PATIENT INFORMATION LEAFLET

Dermovate® Cream (clobetasol propionate)

Your medicine is known by the above name but will be referred to as Dermovate throughout this leaflet.

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

What is in this leaflet:
1. What Dermovate is and what it is used for
2. What you need to know before you use Dermovate
3. How to use Dermovate
4. Possible side effects
5. How to store Dermovate
6. Contents of the pack and other information

1. What Dermovate is and what it is used for

Dermovate contains a medicine called clobetasol propionate. It belongs to a group of medicines called steroids. It helps to reduce swelling and irritation. Dermovate is used to help reduce the redness and itchiness of certain skin problems. These skin problems include:
- frequently relapsing eczema
- psoriasis (thickened patches of inflamed, red skin, often covered by silvery scales), excluding widespread plaque psoriasis
- lichen planus, (a skin disease that causes itchy, reddish-purple, flat-topped bumps on the wrists, forearms or lower legs)
- discoid lupus erythematosus (a disease of the skin most often affecting the face, ears and scalp causing scarring and increased sensitivity of the affected skin to sunlight)
- dermatitis and other skin conditions that have not responded to milder steroid creams or ointments.

2. What you need to know before you use Dermovate

Do not use Dermovate:
- if you are allergic (hypersensitive) to clobetasol propionate or any of the other ingredients of this medicine (listed in Section 6)
- on a child under 1 year of age
- to treat any of the following skin problems, it could make them worse:
  - acne
  - severe flushing of skin on and around your nose (rosacea)
  - spotty red rash around your mouth (perioral dermatitis)
  - itching around your anus or genitals (penis or vagina)
  - infected skin (unless the infection is being treated with an anti-infective medicine at the same time)
  - itchy skin which is not inflamed
  - widespread plaque psoriasis, except single lesions.

Do not use if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before using Dermovate.

Warning and precautions

Talk to your doctor or pharmacist before using Dermovate if:
- you have previously had an allergic reaction with another steroid.
- you are applying the cream under an airtight dressing, including a child’s nappy. These dressings make it easier for the active ingredient to pass through the skin. It is possible to accidentally end up using too much cream.
- make sure that the skin is cleansed before a fresh dressing is applied to prevent infections.
- you are applying the cream on broken or damaged skin or within skin folds.
- you are applying to a large surface area.
- you have psoriasis, your doctor will want to see you more often.
- you are using for a chronic leg ulcer as you may be at increased risk of local allergic reaction or infection.
- you are applying near eyes or on eyelids, as cataracts or glaucoma may result if the cream repeatedly enters the eye.
- you are applying to thin skin such as the face, as Dermovate may cause skin thinning. Use on the face should be limited to 5 days.

Dressings or bandages should not be used on the face where the cream is applied.

Contact your doctor if you experience blurred vision or other visual disturbances.

If an infection develops during the use of this medicine, talk to your doctor or pharmacist.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before using this medicine.

Children
- Do not use this medicine in children under 1 year of age.
- Avoid continuous treatment for a long period of time in infants and children over 1 year of age, as their skin is thinner than adults and as a result may absorb larger amounts.
- Use on children should be limited to 5 days and reviewed weekly.
- Dressings or bandages should not be used on children where the cream is applied.

Other medicines and Dermovate

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicine, especially if you are taking ritonavir and iraconazole medications.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

If you do use Dermovate when breast-feeding do not use it on your breast area to ensure that the baby does not accidentally get Dermovate in their mouth.

Dermovate Cream contains propylene glycol, cetostearyl alcohol and chlorocresol

Propylene glycol may cause skin irritation. Cetostearyl alcohol may cause local skin reactions (eg, contact dermatitis). Chlorocresol may cause allergic reactions.

3. How to use Dermovate

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

Using this medicine

- You usually apply a thin layer of Dermovate once or twice a day. This may be reduced as your skin begins to get better, or stopped when better. Your doctor may prescribe a weaker steroid for you to use instead.
- If you are also using an emollient (moisturiser), allow time for Dermovate to be absorbed into your skin before applying the emollient.
- This cream is for use on your skin only.
- Do not use for more than 4 weeks without talking to your doctor.

If you need treatment for a long time, your doctor may decide you need to use a milder cream or ointment.

If your skin problem worsens or does not improve within 2 to 4 weeks, talk to your doctor.

- The germs that cause infections like the warm and moist conditions under dressings. If directed to cover the treated area with a dressing, always clean the skin before a fresh dressing is put on to help prevent infection of the skin beneath the dressing.
- If you are applying the cream on someone else make sure you wash your hands after use or wear disposable plastic gloves.

Guidance on how to apply the cream

1 Wash your hands.
2 Apply a thin layer to the affected area(s) and gently rub into the skin until it has all disappeared. You can measure how much Dermovate to use with your fingertip. For children you will need to use less cream but still use an adult finger to measure out the fingertip unit. This picture shows one fingertip unit.

3 Unless you are meant to apply the cream to your hands as a part of the treatment, wash them again after using the cream.

For an adult
Do not worry if you find you need a little more or less than this. It is only a rough guide.

For a child aged 1 – 10

<table>
<thead>
<tr>
<th>Number of fingertips units needed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Child’s age</td>
</tr>
<tr>
<td>1-2 years</td>
</tr>
<tr>
<td>3-5 years</td>
</tr>
<tr>
<td>6-10 years</td>
</tr>
</tbody>
</table>

Use in children
• Do not use this medicine on children under 1 year of age.
• It is especially important in children not to exceed the prescribed amount.
• A course of treatment for a child over the age of 1 year should not normally last more than 5 days unless your doctor has told you to use it for longer. Your doctor may want to see the child every week, whilst using the cream.
• Dressings or bandages should not be used on children where the cream is applied.

If you have psoriasis
If you have thick patches of psoriasis on your elbows or knees, your doctor may suggest applying the cream under an airtight dressing. It will only be at night to help the cream to start working. After a short period of time you will then apply the cream as normal.

If you apply Dermovate to your face
You should only apply the cream to your face if your doctor tells you to. It should be limited to only 5 days as the skin on your face thins easily. Dressings or bandages should not be used on the face where the cream is applied. Do not let the cream get into your eyes. If it does, wash it out with plenty of water.

If you use more Dermovate than you should
If you apply too much or if accidentally swallowed, it could make you ill. Talk to your doctor or go to hospital as soon as possible.

If you forget to use Dermovate
If you forget to apply your cream, apply it as soon as you remember. If it is close to the time you are next meant to apply it, wait until this time.

If you stop using Dermovate
If you use Dermovate regularly make sure you talk to your doctor before you stop using it as your condition may get worse if stopped suddenly.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects
Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop using Dermovate and tell your doctor immediately if:
• you find that your skin problem gets worse, you develop a generalised rash or your skin becomes swollen during treatment. You may be allergic to the cream, have an infection or need other treatment.
• you have psoriasis and get raised bumps with pus under the skin. This can happen during or after the treatment and is known as psoratic psoriasis.

Other side effects you may notice when using Dermovate include:
Common (may affect up to 1 in 10 people)
• feeling of burning, pain, irritation or itching where the cream is applied.

Uncommon (may affect up to 1 in 100 people)
• skin thinning, this may cause stretch marks
• blood vessels under the surface of your skin may become more noticeable.

Very Rare (may affect up to 1 in 10,000 people)
Use of Dermovate for a long period of time, or use under an airtight dressing, may cause the following symptoms:
• increased weight
• moon face, rounding of the face
• obesity
• skin thinning
• skin wrinkling
• skin dryness
• changes to the colour of your skin
• increased body hair
• hair loss/lack of hair growth/damaged looking hair

Other very rare skin reactions that may occur are:
• allergic reaction at the site of application
• worsening of condition
• application site irritation/pain
• redness
• rash or hives
• if you have psoriasis you may get raised bumps with pus under the skin. This can happen very rarely during or after treatment and is known as pustular psoriasis
• skin infection
• acne

In children, also look out for the following symptoms:
• delayed weight gain
• slow growth

Very rare side effects that may show up in blood tests or when your doctor gives you a medical examination:
• a decrease in the level of the hormone cortisol in your blood
• increased levels of sugar in your blood or urine
• high blood pressure
• cloudy lens in the eye (cataract)
• increased pressure in the eye (glaucoma)
• weakening of the bones through gradual loss of mineral (osteoporosis); additional tests may be needed after your medical examination to confirm if you have this condition

Not Known (frequency cannot be estimated from the available data)
• blurred vision

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Dermovate
• Keep out of the sight and reach of children.
• Do not use this medicine after the expiry date which is stated on the tube or carton after (Exp). The expiry date refers to the last day of that month.
• Do not store above 30°C. Store in the original package.
• Do not throw away any medicines via wastewater or household waste.

Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.
• If the cream becomes discoloured or show any signs of deterioration, you should seek the advice of your pharmacist.

6. Contents of the pack and other information

What Dermovate contains
• The active ingredient is clobetasol propionate.
• Each gram contains 0.5mg of clobetasol propionate (0.05% w/w).

The other ingredients are: glyceryl monostearate 40-55, aracel 165, beeswax substitute 6621, cetostearyl alcohol, propylene glycol, chlorocresol, sodium citrate, citric acid monohydrate and purified water.

What Dermovate looks like and contents of the pack
Within each carton is a tube with a plastic screw cap. Each 25g tube contains white cream. Each carton contains either 25g or 4 x 25g tubes of cream.

Manufacturer:
GlaxoSmithKline Pharmaceuticals SA, ul. Grunwaldzka 189, 60-322 Poznan, Poland

Procured from within the EU and repackage by: Amimed Direct Ltd, Hendon, London, NW9 6AQ.

Product Licence holder: Sam Pharma Ltd, Unit 20 Garrick Industrial Estate, Irving Way, Hendon, London, NW9 6AQ.

This leaflet was last approved: 09/02/2018
Dermovate® is a registered of the GlaxoSmithKline group of companies.

Blind or partially sighted? Is this leaflet hard to see or read? Call 02082033203 to obtain the leaflet in a format suitable for you.
PATIENT INFORMATION LEAFLET
Clobetasol propionate 0.05% w/w Cream

Your medicine is known by the above name but will be referred to as Clobetasol propionate throughout this leaflet.

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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:
1. What Clobetasol propionate is and what it is used for
2. What you need to know before you use Clobetasol propionate
3. How to use Clobetasol propionate
4. Possible side effects
5. How to store Clobetasol propionate
6. Contents of the pack and other information

1. What Clobetasol propionate is and what it is used for
Clobetasol propionate contains a medicine called clobetasol propionate. It belongs to a group of medicines called steroids. It helps to reduce swelling and irritation.

Clobetasol propionate is used to help reduce the redness and itchiness of certain skin problems. These skin problems include:
- frequently relapsing eczema
- psoriasis (thickened patches of inflamed, red skin, often covered by silvery scales), excluding widespread plaque psoriasis
- lichen planus, (a skin disease that causes itchy, reddish-purple, flat-topped bumps on the wrists, forearms or lower legs)
- discoid lupus erythematosus (a disease of the skin most often affecting the face, ears and scalp causing scarring and increased sensitivity of the affected skin to sunlight)
- dermatitis and other skin conditions that have not responded to milder steroid creams or ointments.

2. What you need to know before you use Clobetasol propionate
Do not use Clobetasol propionate:
- if you are allergic (hypersensitive) to clobetasol propionate or any of the other ingredients of this medicine (listed in Section 6)
- on a child under 1 year of age
- to treat any of the following skin problems, it could make them worse:
  - acne
  - severe flushing of skin and around your nose (rosacea)
  - spotty red rash around your mouth (perioral dermatitis)
  - itching around your anus or genitals (perianal dermatitis)
  - infected skin (unless the infection is being treated with an antibiotic/antifungal medicine at the same time)
  - itchy skin which is not infected
  - widespread plaque psoriasis, except single lesions.

Do not use if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before using Clobetasol propionate.

Warning and precautions
Talk to your doctor or pharmacist before using Clobetasol propionate if:
- you have previously had an allergic reaction with another steroid.
- you are applying the cream under an airtight dressing, including a child's nappy. These dressings make it easier for the active ingredient to pass through the skin. It is possible to accidentally pass it on to others.
- you are applying the cream to your hands after use or wear disposable plastic gloves.
- you are applying the cream on broken or damaged skin or within skin folds.
- you are applying to a large surface area.
- you have psoriasis, your doctor will want to see you more often.
- you are using for a chronic leg ulcer as you may be at increased risk of local allergic reaction or infection.
- you are applying near eyes or on eyelids, as cataracts or glaucoma may result if the cream repeatedly enters the eye.
- you are applying to thin skin such as the face, as Clobetasol propionate may cause skin thinning. Use on the face should be limited to 5 days. Dressings or bandages should not be used on the face where the cream is applied.

Contact your doctor if you experience blurred vision or other visual disturbances.

If an infection develops during the use of this medicine, talk to your doctor or pharmacist.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before using this medicine.

Children
- Do not use this medicine in children under 1 year of age.
- Avoid continuous treatment for a long period of time in infants and children over 1 year of age, as their skin is thinner than adults and as a result may absorb larger amounts.
- Use on children should be limited to 5 days and reviewed weekly.
- Dressings or bandages should not be used on children where the cream is applied.

Other medicines and Clobetasol propionate
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicine, especially if you are taking ritonavir and itraconazole medications.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

If you do use Clobetasol propionate when breast-feeding do not use it on your breast area to ensure that the baby does not accidentally get Clobetasol propionate in their mouth.

Clobetasol propionate Cream contains propylene glycol, cetostearyl alcohol and chlorocresol
Propylene glycol may cause skin irritation. Cetostearyl alcohol may cause local skin reactions (eg. contact dermatitis). Chlorocresol may cause allergic reactions.

3. How to use Clobetasol propionate
Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Using this medicine
- You usually apply a thin layer of Clobetasol propionate once or twice a day. This may be reduced as your skin begins to get better, or stopped when better. Your doctor may prescribe a weaker steroid for you to use instead.
- If you are also using an emollient (moisturiser), allow time for Clobetasol propionate to be absorbed into your skin before applying the emollient.
- This cream is for use on your skin only.
- Do not use for more than 4 weeks without talking to your doctor.
- If you need treatment for a long time, your doctor may decide you need to use a milder cream or ointment.
- If your skin problem worsens or does not improve within 2 to 4 weeks, talk to your doctor.
- The germs that cause infections like the warm and moist conditions under dressings. If directed to cover the treated area with a dressing, always clean the skin before a fresh dressing is put on to help prevent infection of the skin beneath the dressing.
- If you are applying the cream on someone else make sure you wash your hands after use or wear disposable plastic gloves.

Guidance on how to apply the cream
1. Wash your hands.
2. Apply a thin layer to the affected area(s) and gently rub into the skin until it has all disappeared. You can measure how much Clobetasol propionate to use with your fingertip. For children you will need to use less cream but still use an adult finger to measure out the fingertip unit. This picture shows one fingertip unit.
3. Unless you are meant to apply the cream to your hands as a part of the treatment, wash them again after using the cream.

For an adult
Do not worry if you find you need a little more or less than this. It is only a rough guide.

For a child aged 1 – 10

<table>
<thead>
<tr>
<th>Number of fingertip units needed</th>
<th>Child's age</th>
<th>Face and neck</th>
<th>Arm and hand</th>
<th>Leg and foot</th>
<th>Front</th>
<th>Back including buttocks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1-2 years</td>
<td>1 ½</td>
<td>1 ½</td>
<td>2</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>3-5 years</td>
<td>1 ½</td>
<td>2</td>
<td>3</td>
<td>3 ½</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>6-10 years</td>
<td>2</td>
<td>2 ½</td>
<td>4 ½</td>
<td>3 ½</td>
<td>5</td>
</tr>
</tbody>
</table>

Use in children

• Do not use this medicine on children under 1 year of age.
• It is especially important in children not to exceed the prescribed amount.
• A course of treatment for a child over the age of 1 year should not normally last more than 5 days unless your doctor has told you to use it for longer. Your doctor may want to see the child every week, whilst using the cream.
• Dressings or bandages should not be used on children where the cream is applied.

If you have psoriasis

If you have thick patches of psoriasis on your elbows or knees, your doctor may suggest applying the cream under an airtight dressing. It will only be at night to help the cream to start working. After a short period of time you will then apply the cream as normal.

If you apply Clobetasol propionate to your face

You should only apply the cream to your face if your doctor tells you to. It should be limited to only 5 days as the skin on your face thins easily. Dressings or bandages should not be used on the face where the cream is applied. Do not let the cream get into your eyes. If it does, wash it out with plenty of water.

If you use more Clobetasol propionate than you should

If you apply too much or if accidentally swallowed, it could make you ill. Talk to your doctor or go to hospital as soon as possible.

If you forget to use Clobetasol propionate

If you forget to apply your cream, have an infection or need other treatment. If it is close to the time you are next meant to apply it, wait until this time. Do not apply extra Clobetasol propionate to make up for a missed dose.

If you stop using Clobetasol propionate

If you use Clobetasol propionate regularly make sure you talk to your doctor before you stop using it as your condition may get worse if stopped suddenly.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop using Clobetasol propionate and tell your doctor immediately if:
• you find that your skin problem gets worse, you develop a generalised rash or your skin becomes swollen during treatment. You may be allergic to the cream, have an infection or need other treatment.
• you have psoriasis and get raised bumps with pus under the skin. This can happen during or after treatment and is known as pustular psoriasis.

Other side effects you may notice when using Clobetasol propionate include:

Common (may affect up to 1 in 10 people)
• a feeling of burning, pain, irritation or itching where the cream is applied.

Uncommon (may affect up to 1 in 100 people)
• skin thinning, this may cause stretch marks
• blood vessels under the surface of your skin may become more noticeable.

Very Rare (may affect up to 1 in 10,000 people)
Use of Clobetasol propionate for a long period of time, or use under an airtight dressing, may cause the following symptoms:
• increased weight
• moon face, rounding of the face
• obesity
• skin thinning
• skin wrinkling
• skin dryness
• changes to the colour of your skin
• increased body hair
• hair loss/lack of hair growth/damaged looking hair

Other very rare skin reactions that may occur are:
• allergic reaction at the site of application
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• if you have psoriasis you may get raised bumps with pus under the skin. This can happen very rarely during or after treatment and is known as pustular psoriasis
• skin infection
• acne

In children, also look out for the following symptoms:
• delayed weight gain
• slow growth

Very rare side effects that may show up in blood tests or when your doctor gives you a medical examination:
• a decrease in the level of the hormone cortisol in your blood
• increased levels of sugar in your blood or urine
• high blood pressure
• cloudy lens in the eye (cataract)
• increased pressure in the eye (glaucoma)
• weakening of the bones through gradual loss of mineral (osteoporosis); additional tests may be needed after your medical examination to confirm if you have this condition

Not Known (frequency cannot be estimated from the available data)
• blurred vision

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Clobetasol propionate

• Keep out of the sight and reach of children.
• Do not use this medicine after the expiry date which is stated on the tube or carton after (Exp). The expiry date refers to the last day of that month.
• Do not store above 30°C. Store in the original package.
• Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.
• If the cream becomes discoloured or show any signs of deterioration, you should seek the advice of your pharmacist.

6. Contents of the pack and other information

What Clobetasol propionate contains
• The active ingredient is clobetasol propionate.
• Each gram contains 0.5mg of clobetasol propionate (0.05% w/w).
• The other ingredients are glyceryl monostearate 40-55, arlacel 165, beeswax substitute 6621, cetostearyl alcohol, propylene glycol, chlorocresol, sorbitan citrate, citric acid monohydrate and purified water.

What Clobetasol propionate looks like and contents of the pack
Within each carton is a tube with a plastic screw cap. Each 25g tube contains white cream. Each carton contains either 25g or 4 x 25g tubes of cream.

Manufacturer:
GlxaoSmithKllne Pharmaceuticals SA, ul. Grunwaldzka 189, 60-322 Poznan, Poland

Procured from within the EU and repackaged by: Amimed Direct Ltd, Hendon, London, NW9 6AQ.


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