SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

BEEGEE CREAM (Betamethasone Dipropionate Cream USP)

2. Qualitative and quantitative composition

- Betamethasone Dipropionate USP
eq. to Betamethasone..... (0.05 % W/W)
- Cream Base..... (Q.S.)
For the full list of excipients see section 6.1

3. Pharmaceutical form

Cream

4. Clinical particulars

Therapeutic indications

Betamethasone Dipropionate is a synthetic fluorinated corticosteroid. It is active topically and produces a rapid and sustained response in eczema and dermatitis of all types, including atopic eczema, photodermatitis., lichen planus, lichen simplex, prurigo nodularis, discoid lupus erythematosus, necrobiosis lipoidica, pretibial myxedema and erythroderma. It is also effective in less responsive conditions such as psoriasis of the scalp and chronic plaque psoriasis of the hands and feet but excluding widespread plaque psoriasis.

Posology and method of administration

Adults and Children:

Once to twice daily. In most cases a thin film of Beegee Cream should be applied to cover the affected area twice daily. For some patient's adequate maintenance therapy may be achieved with less frequent application.

Beegee Cream is especially appropriate for moist or weeping surfaces and the ointment for dry, lichenified or scaly lesions but this is not invariably so.

Contraindications

Rosacea, acne, perioral dermatitis, perianal and genital pruritus. Hypersensitivity to any of the ingredients of the Beegee Cream presentations contra-indicates their use as does tuberculous and most viral lesions of the skin, particularly herpes simplex, vaccinia, varicella. Beegee Cream should not be used in napkin eruptions, fungal or bacterial skin infections without suitable concomitant anti-infective therapy.

Special warnings and precautions for use

Local and systemic toxicity is common, especially following long continuous use on large areas of damaged skin, in flexures or with polythene occlusion. If used in children or on the face courses should be limited to 5 days. Long term continuous therapy should be avoided in all patients irrespective of age.

Occlusion must not be used.

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

General: Systemic absorption of topical corticosteroids can produce reversible HPA axis suppression with the potential for glucocorticosteroid insufficiency after withdrawal of treatment. Manifestations of Cushing's syndrome also can be produced in some patients by systemic absorption of topical corticosteroids while on treatment. Patients receiving a large dose of a potent topical steroid applied to a large surface area should be evaluated periodically for evidence of 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 corticosteroid**.**

Recovery of HPA axis function is generally prompt and complete upon discontinuation of the drug. Infrequently, signs and symptoms of steroid withdrawal may occur, requiring supplemental systemic corticosteroids.

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.

Paediatric patients may be more susceptible to systemic toxicity from equivalent doses due to their larger skin surface to body mass ratios.

If irritation develops, treatment should be discontinued, and appropriate therapy instituted.

Beegee Cream is not for ophthalmic use.

Paediatric Use:

Paediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced HPA axis suppression and to exogenous corticosteroid-induced HPA axis suppression and to exogenous corticosteroid effects than adult patients because of greater absorption due to a larger skin surface area to body weight ratio. HPA axis suppression, Cushing's syndrome and intracranial hypertension have been reported in paediatric patients receiving topical corticosteroids. Manifestations of adrenal suppression in paediatric patients include linear growth retardation, delayed weight gain, low plasma cortisol levels and an absence of response to ACTH stimulation. Manifestations of intracranial hypertension include a bulging fontanelle, headaches and bilateral papilledema.

Interaction with other medicinal products and other forms of interaction

None stated.

Fertility, pregnancy and lactation

There are no adequate and well controlled studies of the teratogenic potential of topically applied corticosteroids in pregnant women. Therefore, topical steroids should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus.

It is not known whether topical administration of corticosteroids would result in sufficient systemic absorption to produce detectable quantities in breast milk. Systemically administered corticosteroids are secreted into breast milk in quantities not likely to have a deleterious effect on the infant. Nevertheless, a decision should be made whether to discontinue the drug, taking into account the importance of the drug to the mother.

Effects on ability to drive and use machines

None stated.

Undesirable effects

Beegee Cream skin preparations are generally well tolerated and side-effects are rare. The systemic absorption of betamethasone dipropionate may be increased if extensive body surface areas or skin folds are treated for prolonged periods or with excessive amounts of steroids. Suitable precautions should be taken in these circumstances, particularly with infants and children.

The following local adverse reactions that have been reported with the use of Beegee Cream include: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, striae and miliaria.

Continuous application without interruption may result in local atrophy of the skin, striae and superficial vascular dilation, particularly on the face.

Overdose

Excessive prolonged use of topical corticosteroids can suppress pituitary-adrenal functions resulting in secondary adrenal insufficiency which is usually reversible. In such cases appropriate symptomatic treatment is indicated. If HPA axis suppression is noted, an attempt should be made to withdraw the drug, reduce the frequency of application, or to substitute a less potent steroid.

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

5. Pharmacological properties

Pharmacodynamic properties

Beegee Cream preparations contain the dipropionate ester of betamethasone which is a glucocorticoid exhibiting the general properties of corticosteroids.

In pharmacological doses, corticosteroids are used primarily for their anti-inflammatory and/or immune suppressive effects.

Topical corticosteroids such as betamethasone dipropionate are effective in the treatment of a range of dermatoses because of their anti-inflammatory, anti-pruritic and vasoconstrictive actions. However, while the physiologic, pharmacologic and clinical effects of the corticosteroids are well known, the exact mechanisms of their action in each disease are uncertain.

Pharmacokinetic properties

The extent of percutaneous absorption of topical corticosteroids is determined by many factors including vehicle, integrity of the epidermal barrier and the use of occlusive dressings. Topical corticosteroids can be absorbed through intact, normal skin. Inflammation and/or other disease processes in the skin may increase percutaneous absorption.

Occlusive dressings substantially increase the percutaneous absorption of topical corticosteroids.

Once absorbed through the skin, topical corticosteroids enter pharmacokinetic pathways similar to systemically administered corticosteroids. Corticosteroids are bound to plasma proteins in varying degrees, are metabolised primarily in the liver and excreted by the kidneys. Some of the topical corticosteroids and their metabolites are also excreted in the bile.

Preclinical safety data

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

6. Pharmaceutical particulars

List of excipients

Cetomacrogol 1000 INH
Cetostearyl Alcohol BP
White Soft Paraffin BP
Sodium Acid Phosphate BP
Disodium Hydrogen Phosphate BP
Benzyl alcohol BP
Liquid Paraffin (Heavy) BP
Propylene Glycol BP
Purified Water BP

Incompatibilities

None known.

Shelf life
36 months

Special precautions for storage
Store at a temperature not exceeding 30°C.

Nature and contents of container
30 gm lami tube packed in inner carton along with the leaflet.

Special precautions for disposal and other handling
Not applicable.

7. Marketing authorisation holder
KREMOINT PHARMA PVT. LTD.
Plant: B-8, Additional Ambernath,
M.I.D.C., Ambernath (East),
Dist. Thane – 421 506.

8. Marketing authorisation number(s)
Registration Number: 04957/06690/NMR/2018

9. Date of first authorisation/renewal of the authorisation
Approval Date: 04.02.2020

10. Date of revision of the text
Revision of Text : 04.02.2025

1.NAMEOFTHEFINISHED PRODUCT

Lipuiduce-10Tablet

2.QUALITATIVEANDQUANTITATIVECOMPOSITION

ACTIVE INGREDIENTS	PER TABLET (MG)
AtorvastatinCalcium	10.85(equivalenttoAtorvastatin10mg)

Kindlyrefer to Section 6.1 for excipient.

3.PHARMACEUTICALFORM

Whitecolouredfilm-coatedovalshapedtablets,shallow convex faces, plainonbothsides.

4.CLINICALPARTICULARS

Therapeuticindication

Atorvastatinin indicated:

Asanadjuncttherapytodiettoreduceelevatedtotalcholesterol,LDL-cholesterol, apolipoprotein B, triglyceride and increase HDL-cholesterol in patients with:

- Primaryhypercholesterolemia(heterozygousfamilialandnonfamilial).
- Combinedhyperlipidaemia(FredricksonTypesIIa and IIb).
- Hypertriglyceridemia(FredricksonType IV).
- Primarydysbetalipoproteinemia(FredricksonType III).

As an adjunct therapy with other lipid lowering treatment (e.g. LDL apheresis) in homozygous familial hypercholesterolemia to reduce total cholesterol and LDL cholesterol.

4.2 PosologyandMethodofadministration

UsualAdultandadolescentdose:
Oral, the recommended initial dose of atorvastatin is 10 mg once dailywhich maybe adjusted at intervals of 4 weeks. The dosage range in 10 to 80 mg once daily.

Usualpediatricdose:
Dosagehasnotbeen established.

Thepatientshouldbeplacedonastandardcholesterol-loweringdietandweightreduction programs/exercisesbeforereceivingatorvastatinandshouldcontinuetheregimenduring treatmentwith atorvastatin.

Contraindication

- Activeliverdiseaseorunexplained persistentelevationsofserum transaminases.
- Hypersensitivityto anycomponent of this drug.
- Pregnancyand lactation.

Warningsandprecautions

- LiverDysfunction:HMG-CoAreductaseinhibitorshavebeenassociatedwithbiochemical abnormalities of liver function. Therefore, liver function tests should be performed prior to and at 12 weeks following initiation of therapy or elevation in dose, and semi annually thereafter.
- Atorvastatinshouldbeusedwithcautioninpatientswithalcoholism,organtransplantwith immunosuppressant therapy and/ or patients who have a history of liver disease.
- Serious conditions such as hypotension, severe acute infection, severe metabolic, endocrine, orelectrolytedisorder,uncontrolledseizures,majorsurgery,ortraumamayincreasedriskof secondary renal failure if rhabdomyolysis occurs.

Drug Interactions

- The risk of myopathy increased with concurrentadministration of cyclosporine, fibric acidderivatives, niacin (nicotinic acid), erythromycin or azole antifungals.
- Co-administration with antacid reduces plasma concentrations of atorvastatin by approximately 35%.
- Concurrentuseofatorvastatinwithcholestyramineorcolestipolmaydecreasethe bioavailability of atorvastatin.
- Concurrentuse withdigoxin maycauseanelevation inserum digoxin concentration.
- Concurrent use with anticoagulants, coumarin- or indandione derivative may increase bleeding or prothrombin time.
- Concurrent use with large amounts of grapefruit juice has been reported to significantly increase the serum concentrations and the area under the plasma concentration-time curve (AUC).
- Co-administration of atorvastatin with an oral contraceptive may increase AUC value for norethindrone and ethinyl estradiol by approximately 30% and 20% respectively.
- Plasmaconcentrationsofatorvastatinincreasedwithco-administrationof erythromycin.
- Caution should be exercised when if an HMG-CoA reductase inhibitor is administered concomitantly with drugs that may decrease the levels or activity of endogenous steroid hormones, such as ketoconazole, spironolactone, and cimetidine.

4.6 Pregnancyandlactation

Atorvastatin is not recommended during pregnancy, in women who plan to become pregnant in the near future, or during lactation.

4.7 Effectsonabilitytodriveanduse machines

Not applicable.

4.8 MainSide/AdverseEffects

Myalgia,myositis,rhabdomyolysis,constipation,diarrhea,heartburn,stomachpain,dizziness, headache, nausea, skin rash, insomnia

4.9 Overdose

Thereisnospecifictreatmentofatorvastatinoverdosage.Intheeventofanoverdose,the patient should be treated symptomatically, and supportive measures instituted as required.

5.PHARMACOLOGICAL PROPERTIES

5.1Pharmacodynamicproperties

Atorvastatin is a selective, competitive inhibitor of 3-Hydroxy-3-methylglutaryl coenzyme A (HMG-CoA) reductase. The inhibition of HMG-CoA reductase prevents conversion of HMG-CoA to mevalonate, the rate-limiting step in cholesterol biosynthesis. Inhibition of cholesterol synthesis in the liver leads to upregulation of low-density lipoprotein (LDL) receptors and an increase in catabolism of LDL cholesterol. It may also reduce the production of LDL as a result of inhibition of hepatic synthesis of verylow-densitylipoprotein (VLDL), the precursorof LDL.

HMG-CoA reductase inhibitors reduce LDL-cholesterol, VLDL-cholesterol, and to a lesser extent, plasma triglyceride concentration, and slightly increase high-density lipoprotein (HDL) concentration.

5.2Pharmacokinetic properties

Atorvastatin is rapidly absorbed after oral administration; maximum plasma concentrationoccurs within 1 to 2 hours. It has low absolute bioavailability of about 12% due to presystemic clearance in the gastrointestinal mucosa and/ or first-pass metabolism in the liver, its primary sites of action.

Atorvastatin is 98% bound to plasma proteins. It is metabolizedbyortho- and parahydroxylation andbeta-oxidationtoactivemetabolites.Thedruganditsmetabolitesareeliminatedprimarilyin the bile. The mean plasma elimination half-life is approximately 14 hours.

5.3 PreclinicalSafetyData

NOT APPLICABLE

6. PHARMACEUTICALPARTICULARS

List ofexcipients

Lactose Monohydrate
MicrocrystallineCellulose
Calcium Carbonate
Croscarmellose Sodium
Polysorbate 80
Polyvinylpyrrolidone
Magnesium stearate
Hydroxypropyl methylcelluose E-5
HydroxypropylmethylcelluloseE-15 Titanium
Dioxide
Talc
PropyleneGlycol

Incompatibilities

NOTAPPLICABLE

Shelflife

2.5 yearsfromdateofmanufacture

Specialprecautionforstorage

Storebelow30°C.Protectfromlightandmoisture.

Natureandcontentsof container

PrimaryPackaging		
1	Materialdescription Width Materialspecifications Sealing Winding	:ColdFormPlainFoilforLipiduce-10 :120 mm : 25OPA–45–PVC60 :Heatsealonbrightside :Dullsidetop/brightsidedown
2	Material description Width Specification	:Lipiduce-10aluminiumfoil : 120 mm :Foilproperty:Silverplainhardtempered20micron aluminium foil with 6276 primer on bright and heat seal on dull surface.
SecondaryPackaging		
3	Materialdescription Dimension	:Lipiduce-10(3x10)UnitBox :117.5mm(L)x65mm(W)x24mm(H)
4	Materialdescription Dimension	:PlaincartonforLipiduce-10 : 480mm(L) x262mm(W)x249mm(H)
5	Materialdescription Dimension	:Lipiduce-10ProductInsert : 160mm(W) x130mm(H)

6.6 Instructionsforuseandhandling<and disposal>

NOT APPLICABLE

7.MARKETINGAUTHORISATION HOLDER

Hovid Berhad
Name:HOVIDBhd.
Address:121,JalanTunkuAbdulRahman,
(Jalan Kuala Kangsar)
30010Ipoh,Perak, Malaysia

ManufacturerName:

Name	:	HOVID Bhd.Address
	:	Lot56442,7½Miles, JalanIpoh/Chemor, 31200 Chemor, Perak., Malaysia.

8.NUMBER(S)INTHENATIONALREGISTEROFFINISHEDPHARMACEUTICAL PRODUCTS

HOV/MAL/031

9.DATE OFFIRSTAUTHORISATION\

2016

10.DATEOFREVISIONOFTHETEXT

October2017