lesion, scab, skin disorder, pigmentation disorder, erythema, skin burning sensation
Rare:	Dry skin, dermatitis contact, eczema
Not known:	Rash* Acute generalised Exanthematous pustulosis (AGEP)
General disorders and administration site conditions	
Uncommon:	Pain, application site pain, application site irritation
Rare:	Condition aggravated

* Based on post-marketing experience.

- **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via any point of contact of Torrent Pharma available at: http://www.torrentpharma.com/Index.php/site/info/adverse_event_reporting.

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.

Terbinafine Hydrochloride

The low systemic absorption of topical terbinafine renders over dose extremely unlikely.

Symptoms

Should a larger amount of terbinafine cream be inadvertently ingested, adverse effects similar to those observed with an over dose of terbinafine tablets are to be expected. These include headache, nausea, epigastric pain and dizziness.

Treatment

If accidentally ingested, the recommended treatment of over dose consists of eliminating the active substance, primarily by the administration of activated charcoal, and giving symptomatic supportive therapy if needed.

5. Pharmacological properties

5.1 Mechanism of Action

Like other topical corticosteroids, Mometasone furoate has anti-inflammatory, antipruritic, and vasoconstrictive properties. The mechanism of the anti-inflammatory activity of the topical steroids, in general, is unclear. However, corticosteroids are thought to act by the induction of phospholipase A2 inhibitory proteins, collectively called lipocortins. It is postulated that these proteins control the biosynthesis of potent mediators of inflammation such as prostaglandins and leukotrienes by inhibiting the release of their common precursor arachidonic acid. Arachidonic acid is released from membrane phospholipids by phospholipase A2.

Terbinafine Hydrochloride

Terbinafine interferes specifically with fungal sterol biosynthesis at an early step. This leads to a deficiency in ergosterol and to an intracellular accumulation of squalene, resulting in fungal cell death. Terbinafine acts by inhibition of squalene epoxidase in the fungal cell membrane**.**

The enzyme squalene epoxidase is not linked to the cytochrome P-450 system. Terbinafine does not influence the metabolism of hormones or other drugs.

5.2 Pharmacodynamic properties

Mometasone Furoate

Pharmacotherapeutic group: Mometasone, ATC code: D07AC13

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

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.

Terbinafine Hydrochloride

Pharmacotherapeutic group: Antifungal for topical use (ATC code D01A E15)

Terbinafine is an allylamine that has a broad spectrum of antimycotic activity. It has an antimycotic effect on fungal infections of the skin caused by dermatophytes such as *Trichophyton* (e.g. *T. rubrum, T. mentagrophytes, T. verrucosum, T. violaceum*), *Microsporum canis* and *Epdermophyton floccosum.* At low concentrations terbinafine has a

fungicidal effect against dermatophytes and moulds. Its activity against yeasts is fungicidal (e.g. *Pityrosporum orbiculare* or *Malassezia furfur*) or fungistatic, depending on the species.

5.3 Pharmacokinetic properties

Mometasone Furoate

Reported pharmacokinetic studies have indicated that systemic absorption following topical application of Mometasone Furoate cream 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.

Terbinafine Hydrochloride

Less than 5% of the dose is absorbed after topical application to humans: systemic exposure is thus very low.

6. Nonclinical properties

6.1 Animal Toxicology or Pharmacology

Mometasone Furoate

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

Terbinafine Hydrochloride

As per reported data, in long-term studies (up to 1 year) in rats and dogs no marked toxic effects were seen in either species up to oral doses of about 100 mg/kg a day. At high oral doses, the liver and possibly also the kidneys were identified as potential target organs.

In a two-year oral carcinogenicity study in mice, no neoplastic or other abnormal findings attributable to treatment were made up to doses of 130 (males) and 156 (females) mg/kg a day. In a two-year oral carcinogenicity study in rats at the highest dose level, 69 mg/kg a day, an increased incidence of liver tumours was observed in males. The changes, which may be associated with peroxisome proliferation, have been shown to be species-specific since they were not seen in the carcinogenicity study in mice or in other studies in mice, dogs or monkeys.

During the studies of high dose oral terbinafine in monkeys, refractile irregularities were observed in the retina at the higher doses (non-toxic effect level was 50 mg/kg). These irregularities were associated with the presence of a terbinafine metabolite in ocular tissue and disappeared after drug discontinuation. They were not associated with histological changes. A standard battery of in vitro and in vivo genotoxicity tests revealed no evidence of a mutagenic or clastogenic potential for the drug.

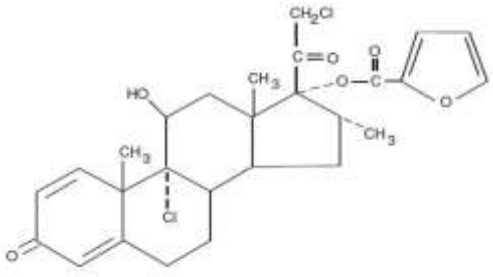
No adverse effects on fertility or other reproduction parameters were observed in studies in rats or rabbits.

7. Description

Mometasone Furoate

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

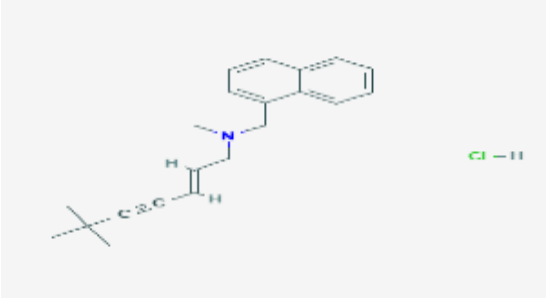
Chemically, Mometasone furoate is 9α, 21-dichloro-11β-hydroxy-16α-methyl-3,20-dioxopregna-1,4-diene-3,20-dione 17-yl-furan-2-carboxylate, with the empirical formula $C_{27}H_{30}Cl_2O_6$, a molecular weight of 521.4 and the following structural formula:



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.

Terbinafine Hydrochloride

Chemically, Terbinafine Hydrochloride is N-(6,6-dimethyl-2-hepten-4-ynyl)-N-methyl-(E)-hydrochloride, with the empirical formula $C_{21}H_{25}N,HCl$, a molecular weight of 327.9 and the following structural formula:



Terbinafine Hydrochloride is a white, crystalline powder; hygroscopic which is freely soluble in dehydrated alcohol and in methanol; slightly soluble in acetone; very slightly or slightly soluble in water.

Mometasone Furoate with Terbinafine Hydrochloride Cream is white Colour, smooth cream free from lumps. The excipients used are Propylene Glycol, Cetosteryl Alcohol, Cetomacrogol 1000, Petroleum Jelly White, Liquid Paraffin, Butylated Hydroxy Toluene, EDTA Sodium, Sodium Dihydrogen Phosphate Dihydrate, Benzyl Alcohol and Purified Water.

8. Pharmaceutical particulars

8. 1 Incompatibilities

Not applicable.

8. 2 Shelf-life

Do not use later than the date of expiry.

8. 3 Packaging information

MOMOZ T is available in 10g tube.

8. 4 Storage and handing instructions

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

Keep out of reach of children.

Close the cap tightly after use.

9. Patient Counselling Information

Package leaflet: Information for the user

MOMOZ T

Mometasone furoate and Terbinafine Hydrochloride

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 T is and what it is used for

MOMOZ T is combination of Mometasone Furoate and Terbinafine Hydrochloride Cream. 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. In adults and children, **Terbinafine** is an antifungal. It kills fungi, which cause skin infections.

MOMOZ T is used for the treatment of Topical fungal infection associated with inflammation & pruritis.

9.2 What you need to know before you use MOMOZ T

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

- An allergy (hypersensitivity) to Terbinafine Hydrochloride, Mometasone furoate or any other corticosteroid or any of the other ingredients of this medicine 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 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 T, you should stop using it and tell your doctor.

If you think that you have developed an infection on your skin while using MOMOZ T, 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 T

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

Do not use this cream if you are breast-feeding as terbinafine hydrochloride can pass into breast milk.

Driving and using machines

MOMOZ T should not affect your ability to drive or operate machines.

This cream contains benzyl alcohol which may cause allergic reactions and mild local irritation. This medicine also contains and cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis).

9.3 How to use MOMOZ T

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

Use in children

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

Before using MOMOZ T

You should always follow these instructions when using MOMOZ T:

• 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 T 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 T

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 T

If you have been using MOMOZ T 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 T 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 T:

- 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
- tingling
- excessive hair growth
- softening of the skin and stretch marks
- Blurred vision.

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

Other side effects

Common (may affect up to 1 in 10 people):

- Skin peeling, itching.

Uncommon (may affect up to 1 in 100 people):

- skin lesions, scab, redness, burning, pain and irritation at the site of Application. These effects are harmless and usually you can continue with the treatment.

Rare (may affect up to 1 in 1,000 people):

Eye irritation, dry skin, contact dermatitis, eczema, worsening of symptoms.

Not Known:

Acute generalised Exanthematous pustulosis (AGEP)

- **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via any point of

contact of Torrent Pharma available at: http://www.torrentpharma.com/Index.php/site/info/adverse_event_reporting.

9.5 How to store MOMOZ T

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

Keep out of reach of children. Close the cap tightly after use.

9.6 Contents of the pack and other information

Mometasone Furoate I.P... 0.1% w/w Terbinafine Hydrochloride I.P1.0 % w/w

The excipients used are Propylene Glycol, Cetosteryl Alcohol, Cetomacrogol 1000, Petroleum Jelly White, Liquid Paraffin, Butylated Hydroxy Toluene, EDTA Sodium, Sodium Dihydrogen Phosphate Dihydrate, Benzyl Alcohol and Purified Water.

MOMOZ T is available in 10g tube.

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 30.11.2017

12. Date of revision

Not Applicable

MARKETED BY

TORRENT PHARMACEUTICALS LTD.

IN/ MOMOZ T 1 and 0.1 %w/w /APR-20/01/PI