

SAME SIZE ARTWORK
LEAFLET SIZE : 150 mm x 320 mm

25 mm


20 mm

25 mm

320 mm

150 mm

SCHEDULING STATUS: S4

PROPRIETARY NAME AND (DOSAGE FORM):
MOMATE OINTMENT 

COMPOSITION:
Each gram of the Ointment contains 1 mg of mometasone furoate as mometasone base.
Other ingredients of the product are hexylene glycol, white wax, propylene glycol (55 % mono-ester), phosphoric acid, white petroleum and purified water.

PHARMACOLOGICAL CLASSIFICATION:
A13.4.1 Corticosteroids with or without anti-infective agents

PHARMACOLOGICAL ACTION:
Pharmacodynamics:
Mometasone is a medium-potency synthetic topical steroid that has anti-inflammatory, antipruritic and vasoconstrictive actions.

Pharmacokinetics:
A minimal amount of mometasone is absorbed after topical application to normal skin. That which is absorbed is metabolised in the liver and excreted in the urine.

INDICATIONS:
MOMATE OINTMENT is indicated for the relief of inflammatory manifestations of psoriasis and corticosteroid-responsive dermatoses.

CONTRA-INDICATIONS:
MOMATE OINTMENT is contra-indicated in those who are sensitive to any of the ingredients. **MOMATE OINTMENT** is contra-indicated in treatment of viral infections such as, herpes simplex, vaccinia and varicella. It is also contra-indicated in patients with untreated fungal infections. **MOMATE OINTMENT** is contra-indicated in pregnancy and lactation (see pregnancy and lactation)

WARNINGS:
MOMATE OINTMENT is not for ophthalmic use. Safety and efficacy of **MOMATE OINTMENT** in paediatric patients for more than three weeks of use have not been established. Use in paediatric patients under the age of two years is not recommended.

INTERACTIONS:
There are no known interactions with the topical use of **MOMATE OINTMENT**.

PREGNANCY AND LACTATIONS:
MOMATE OINTMENT should not be used in pregnancy and lactation. Corticosteroids have been shown to be teratogenic in animals following dermal application. As these agents may be absorbed percutaneously, teratogenicity following topical application cannot be excluded. **MOMATE OINTMENT** should therefore not be used during pregnancy and lactation.

DOSAGE AND DIRECTIONS FOR USE:
A thin film of **MOMATE OINTMENT** should be applied to completely cover the whole affected area once daily.
MOMATE OINTMENT may be used with caution in paediatric patients from the age of two years and older.
Treatment should be discontinued once the condition is under control. Duration of therapy is dependent on clinical response and may vary from a few days to a longer period of time. It should, however, not be continued for longer than three weeks without the patient being re-evaluated.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:
Long-term continuous therapy with **MOMATE OINTMENT** may cause atrophic changes in the skin leading to thinning, loss of elasticity, dilatation of superficial blood vessels, telangiectasiae and ecchymoses, especially if applied to the face or if occlusive dressings are used.
Discontinue treatment if irritation or sensitisation occurs and treat appropriately. In facial dermatoses, **MOMATE OINTMENT** should be used cautiously and for short periods only, as a steroid rosacea-like facies may be produced.

Endocrine disorders:
Systemic absorption may occur, especially when large quantities of the ointment are used or applied to large areas of the body or to damaged skin and when an occlusive dressing technique is applied. This may result in benign intracranial hypertension.

Less frequent:
Cushingoid state, depression of the hypothalamic-pituitary-adrenal axis with consequent suppression of the adrenal gland, and growth retardation may occur. These effects are most likely to be severe in children.

Skin and subcutaneous tissue disorders:
Less frequent:
Allergic contact dermatitis, burning, dryness, folliculitis, irritation, itching, secondary infection, and skin atrophy, acneiform eruptions, perioral dermatitis, hypertrichosis, hypopigmentation, miliaria, maceration of the skin and striae.

SPECIAL PRECAUTIONS:
Safety of use for more than three weeks has not been established and **MOMATE OINTMENT** should therefore be used for short courses only.
MOMATE OINTMENT should not be applied to any skin crease areas and especially not in the nappy area of infants. Its use in children under the age of two years is not recommended, (See **DOSAGES AND DIRECTIONS FOR USE**).

Use with caution near the eyes.
If **MOMATE OINTMENT** is used for the treatment of psoriasis, pustular form of the disease may be provoked.
If a secondary bacterial infection is present, suitable concomitant antimicrobial therapy should be applied.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
Refer to **"SIDE-EFFECTS AND SPECIAL PRECAUTIONS"**.
Excessive or prolonged use of **MOMATE OINTMENT** can suppress pituitary-adrenal function, resulting in secondary adrenal insufficiency, but may also produce manifestations of hypercorticism, including Cushing's syndrome.
Acute hypercorticoicid symptoms are usually reversible. Treat electrolyte imbalance, if necessary. In cases of chronic toxicity, slow withdrawal of **MOMATE OINTMENT** is advised. **TREATMENT IS SYMPTOMATIC AND SUPPORTIVE.**

IDENTIFICATION:
Translucent white soft ointment

PRESENTATION:
MOMATE OINTMENT is packaged in 20 g closed end nozzle laminated collapsible aluminium tubes and 50 g close end nozzle laminated tubes

STORAGE INSTRUCTIONS:
Store at or below 25°C
For External Use Only
Do not use after the expiry date stated on the pack

KEEP OUT OF REACH OF CHILDREN
REGISTRATION NUMBER:
44/13.4.1/0095


NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION
Glenmark Pharmaceuticals South Africa (Pty) Limited
Vorna Valley
Midrand

DATE OF PUBLICATION OF THE PACKAGE INSERT
26 October 2012

Read all of this leaflet carefully before you start applying MOMATE OINTMENT

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- MOMATE OINTMENT** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

Scheduling Status of the medicinal product: S4

(Proprietary) name, strength and pharmaceutical form
MOMATE OINTMENT 

1. What MOMATE OINTMENT contains:
The active substance is mometasone furoate,
Other ingredients of the product are hexylene glycol, white wax, propylene glycol (55 % mono-ester), phosphoric acid, white petroleum and purified water.

2. What MOMATE OINTMENT is used for:
Mometasone belongs to a class of medicines known as corticosteroids.
MOMATE OINTMENT is used for the treatment of inflammation caused by psoriasis and is also used in skin conditions that respond to corticosteroids.

3. Before you use MOMATE OINTMENT:
Do not use MOMATE OINTMENT:

- If you are allergic (hypersensitive) to mometasone furoate or any of the other ingredients
- If you have viral infections, such as herpes simplex, vaccinia and varicella or untreated fungal infections.
- If you are pregnant or breastfeeding
- In any skin crease area like face, groin or armpits unless directed to do so by a doctor, and especially not in the nappy area of infants.
- Do not use **MOMATE OINTMENT** for other skin problems without first checking with your doctor.
- Do not use **MOMATE OINTMENT** more often or for longer time than you doctor ordered.

Do not bandage or otherwise wrap the skin being treated unless directed to do so by your doctor.

Take special care with MOMATE OINTMENT:
Wash your hands after using hands to apply **MOMATE OINTMENT**. If you accidentally get **MOMATE OINTMENT** in your eyes, flush it with water.
In eczema of the face **MOMATE OINTMENT** should be used cautiously and for short period only.
Please consult your doctor regularly in cases where **MOMATE OINTMENT** is used on a large area of the body for a longer period, especially when it is used in children.
Be careful not get **MOMATE OINTMENT** in your eyes. **MOMATE OINTMENT** is not for use in the eyes
Do not use **MOMATE OINTMENT** for periods longer than three weeks in children.
Do not use **MOMATE OINTMENT** in children under the age of two years.
Stop using **MOMATE OINTMENT** and seek immediate medical attention:
If irritation or sensitisation occurs.

Pregnancy and breastfeeding:
MOMATE OINTMENT should not be used in pregnancy or breastfeeding.
If you are pregnant or breastfeeding your baby while using **MOMATE OINTMENT**, please consult your doctor, pharmacist or other healthcare professional for advice.

Using other medicines with MOMATE OINTMENT:
If you are using other medicines on a regular basis, including complimentary or traditional medicines, the use of **MOMATE OINTMENT** with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

4. How to use MOMATE OINTMENT:
Always apply **MOMATE OINTMENT** exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.
MOMATE OINTMENT is not recommended for use in children under two years.
If you forget to use **MOMATE OINTMENT**:
Try to apply your medicine at the same time every day. If you miss a dose, apply it as soon as possible unless it is nearly time to apply again.
Effects when treatment with **MOMATE OINTMENT** is stopped:
Do not stop applying **MOMATE OINTMENT** without first consulting your doctor.
If you have any further questions on the use of **MOMATE OINTMENT**, ask your doctor or pharmacist.

5. Possible side-effects:
MOMATE OINTMENT may cause the following side-effects, and if they do occur they may need medical attention:
Less frequent:
Allergic eczema, burning, dryness, pustules around the hair strands, irritation, itching, secondary infection, thinning of the skin, acne-like sores, red bumps around the mouth, excessive hair growth, lightening of the skin, sweat rash, wrinkling of the skin and stripes.
Not all side-effects reported for **MOMATE OINTMENT** are included in this leaflet. Should your general health worsen while using **MOMATE OINTMENT**, please consult your doctor, pharmacist or other healthcare professional for advice.
If any of the side-effects get serious, or if you notice any side-effects not listed in this leaflet, tell your doctor or pharmacist.

6. Storing and disposing of MOMATE OINTMENT:
Keep all medicines out of the reach and sight of children.
Store at or below 25°C
For External Use Only
Do not use after the expiry date stated on the pack
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets)

7. Presentation of MOMATE OINTMENT:
MOMATE OINTMENT is packaged in 20 g closed end nozzle laminated collapsible aluminium tubes and 50 g close end nozzle laminated tubes

8. Identification of MOMATE OINTMENT:
Translucent white ointment

9. Registration number:
44/13.4.1/0095

10. Name and address of registration holder:
Glenmark Pharmaceuticals South Africa (Pty) Ltd
Vorna Valley
Midrand

11. Date of publication:
26 October 2012

PE0000 ZA

SKEDULERINGSSTATUS: S4

EIENDOMSNAAM (EN DOSEERVORM):

MOMATE OINTMENT (SALF) 

SAMESTELLING:

Elke gram van die Salf bevat 1 mg mometasoonfuroaat as mometasoonbasis. Ander bestanddele van die produk is heksileenglikol, wit was, propileenglikol (55% mono-ester), fosforiese suur, wit petroleum en gesuiwerde water.

FARMAKOLOGIESE KLASSIFIKASIE:

A13.4.1 Kortikosteroïede met, of sonder anti-infektiewe middels

FARMAKOLOGIESE WERKING:

Farmakodinamika:
Mometasoon is 'n medium-sterkte sintetiese topikale steroïed wat anti-inflammatoriese, koorswerende en vatvermouende werkings het.

Farmakokinetika:
'n Minimale hoeveelheid mometasoon word na topikale aanwending op normale vel geabsorbeer. Dit wat geabsorbeer word, word in die lewer gemetaboliseer en in die urine uitgeskel.

INDIKASIES:

MOMATE OINTMENT word aangedui vir die verligting van inflammatoriese manifestasies van psoriase en kortikosteroïed-responsiewe dermatoses.

KONTRA-INDIKASIES: **MOMATE OINTMENT** is teenaangedui in dié wat sensitief is teenoor enige van die bestanddele.

MOMATE OINTMENT is teenaangedui in die behandeling van virale infeksies soos herpes simpleks, vaccinia en varicella. Dit is ook teenaangedui by pasiënte met onbehandelde swaminfeksies.

MOMATE OINTMENT is teenaangedui in swangerskap en laktasie (sien swangerskap en laktasie).

WAARSKUWINGS: **MOMATE OINTMENT** is nie vir oftalmiese gebruik bedoel nie. Die veiligheid en doeltreffendheid van **MOMATE OINTMENT** in pediatriese pasiënte vir langer as drie weke van gebruik is nie vasgestel nie. Gebruik in pediatriese pasiënte onder die ouderdom van twee jaar word nie aanbeveel nie.

INTERAKSIES:

Daar is geen interaksies met die topikale gebruik van **MOMATE OINTMENT** bekend nie.

SWANGERSKAP EN LAKTASIE:

MOMATE OINTMENT behoort nie in swangerskap en laktasie gebruik te word nie. Daar kon aangedui word dat kortikosteroïede teratogenies was in diere na dermale aanwending. Omdat hierdie middels perkutaan geabsorbeer mag word, kan teratogenisiteit na topikale aanwending nie uitgesluit word nie.

MOMATE OINTMENT behoort dus nie tydens swangerskap en laktasie gebruik te word nie.

DOISIS EN GEBRUIKSAANWYSINGS:

'n **Dun film MOMATE OINTMENT** behoort aangewend te word om die hele aangetasde gebied een keer daaglik heiltemal te bedek.

MOMATE OINTMENT mag met omsigtigheid in pediatriese pasiënte vanaf die ouderdom van twee jaar en ouer gebruik word.

Behandeling moet gestaak word sodra die toestand onder beheer is. Die duur van terapie is afhanklik van die kliniese respons en mag varieer van 'n paar dae tot 'n langer tydperk. Dit behoort egter nie vir langer as drie weke voortgesit te word nie sonder dat die pasiënt weer geëvalueer word.

NEWE-EFFEKTE EN SPESIALE VOORSORGMATREËLS:

Langtermyn gedurende terapie met **MOMATE OINTMENT** mag tot atrofiese veranderinge in die vel lei wat veroorsaak dat die vel dun word, sy elastisiteit verloor, dat oppervlakkige bloedvate dilateer, en telangiëktases en egmose voorkom, veral as dit op die gesig aangewend word of as okklusiewe verbande gebruik word. Staak behandeling indien irritasie of sensitisering voorkom en behandel

toepaslik. In dermatoses van die gesig behoort **MOMATE OINTMENT** versigtig en slegs vir kort tydperke gebruik te word, omdat dit 'n steroïed rosacea-agtige gelaat mag veroorsaak.

Endokriene versteurings:

Sistemiese absorpsie mag voorkom, veral as groot hoeveelhede van die salf gebruik word of as dit op groot oppervlaktes van die liggaam of op beskadigde vel aangewend word en as 'n okklusiewe verband-tegniek aangewend word. Dit mag benige intrakraniale hipertensie veroorsaak.

Minder frekwent:

'n Cushingoïede toestand, depressie van die hipotalamiese-pituitêre-adrenale-as met daaropvolgende onderdrukking van die adrenale klier en groeivertraging mag voorkom. Hierdie effekte is meer geneig om by kinders ernstig te wees.

Vel- en onderhuidse weefselversteurings:

Minder frekwent:

Allergiese kontakdermatitis, branderigheid, droogheid, follikulitis, irritasie, jeuk, sekondêre infeksie, en velatrofie, akneagtige erupsies, periorale dermatitis, hipertrikose, hipopigmentasie, milia, maserasie van die vel en striae.

SPESIALE VOORSORGMATREËLS:

Veiligheid van gebruik vir langer as drie weke is nie vasgestel nie en **MOMATE OINTMENT** behoort dus slegs vir kort kursusse gebruik te word.

MOMATE OINTMENT behoort nie op enige velvou-gebiede en veral nie die luer-gebied van kleinkinders aangewend te word nie. Die gebruik daarvan by kinders jonger as twee jaar word nie aanbeveel nie (Sien **DOISIS EN GEBRUIKSAANWYSINGS**).

Gebruik met omsigtigheid naby die oë. Indien **MOMATE OINTMENT** vir die behandeling van psoriase gebruik word, mag die pustulêre vorm van die siekte uitgelok word. Indien 'n sekondêre bakterieële infeksie teenwoordig is, behoort geskikte gelyktydige antimikrobiale terapie aangewend te word.

BEKEDE SIMPTOME VAN OORDOOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:

(Verwys na **NEWE-EFFEKTE EN SPESIALE VOORSORGMATREËLS**.)

Oormatige of langdurige gebruik van **MOMATE OINTMENT** kan die pituitêre adrenale funksie onderdruk, wat sekondêre adrenale ontoereikendheid kan veroorsaak, maar dit mag ook manifestasie van hiperkortikisme, insluitend Cushing-sindroom, produseer.

Akute hiperkortikoïede simptome is gewoonlik omkeerbaar. Behandel elektrolietwanbalans, indien nodig.

In gevalle van chroniese toksisiteit, word stadige onttrekking van **MOMATE OINTMENT** aanbeveel. **BEHANDELING IS SIMPTOMATIES EN ONDERSTEUNEND.**

IDENTIFIKASIE:

Deurskynende wit sagte salf.

AANBIEDING:

MOMATE OINTMENT word verpak in 20 g gelamineerde voubare aluminium buise met 'n geslote-end mondstuk en 50 g gelamineerde buise met 'n geslote-end mondstuk.

BERGINGSAAANWYSINGS:

Bewaar onder of benede 25°C. Slegs vir Uitwendige Gebruik. Moenie na die vervalidatum wat op die verpakking genoem word, gebruik nie.

HOU BUITE BEREIK VAN KINDERS

REGISTRASIE-NOMMER:

44/13.4.1/0095

NAAM EN BESIGHEIDSDRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT:

Glenmark Pharmaceuticals South Africa (Pty) Ltd

Vorna Valley

Midrand

DATUM VAN PUBLIKASIE VAN DIE VOUBILJET

26 Oktober 2012

Lees hierdie hele brosjure versigtig voordat jy begin om MOMATE OINTMENT aan te wend

- Hou hierdie brosjure. Jy mag dit weer moet lees.
- Indien jy enige verdere vrae het, vra asseblief jou dokter of jou apteker.
- MOMATE OINTMENT** is vir jou persoonlik voorgeskryf en jy moet nie jou medisyne met ander mense deel nie. Dit kan hulle skade aandoen, al is hulle simptome dieselfde as joune.

Skeduleringstatus van die medisinale produk: S4

(Eiendoms)naam, sterkte en farmaseutiese vorm:

MOMATE OINTMENT 

1. Wat MOMATE OINTMENT bevat:

Die aktiewe stof is mometasoonfuroaat. Ander bestanddele van die produk is heksileenglikol, wit was, propileenglikol (55% mono-ester), fosforiese suur, wit petroleum en gesuiwerde water.

2. Waarvoor MOMATE OINTMENT gebruik word:

Mometasoon behoort aan 'n klas van medisyne wat as kortikosteroïede bekend staan.

MOMATE OINTMENT word gebruik vir die behandeling van inflammasie wat deur psoriase veroorsaak word en word ook gebruik in velbestande wat op kortikosteroïede reageer.

3. Voordat jy MOMATE OINTMENT gebruik:

Moenie MOMATE OINTMENT gebruik nie:

- Indien jy allergies (hipersensitief) is vir mometasoonfuroaat of enige van die ander bestanddele.
- Indien jy virale infeksies soos herpes simpleks, vaccinia en varicella of onbehandelde swaminfeksies het.
- Indien jy swanger is of borsvoed
- In enige velvou-gebied soos die gesig, lies of oksels, tensy jou dokter instruksies gegee het dat jy dit moet doen, en veral nie in die luer-gebied van kleinkinders nie.
- Moenie **MOMATE OINTMENT** vir ander velprobleme gebruik nie sonder om eers met jou dokter te gesels.
- Moenie **MOMATE OINTMENT** meer dikwels of vir 'n langer tyd as wat jou dokter aanbeveel het, gebruik nie.

Moenie die vel wat behandel word, verbind of andersins toedraai nie tensy jou dokter vir jou aanwysings gegee het om dit te doen.

Neem spesiale sorg met MOMATE OINTMENT:

Was jou hande nadat jy jou hande gebruik het om **MOMATE OINTMENT** aan te wend. Indien **MOMATE OINTMENT** per abuis in jou oë beland, moet dit met water gespoel word.

In ekseem van die gesig, behoort **MOMATE OINTMENT** versigtig en slegs vir kort tydperke gebruik te word.

Raadpleeg asseblief jou dokter gereeld in gevalle waar **MOMATE OINTMENT** op 'n groot oppervlak van die liggaam vir 'n langer tydperk gebruik word, veral as dit by kinders gebruik word.

Wees versigtig om nie **MOMATE OINTMENT** in aanraking met jou oë te laat kom nie. **MOMATE OINTMENT** is nie vir gebruik in die oë bedoel nie. Moenie **MOMATE OINTMENT** vir tydperke langer as drie weke by kinders gebruik nie.

Moenie **MOMATE OINTMENT** by kinders onder die ouderdom van twee jaar gebruik nie.

Staak die gebruik van MOMATE OINTMENT en kry onmiddellik mediese hulp:

Indien irritasie of sensitisering voorkom.

Swangerskap en borsvoeding:

MOMATE OINTMENT behoort nie in swangerskap of borsvoeding gebruik te word nie.

Indien jy swanger is of jou baba borsvoed terwyl jy **MOMATE OINTMENT** gebruik, moet jy asseblief jou dokter, apteker of ander gesondheidsorgdeskundige vir advies raadpleeg.

Gebruik van ander medisyne saam met MOMATE OINTMENT:

Indien jy ander medisyne gereeld neem insluitend komplementêre en tradisionele medisyne, mag die gelyktydige gebruik van **MOMATE OINTMENT** saam met hierdie medisyne, ongewenste interaksies veroorsaak. Raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgdeskundige vir advies.

4. Hoe om MOMATE OINTMENT te gebruik:

Wend **MOMATE OINTMENT** altyd presies aan soos jou dokter of apteker aanbeveel het. Jy behoort met jou dokter of apteker te gesels indien jy nie seker is nie.

MOMATE OINTMENT word nie vir gebruik by kinders onder die ouderdom van twee jaar, aanbeveel nie.

Indien jy vergeet om MOMATE OINTMENT te gebruik:

Probeer om jou medisyne op dieselfde tyd elke dag aan te wend. Indien jy 'n dosis oorslaan, wend dit so gou as moontlik aan tensy dit amper tyd is dat jy dit weer moet aanwend nie.

Effekte wanneer behandeling met MOMATE OINTMENT gestaak word:

Moenie ghou om **MOMATE OINTMENT** aan te wend nie, sonder om eers jou dokter te raadpleeg.

Indien jy enige verdere vrae oor die gebruik van **MOMATE OINTMENT** het, moet jy jou dokter of apteker daarvoor vra.

5. Moontlike nuwe-effekte:

MOMATE OINTMENT mag die volgende nuwe-effekte veroorsaak, en indien dit voorkom, mag dit mediese aandag nodig hê:

Minder frekwent:

Allergiese ekseem, branderigheid, droogheid, pustules rondom die hare, irritasie, jeuk, sekondêre infeksie, die vel wat dunner word, akneagtige sere, rooi bulte rondom die mond, oormatige haargroei, die vel wat ligter word, sweet uitslag, verimpeling van die vel en strepe.

Nie al die nuwe-effekte wat vir **MOMATE OINTMENT** aangemeld is, word in hierdie brosjure ingesluit nie. Indien jou algemene gesondheid sou vererger terwyl **MOMATE OINTMENT** gebruik word, raadpleeg asseblief jou dokter, apteker of 'n ander lid van die professionele gesondheidsorgpersoneel vir advies.

Indien enige van die nuwe-effekte ernstig word, of as jy bewus word van enige nuwe-effekte wat nie in hierdie brosjure gely is nie, moet jy jou dokter of apteker daarvan vertel.

6. Opberging en wegdoening van MOMATE OINTMENT:

Hou alle medisyne buite die bereik en sig van kinders. Bewaar onder of benede 25°C. Slegs vir Uitwendige Gebruik.

Moenie na die vervalidatum wat op die verpakking aangegee word, gebruik nie. Neem alle ongebruikte medisyne terug na jou apteker. Moenie ongebruikte medisyne in dreine of rioolsisteme (bv. toilette) weggooi nie.

7. Aanbieding van MOMATE OINTMENT:

MOMATE OINTMENT word verpak in 20 g gelamineerde voubare aluminium buise met 'n geslote-end mondstuk en 50 g gelamineerde buise met 'n geslote-end mondstuk.

8. Identifikasie van MOMATE OINTMENT:

Deurskynende wit salf

9. Registrasienommer

44/13.4.1/0095

10. Naam en adres van registrasiehouer

Glenmark Pharmaceuticals South Africa (Pty) Ltd

Vorna Valley

Midrand

11. Datum van publikasie

26 Oktober 2012

PE00000 ZA

20 mm

320 mm

150 mm

ICONGRAPHICS CODE:

GLENMARK PHARMACEUTICALS LTD.		This is an Important Document. Please handle it Carefully, Initials & Remarks only in Space Provided below.		PANTONE SHADE	
PRODUCT	:				
Product Code	:		Version	:	
Item	:		Location	:	
Reason For Changing of A/W:					
DEPARTMENT	CHECK LIST FOR APPROVAL		CHECKED BY:	AUTHORISED BY:	
Packaging Development	Item code, Version, Consistency of Design, over print area, Pack Size, Carton size, label size, foil width, repeat length, specification & Layout				
Regulatory affair	Regulatory Text.				
Corporate QA	Entire Text Matter				
Medical Dept	Strength & Dosage, Route of Administration, Indication, Contraindication, Caution, Precaution, Any Other Medical Information (for Leaflet)				
Marketing Local / Export	Colour, Logo, Brand Name, Design, Additional Information & Other Than English Text, as per Party requirement				
Points / notes for correction :					Supersedes Artwork Code

VERSION: 3 DATE: 05-02-13
 VERSION: 2 DATE: 28-11-12
 VERSION: 1 DATE: 16-11-12