Public Assessment Report
Diprolieve Cream
Alclometasone dipropionate
PL 00201/0276
Schering-Plough Ltd

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Lay Summary

This application concerns the reclassification of Diprolieve Cream from prescription only medicine (POM) to Pharmacy (P). Diprolieve is used in the treatment of eczema and dermatitis.

The evidence was found to support the reclassification of Diproleve cream from Prescription Only Medicine to Pharmacy. This view was supported during the public consultation phase. A marketing authorisation was granted on 17/09/2009.
Scientific Discussion

INTRODUCTION

This is a POM to P reclassification application for alclometasone dipropionate 0.05% cream to be marketed under the name Diprolieve Cream in a 15g pack for:

The short term symptomatic treatment and control of patches of eczema and dermatitis, including atopic and primary irritant and allergic dermatitis (excluding seborrhoeic dermatitis) in adults and children aged 12 years and over.

The reclassification application for Diprolieve has been submitted in parallel with an abridged MA application in accordance with 10.1 (a) (i) of Directive 2001/83/EC claiming “essential similarity” to the currently authorised Modrasone Cream (PL 00201/0060). It is intended that The Boots Company plc will be included on the MA as own-label distributors of the pharmacy product as “Boots Pharmacy Eczema & Dermatitis Relief Cream”.

Alclometasone Dipropionate 0.05% was granted a MA in the UK in 1985 and is currently marketed as Modrasone. It has prescription only status worldwide and is indicated for the treatment of inflammatory and pruritic manifestations of corticosteroid responsive dermatoses.

Alclometasone is a moderately potent non-fluorinated synthetic corticosteroid. Up until 2001, hydrocortisone 1% cream was the only topical steroid available without prescription if used in accordance with certain restrictions. Clobetasone butyrate, under the trade name Eumovate Eczema and Dermatitis Cream, was granted P status for “the short term treatment and control of patches of eczema and dermatitis including atopic and primary irritant and allergic dermatitis” in adults and children over the age of 12 years.

Whilst the current indications for alclometasone dipropionate are quite broad, the proposed indication for Diprolieve is identical to one approved for Eumovate Eczema and Dermatitis Cream.

ASSESSMENT

MEDICAL ASSESSMENT

The efficacy of the product has already been established by granting of an MA for the wider indication of “treatment of inflammatory and pruritic manifestations of corticosteroid responsive dermatoses”. The dose dosage is also within the approved dosage regimen.
2.1 Safety profile
The safety profile of alclometasone is based on the original clinical trials, a post-marketing surveillance study and spontaneous adverse reaction reports. In trials, 4% of patients experienced adverse reactions and these tended to be minor and transient. Three percent reported burning or stinging. The surveillance study was carried out in general practice, involved both the cream and ointment formulations, and included 3150 patients with steroid-responsive dermatoses. During the study, 2.6% reported adverse events of which 80% involved discomfort on application and/or disease exacerbation.

For the period 1992-2003, worldwide exposure to the cream is estimated to be 6 million patients, of which UK exposure was approximately 500,000. There have only been 79 adverse event reports worldwide with both cream and ointment formulations (estimated total exposure of 8 million patients). Whilst there have been no particular safety signals, the clinical overview does not discuss theoretical risks of skin atrophy or adrenal suppression with topical steroid use and whether or not these are likely to be affected by over the counter use. There were no reports of skin thinning or adrenal suppression in the surveillance study over a period of 21 days. Review of line listings of spontaneous reports indicate a single report of skin atrophy and one of adrenal insufficiency, the latter was with the ointment and multiple steroid preparations had been in use prior to the event.

2.2 Relative potency
In terms of safety, there is a particular statement in the SPC for alclometasone that poses some concern and has not been mentioned in the Overview. In section 5.1 Pharmacodynamic properties, it states:

"Preclinical studies have shown alclometasone dipropionate to be approximately 2/3 as potent as betamethasone valerate and 60 x as potent as hydrocortisone". Betamethasone is classified as a potent steroid and although hydrocortisone is a mild steroid, non-prescription use is restricted to formulations \( \leq 1\% \). The clinical significance of this statement with respect to safety has not been addressed.

It would be good practice to treat with the least potent agent that produces a clinical response. The proposed SPC and PIL do not address this; however this is also the case for Eumovate cream, which is also a moderately potent steroid. The potency of Diprolieve relative to Eumovate needs to be established.

Request for Supplementary information
The applicant was asked to provide:

(i) The data behind the SPC statement in Section 5.1: “Pre-clinical studies have shown alclometasone dipropionate to be approximately 2/3 as potent as betamethasone valerate and 60 X as potent as hydrocortisone”

(ii) A ranking for alclometasone within the moderately potent corticosteroids group (Group II).
(iii) Information concerning the relative safety of alclometasone compared to hydrocortisone 1% and Clobetasone butyrate 0.05%

The data confirm that the potency of alclometasone is approximately 2/3 that of betamethasone valerate however it has less systemic effects than the other corticosteroids tested, including betamethasone valerate, dipropionate and flucinonide.

In relation to potency, the available evidence indicates that whilst the vasoconstrictor assay predicts alclometasone 0.05% to be as potent as betamethasone dipropionate i.e. group II (I being the highest and VII lowest), clinical efficacy was not found to correspond with this potency level. From the information available, alclometasone is more potent than hydrocortisone and similar in potency to clobetasone 0.05%, which is reflected in the BNF system of classification.

The data on relative safety indicate that there is no cause for concern in relation to adrenal suppression when alclometasone is used according to the SPC. Furthermore available evidence indicates no significant differences between alclometasone and hydrocortisone in relation to either their potential to cause skin atrophy (following application for 3 – 6 weeks) or the incidence of local adverse reactions.

ASSESSMENT OF POM CRITERIA

3.1 A direct or indirect danger exists to health, even when used correctly, if utilised without medical supervision

The risk of complications of chronic steroid application will be reduced by limiting treatment to 7 days without medical advice and the tube size to 15 g. In addition, it is recommended to apply the cream twice a day rather than the POM recommendation of 2-3 times a day. Application is to be without occlusion to reduce systemic absorption. Patients will also be advised not to treat children under the age of 12 years unless under a doctor's supervision.

As is the case with all topical steroids, adrenal suppression is a possible risk with long-term use, particularly in infants and under occlusion. Alclometasone did not cause adrenal suppression, based on serum cortisol levels, in healthy volunteers after application of 30 g twice daily to 80% of the body surface under occlusive dressing over 21 days (C81-004-01). Similarly based on the parameter of serum cortisol levels, the pituitary-adrenal axis was not suppressed in 12 patients with psoriasis or atopic dermatitis over 7 day’s treatment with ointment.

The sensitivity/specificity of the assays used is not known, and more detailed investigations such as Synacthen stimulation were not carried out. There is however no indication that adrenal suppression is a problem if used in accordance with the SPC.

Hypersensitivity and application site reactions do occur and patients will be advised to stop treatment if signs of irritation or sensitisation occur. Review of the DAP and PAP is unremarkable.
Medical supervision is required for treatment of psoriasis due to danger of rebound exacerbation. Patients will be advised not to use the cream on the face as it may cause acneform pustules or perioral dermatitis.

In common with other corticosteroids, animals have shown reproductive toxicity. It is not known if topical application could result in sufficient systemic absorption to be detected in breast milk. Pregnant or lactating women should seek the advice of a doctor or pharmacist.

There is no reason why use of Diprolieve should pose an indirect danger.

3.2 Frequently and to a very wide extent used incorrectly and as a result is likely to present a direct or indirect danger to health

Use of Diprolieve cream is contraindicated in rosacea, acne, perioral dermatitis, and viral skin lesions. It should also not be used for fungal or bacterial (e.g. impetigo) skin infections. Patients will therefore be advised not to use the cream on the groin, genitals, breast creases or toe web spaces, as these are common sites for such infections. Medical advice is to be sought for seborrhoeic dermatitis as this involves areas of skin where Diprolieve Cream should not be used.

The fingertip unit method will be described to ensure that excessive exposure does not occur. Patients are warned not to initiate treatment of the same site for a third time without seeking medical advice. This would help prevent incorrect use due to misdiagnosis. Acute overdose is not a concern. The availability of Pharmacy of 1% hydrocortisone formulations as P medicines over several years has not given rise to any significant issues.

3.3 Contains substances or preparations of substances of which the activity requires, or the side effects require, further investigation

The active, alclometasone has been available in the UK since 1985 with no particular safety concerns. The safety profile has been characterised.

DISCUSSION

The principle of self-diagnosis and short-term management of eczema and dermatitis in adults and children over the age of 12 years is already well established. Detailed CSM guidance was made available on the criteria for P status of Hydrocortisone cream. More recently a moderately potent corticosteroid, Clobetasone Butyrate 0.05% (Eumovate) was reclassified as a P medicine for limited indications, under conditions consistent with the original guidelines for hydrocortisone.

The MA holder for alclometasone dipropionate has submitted an application to make the product available without prescription for the same indications with similar contraindications and precautions for use as Eumovate Eczema and Dermatitis Cream, under the trade names Diprolieve Cream/Boots Pharmacy
Eczema & Dermatitis Relief Cream. Efficacy of the product in the indications sought is established. The safety profile of the product in POM usage has been characterised. There has only been one report of adrenal suppression within the context of 8 million patients exposed to both cream and ointment formulations.

Pre-clinical studies demonstrate high topical potency of alclometasone, which is consistent with the vasoconstrictor assay results. However, this assay is said not to always correlate with clinical efficacy in psoriasis, which was the model used for bilateral paired comparisons.

According to the information available alclometasone is more potent than hydrocortisone 1% and similar in potency to clobetasone butyrate 0.05% based on the BNF system of classification. The more detailed Cornell and Stoughton classification ranks alclometasone in category VI, based on clinical efficacy. Alclometasone appears to be an agent where the vasoconstrictor assay did not predict clinical efficacy, since based on the assay it would be classed as a group II, or potent steroid. According to the Stoughton system of classification, clobetasone is stated as being V in one paper i.e. more potent than alclometasone, but not mentioned or categorised in others.

Greater potency of alclometasone than hydrocortisone 1% is evident. There are no definitive data differentiating clobetasone butyrate from alclometasone.

Since clobetasone butyrate 0.05% is already available as a pharmacy medicine, it would seem appropriate for alclometasone 0.05% be reclassified as a P medicine with identical indications and restrictions.

PRELIMINARY CONCLUSION

It is not considered necessary to seek CSM advice on the proposed reclassification of alclometasone 0.05% as the proposed product particulars are the same as those for clobetasone 0.05% cream. CSM will be invited to comment as part of the consultation procedure.

CONSULTATION

ARM 29 (Appendix 1) proposing pharmacy availability of Diprolieve was issued on 17 June, with a deadline for responses of 29 July 2005.

RESPONSES TO CONSULTATION AND DISCUSSION

There were 14 responses, of which 10 commented specifically on the proposals. All supported the application although some comments and points for clarifications were raised.

ASSESSOR’S OVERALL CONCLUSIONS ON QUALITY AND ADVICE

The product may be reclassified as Pharmacy and a marketing authorisation granted.

The SPC, patient information leaflet and labelling were amended during the procedure.
Overall Conclusion and Risk/Benefit Analysis

Quality
The product has been demonstrated to have satisfactory quality.

Pre-Clinical
There were no new concerns regarding the pre-clinical data of Diproleve Cream.

Clinical
A review of clinical data supported the reclassification of Diproleve cream from Prescription Only Medicine to Pharmacy.

Risk/Benefit Analysis
The risk benefit of the reclassification of Diproleve cream to Pharmacy from Prescription Only Medicine was found to be positive.
**Steps Taken During Assessment**

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<td>1</td>
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<td>Following standard checks and communication with the applicant the MHRA considered the application valid on 25/02/2004.</td>
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<td>The application was determined on 17/09/2009.</td>
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Steps Taken after Assessment

No non-confidential changes have been made to the market authorisation.
SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Diprolieve Eczema and Dermatitis Cream.
Boots Pharmacy Eczema and Dermatitis Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Alclometasone Dipropionate 0.05% w/w

For excipients, see 6.1

3 PHARMACEUTICAL FORM

Cream

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Diprolieve Eczema and Dermatitis Cream is indicated for the short-term treatment and control of patches of eczema and dermatitis including atopic eczema and primary irritant and allergic dermatitis.

4.2 Posology and method of administration

Diprolieve Eczema and Dermatitis Cream is indicated for use in adults and children 12 years and older. Use in children under 12 years only on advice of a doctor.

Diprolieve Eczema and Dermatitis Cream should be applied sparingly (see section 6.6 Instructions for Use/Handling) to the affected area twice a day for up to 7 days. If the condition resolves within 7 days, treatment with Diprolieve Eczema and Dermatitis Cream should be stopped. If the condition does not improve in the first 7 days or becomes worse the consumer will be advised to see a doctor. If after 7 days of treatment
improvement is seen but further treatment is required, the consumer will be advised to see a doctor.

4.3 Contraindications

Hypersensitivity to Diprolieve Eczema and Dermatitis Cream or any of the ingredients; rosacea; acne and perioral dermatitis; tuberculous and viral lesions of the skin, particularly Herpes Simplex; vaccinia; varicella.

Diprolieve Eczema and Dermatitis Cream should not be used on broken skin or in fungal (eg candidiasis, tinea) or bacterial skin infections (eg impetigo).

4.4 Special warnings and precautions for use

As with all topical corticosteroids absorption can be increased by the use of occlusion, which in infants can lead to adrenal suppression. In addition, the management of eczema and dermatitis in infants and young children requires the supervision of a physician. Self-management is therefore limited to adults and children aged 12 years and over for no more than 7 days continuous treatment without occlusion.

Consumers will be advised not to initiate treatment of the same site for a third time without seeking medical advice to confirm the diagnosis.

Consumers should be advised to use Diprolieve Eczema and Dermatitis Cream only for the treatment of eczema or dermatitis, as it may mask or exacerbate other conditions. In particular, consumers will be advised not to use Diprolieve Eczema and Dermatitis Cream on the groin, breast-fold, genitals or between the toes as these are common sites of fungal infections.

Diprolieve Eczema and Dermatitis Cream should not be used on the face as it may cause acneform pustules or perioral dermatitis.

Diprolieve Eczema and Dermatitis Cream is not for ophthalmic use. Care should be taken not to get cream in the eye due to the risk of glaucoma following topical application.

Medical advice should be sought in seborrhoeic dermatitis since this involves areas of skin where Diprolieve Eczema and Dermatitis Cream should not be used.

Consumers should be warned not to use other topical corticosteroids, either prescribed or obtained over-the-counter (such as hydrocortisone) at the same time as Diprolieve Eczema and Dermatitis Cream as this may increase the risk of unwanted effects.
Consumers should be advised that they should not use topical alclometasone dipropionate for the treatment of psoriasis as rebound exacerbation may be a problem. This condition should be managed under the care of a physician.

4.5 Interaction with other medicinal products and other forms of interaction

None Known.

4.6 Pregnancy and lactation

There are no adequate data from the use of Diprolieve Eczema and Dermatitis Cream in pregnant women. Studies in animals have shown reproductive toxicity (see section 5.3) but the potential risk for humans is unknown.

It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Women who are pregnant or breast-feeding will be advised not to use Diprolieve Eczema and Dermatitis Cream but to seek the advice of a pharmacist or doctor.

4.7 Effects on ability to drive and use machines

There is no evidence that Diprolieve Eczema and Dermatitis Cream can have any effect on the ability to drive or operate machinery.

4.8 Undesirable effects

Hypersensitivity and application site reactions, such as burning, stinging and irritation, have occurred rarely in a few patients following short-term (up to 7 days) use. Consumers should be advised to stop treatment if signs of irritation and sensitisation occur. Exacerbation of symptoms may occur.

4.9 Overdose

Acute overdosage is unlikely. Excessive prolonged use of topical corticosteroids can suppress pituitary-adrenal function resulting in secondary adrenal insufficiency which is usually reversible. In such cases appropriate symptomatic treatment is indicated. In cases of chronic toxicity, corticosteroids should be withdrawn slowly. There is also a risk of skin atrophy with the chronic use of topical steroids.
The steroid content is so low as to have little or no effect in the unlikely event of accidental oral ingestion.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Corticosteroids, dermatological preparations – Corticosteroids, moderately potent (group II), ATC code D07A B10

Alclometasone dipropionate is a non-fluorinated, topically active synthetic corticosteroid. Pharmacological studies in man and animals have demonstrated that alclometasone dipropionate suppresses local inflammation at doses producing minimal systemic effects. Preclinical studies have shown alclometasone dipropionate to be approximately 2/3 as potent as betamethasone valerate and 60 x as potent as hydrocortisone.

The anti-inflammatory properties of alclometasone dipropionate reduce the erythema, induration and pruritus associated with these conditions.

Diprolieve Eczema and Dermatitis Cream has no effect on hypothalamic-pituitary-adrenal function, as measured by plasma cortisol levels, as demonstrated by application of large amounts of the cream to healthy volunteer adults under whole body occlusion.

5.2 Pharmacokinetic properties

Not applicable in view of topical action and application.

5.3 Preclinical safety data

Alclometasone dipropionate cream appears to be a relatively non-toxic and non-irritating drug product that produces no unusual or unexpected teratologic effects in laboratory animals. A wide margin of safety was demonstrated in all species studied. Acute oral and intraperitoneal doses more than 3,000 times the proposed topical human dose were without any toxicologically significant effects.

Topical administration of corticosteroids to pregnant animals can cause abnormalities in foetal development. The relevance of this finding to human beings has not been established; however, topical steroids should not be used extensively in pregnancy i.e. in large amounts or for long periods.
6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Propylene glycol
- White soft Paraffin
- Cetostearyl alcohol
- Glyceryl Stearate PEG 100 stearate
- Polyoxyethylene (20) cetyl ether
- Sodium dihydrogen phosphate dihydrate
- Chlorocresol
- Phosphoric acid
- Purified Water

6.2 Incompatibilities

None Known.

6.3 Shelf life

60 months

6.4 Special precautions for storage

Do not store above 25°C

6.5 Nature and contents of container

Aluminium tubes with white LDPE caps.
Pack sizes: 15g

6.6 Instructions for use and handling, and disposal

Knowing how much cream to use can be difficult. The fingertip unit method is one easy way. A fingertip unit is the amount of cream you can squeeze on to your fingertip from the tip to the first crease. Half a fingertip unit (see diagram) will cover a patch of skin the same size as the palm of your hand.
Follow these instructions:

- Wash your hands and dry them.
- Squeeze out the correct amount of cream on to your index finger. The diagram gives you an idea of how much to use.
- Gently rub the cream in to the area of skin which you are treating, until the cream disappears.
- Wash your hands again (unless it is your hands you are treating).

Use the fingertip unit as a guide. For smaller areas, use a smaller amount. The cream isn’t meant to treat large areas.

If you forget or miss a dose, use it when you remember.

Don’t worry if you use a bit too much cream by mistake, but try to keep to the fingertip unit. Using steroids on the skin continuously over many weeks or months can cause skin thinning.

Do not cover the treated area of skin with anything other than your clothes. Plasters, dressings, gloves or cling film should not be used as they can cause more of the medicine to pass through the skin.

7 MARKETING AUTHORISATION HOLDER

Schering-Plough Ltd
Shire Park
Welwyn Garden City
Hertfordshire
AL7 1TW

8 MARKETING AUTHORISATION NUMBER(S)

PL 00201/0276

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

17/09/2009
10 DATE OF REVISION OF THE TEXT

17/09/2009
PL 00201/0276

Labels and Leaflets

PATIENT INFORMATION LEAFLET

Diprolieve Eczema and Dermatitis Cream
Alcromelone Dipropanate 0.05%

Please read this leaflet carefully before you start using this medicine.

This leaflet will tell you about Diprolieve Eczema and Dermatitis Cream which is available without a doctor's prescription to treat eczema and dermatitis. You should follow the advice and instructions contained in this leaflet to make sure the cream works properly.

Keep this leaflet. You may need to read it again. Ask your pharmacist if you need more help or advice.

The active ingredients in Diprolieve Eczema and Dermatitis Cream is Alcromelone Dipropanate 0.05%. Other ingredients are propylene glycol, white soft paraffin, cetylstearyl alcohol, glyceryl stearate PEG 100 stearate, polyoxyethylene (20) ester ether, sodium dihydrogen phosphate/ dihydroxy, chlorohexed, phosphoric acid, purified water. The cream comes in 15g tubes.

Marketing Authorisation Holder: Schering-Plough Ltd, Shire Park, Welwyn Garden City, Hertfordshire AL7 1TW

Manufacturer: Schering-Plough Labe NV, Heist-op-den-Berg, Belgium.

1. What type of medicine is this?

Diprolieve Eczema and Dermatitis Cream is one of a group of medicines called topical corticosteroids. "Topical" means they are put on the skin. "Corticosteroids" are used to control inflammation. The cream works by stopping the skin's response to the trigger that causes skin flare-ups. It reduces the inflammation that causes eczema and dermatitis. The cream has been available on prescription under a different name for many years.

Topical corticosteroids should not be confused with "steroidal" steroids mixed by some athletes and taken as tablets or injection. They are completely different.

2. What is the cream for?

Use Diprolieve Eczema and Dermatitis Cream on patches of itchy or inflamed skin to relieve the itching and irritation of eczema and dermatitis, for up to 7 days. If you are not sure what is causing your skin problem, ask a pharmacist or doctor.

3. Before using the cream

Make sure you have read the following points before using the cream.

Do not use the cream:

- If you have ever had an allergic reaction to this cream or any of its ingredients.
- On children under the age of 12, unless a doctor tells you to.
- If you are pregnant, think that you may be pregnant, or breast-feeding. You should talk to a doctor or pharmacist.

Do not use the cream on certain areas of the body.

- On your face as it may cause acne or spotty red rash around the mouth (perioral dermatitis) but it's OK on the neck and ears.
- On your groin, breast, folds, genitalia (private parts) or the anal (back passage).
- Between your toes.

Be especially careful that you do not get the cream in your eyes due to risk of glaucoma.

Do not use the cream on any other skin problems as it could make these worse.

Do not use the cream on:

- Rosacea (overactive flushing of skin on and around the nose), spotty red rash around the mouth (perioral dermatitis) or acne or seborrheic dermatitis. These involve areas of skin where the cream should not be used.
- Skin infections - such as cold sores, chickenpox; TB of the skin; impetigo; impetigo; broken skin athletes foot and thrush.
- Perniosis - this needs to be treated by your doctor.

The cream contains propylene glycol, cetylstearyl alcohol and chlorohexid, which may cause skin irritation, skin reactions such as contact dermatitis, and allergic reactions.

Do not use hydrocortisone, or any other steroid-containing creams and ointments, on the skin whilst you are using Diprolieve Eczema and Dermatitis Cream, as you would be increasing the risk of unwanted effects.

If your rash gets better but comes back:

Do not treat the same patch more than twice without taking advice from your doctor. It is possible that you are treating the wrong skin condition or that you are still in contact with your allergic triggers.

4. How to use the cream

Adults and children over the age of 12 years:

Use the cream twice a day for up to 7 days.

Knowing how much cream to use can be difficult. The fingertip unit method is one easy way. A fingertip unit is the amount of cream you can squeeze onto your fingertip from the tip to the first crease. Half a fingertip unit (see diagram) will cover a patch of skin the same size as the palm of your hand.

Follow these instructions:

- Wash your hands and dry them.
- Squeeze out the correct amount of cream on to your index finger.
- The diagram here gives you an idea of how much to use.
- Gently rub the cream in to the area of skin which you are treating, until the cream disappears.
- Wash your hands again (unless it is your hands you are treating).
Use the fingertip unit as a guide. For smaller areas, use a smaller amount. The cream isn’t meant to treat large areas.

If you forget or miss a dose, use it when you remember. Do not worry if you use a bit too much cream by mistake—just try to keep to the fingertip unit. Using steroids on the skin continuously over many weeks or months can cause skin thinning.

Do not cover the treated area of skin with anything other than your clothes. Pleated, drawstring, gloves, or cling film should not be used as they can cause more of the medicine to pass through the skin.

5. While using the cream

Diprolieve Eczema and Dermatitis Cream is meant to control skin conditions that improve within 7 days of starting treatment. If you think you need further treatment after 7 days, stop using the cream and see your pharmacist or doctor.

If your skin condition clears up in less than 7 days, stop using the cream. Use of an emollient (see box opposite) may help maintain the condition of the skin.

If your skin gets worse or does not improve within 7 days, stop using the cream and see your pharmacist or doctor.

If your skin condition improves after using the cream, but then your symptoms return, you may still be reacting to a trigger. Check the examples of common triggers in the box opposite. If you can’t work out what is wrong, ask your doctor for advice.

6. Possible side effects

Most people find that when the cream is used correctly by following the advice given on the can, it does not cause any problems. However, rarely, a few people may find that their skin condition gets worse during treatment. This may be due to a skin infection, or a trigger you haven’t recognised, or an allergy to the cream. Irritation, burning or stinging may occur very rarely when the cream is applied to the skin. If your skin condition gets worse, or if your skin is irritated after applying the cream, stop using it and see your doctor.

7. Storing the cream

The cream should be stored below 25°C. Do not use the cream after the use by date stamped on the tube and carton. Keep the cream out of the reach and sight of children.

More about eczema and dermatitis

Dermatologists (skin specialists) often advise people with eczema or dermatitis to use emollients (moisturisers) in the form of creams and bath oils. Emollients coat the skin with a waterproof layer and prevent excessive water loss. So they help keep the skin moist, supple and soft, which can reduce flare-ups. Perfumed soaps and toiletries should be avoided. Ask your pharmacist for further information.

Some people find that their skin rash returns after treatment, or never disappears completely. This is often because they are still in contact with the trigger, which is causing repeat reactions. Examples of common triggers are given below. If you can’t work out what’s wrong, ask your pharmacist or doctor for advice.

Atopic eczema/dermatitis often runs in families and may be linked with other conditions such as asthma and hayfever. Triggers for this type of eczema include dust, pets’ fur or pollen. Certain foods can also be a trigger.

Allergic contact eczema/dermatitis is set off by a chemical or substance coming into contact with the skin. Common examples include nickel in jewellery and clothing, soap powders and soaps, chrome in cement, some plants, chemicals found in shampoos and cosmetics. Many different substances which you may use at work can also cause eczema, such as rubber and various dyes.

Inflammatory contact eczema/dermatitis occurs when the skin is repeatedly exposed to harsh or irritating substances such as detergents or excessive washing of the hands.

Self help tips:

- Avoid overheating, caused by too much clothing or bedding for example, as this can make your irritation worse.
- Very hot climates are not ideal because sweating makes eczema worse.
- Keep nails short as scratching may damage your skin and can make your symptoms worse.
- Try to avoid stress or emotional upsets.
- Be aware that infections anywhere in the body such as colds or flu may make eczema worse.

Further information on eczema and dermatitis:

You may be able to find out more from websites. You can contact the National Eczema Society, Hill House, Highgate Hill, London, N10 3BA. Helpline 0207 241 3604, helpline@eczema.org, www.eczema.org

If you have any other questions about Diprolieve Eczema and Dermatitis Cream or are not sure about anything, ask a pharmacist or doctor for advice.

Date of preparation: September 2004
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UKPAR Schering Plough Ltd, Diprolieve Cream
Diprolieve® Eczema and Dermatitis Cream

Albomethasone Dipropionate 0.05%
For itchy, red and irritated skin

Relieves the itching and irritation of a flare up of eczema and dermatitis

Adults and children 12 years of age and over: Apply to the affected area twice a day for up to 7 days. If your skin does not improve or gets worse within a week, stop using the cream and see your doctor.

Active ingredient: Albomethasone dipropionate 0.05%. Other ingredients: Propylene glycol, White soft paraffin, Cetostearyl alcohol, Glycerol stearate, PEG 1100 stearate, Polyoxyethylene (20) cetyl ether, Sodium dihydrogen phosphate dipropionate, Chloroform, PEG 60 hydrogenated castor oil, Purified water.

Do not store above 25°C.

Keep all medicines out of the reach and sight of children.

PL 00201/0276

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Eczema & Dermatitis Cream 0.05%
(Aclometasone Dipropionate)

- Read leaflet for full instructions.
- Treats and controls flare up of small patches of eczema and dermatitis.
- How to use this medicine
  - Follow the instructions in the leaflet.
  - Adults and children over 12 years: Apply sparingly to the affected area twice a day for up to 7 days.

- Active Ingredient: This cream contains Aclometasone Dipropionate 0.05% w/w.
- Also contains: Propylene glycol, white soft paraffin, cetostearyl alcohol, cetearyl palmitate, PEG 100 glycerate, polyethylene (20) cetyl ether, sodium dihydrogen phosphate dihydrate, chloroform, phenoxyethanol, purified water.

Store below 25°C.
Keep all medicines out of the sight and reach of children.
PL 00201/0276

Boots Pharmacy
Nottingham NG3 3AA
PL held by Schering-Plough Ltd.
Waltham Garden CW3 7JW
Eczema & Dermatitis Cream 0.05% (Alclometasone Dipropionate)

Specifically to:
- Treat flare up of inflamed skin
- Reduce redness & itching

How to use
Use only on the skin.
Keep away from eyes.
Place tube seal with end of cap. Wash your hands and dry them.
Follow the instructions in the leaflet.
Adults and children over 12 years:
Apply sparingly to the affected area twice a day for up to 7 days.
If symptoms worsen or do not go away within 7 days, talk to your doctor.
Active Ingredient
Alclometasone Dipropionate 0.05% w/w
Also contains:
Propylene glycol, white soft paraffin, cetostearyl alcohol, glyceryl stearate PEG 100 stearate, polyoxyethylene (20) cetyl ether, sodium dihydrogen phosphohydrazide, chloromers, phosphoric acid, purified water.

How to store
Store below 25°C.
Keep all medicines out of the sight and reach of children.
Use by the date on the end flap of carton.
Manufactured for播出 Pharmacy, Nottingham NG2 3AA, Product Licence held by Schering-Plough Ltd, Welwyn Garden City AL7 1TW, PL 0201/0276
If you need more advice ask your pharmacist.

For the short term treatment and control of flare up of patches of eczema and dermatitis, including atopic eczema and primary irritant and allergic dermatitis.

Before you use
Do not use:
- If you are allergic to any of the ingredients
- On the same area of skin more than twice without consulting a doctor
- On broken or infected skin, or to treat any other skin condition
- On your face, groin, genital areas, breast folds or between your toes
- Dressings or plasters over the cream
- Talk to your pharmacist or doctor:
  - If you are pregnant or breastfeeding

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