Dermovate® Cream
(clobetasol propionate)

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

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 eczema, psoriasis, lichen planus, discoid lupus, dermatitis and other skin conditions that have not responded to milder steroid creams or ointments.

2 How to 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 old;
• 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 back passage or private parts;
  - infected skin (unless the infection is being treated with an anti-infective medicine at the same time);
  - itchy skin which is not inflamed;
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:
• 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.
• you have psoriasis, your doctor will want to see you more often.
• you are applying the cream on broken skin or within skin folds.
• 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 or on children 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. Use on the face should be limited to 5 days.

3 How to use Dermovate
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

4 Possible side effects
5 How to store Dermovate

6 Contents of the pack and other information
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 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 pustular psoriasis.

Other side effects you may notice when using Dermovate 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)
• Stretch marks may develop.
• Warts under the surface of your skin may become more noticeable.

Rare (may affect up to 1 in 1,000 people)
• An increased risk of infection
• An allergic skin reaction where the cream is applied
• Rash, itchy bumpy skin or redness of the skin
• Thinning and dryness of your skin and it may also damage or wrinkle more easily
• An increase or reduction in hair growth or hair loss and changes in skin colour
• Weight gain, rounding of the face
• Delayed weight gain or slowing of growth in children
• Bones can become thin, weak and break easily
• Cloudy lens in the eye (cataract) or increased pressure in the eye (glaucoma)
• Increased blood sugar levels or sugar in the urine
• High blood pressure

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

By reporting side effects you can help provide more information on the safety of this medicine.
Clovate® Cream
(clobetasol propionate)

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 of the side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

Your medicine is called Clovate Cream, however throughout this leaflet it will be referred to as Clovate.

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

1. What Clovate is and what it is used for

Clovate contains a medicine called clobetasol propionate. It belongs to a group of medicines called steroids. It helps to reduce swelling and irritation. Clovate is used to help reduce the redness and thickness of certain skin problems such as eczema, psoriasis, lichen planus, discoid lupus, dermatitis and other skin conditions that have not responded to milder steroid creams or ointments.

2. What you need to know before you use Clovate

Do not use Clovate:
- 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 old.
- To treat any of the following skin problems, it may 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 back passage or private parts
  - infected skin (unless the infection is being treated with an anti-infective medicine at the same time)
  - itchy skin which is not inflamed.

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

Warning and precautions
Talk to your doctor or pharmacist before using Clovate 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.
- You have psoriasis, your doctor will want to see you more often.
- You are applying the cream on broken skin or on skin folds.
- 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 or on children 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. Use on the face should be limited to 5 days.

3. How to use Clovate

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 Clovate 1 or 2 times a day. This may be reduced as your skin begins to get better, or stopped when better.
- This cream is for use on your skin only.
- Do not use on large areas of the body for a long time (such as every day for many weeks or months). If you need treatment for a long time, your doctor may decide you need to use a milder cream or ointment.
- The germs that cause infections like warm and moist conditions under dressings so always clean the skin before a fresh dressing is put on.
- If you are applying the cream on someone else make sure you wash your hands after use or wear disposable plastic gloves.
- If your skin problem does not improve in 2 to 4 weeks, talk to your doctor.

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 Clovate 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
4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Stop using Clovate 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 pustular psoriasis.

Other side effects you may notice when using Clovate 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)
- Stretch marks may develop.
- Veins under the surface of your skin may become more noticeable.

Rare (may affect up to 1 in 1,000 people)
- An increased risk of infection
- An allergic skin reaction where the cream is applied
- Rash, itchy bumpy skin or redness of the skin
- Thinning and dryness of your skin and it may also damage or wrinkle more easily
- An increase or reduction in hair growth or hair loss and changes in skin colour.
- Weight gain, rounding of the face
- Delayed weight gain or slowing of growth in children
- Bones can become thin, weak and break easily
- Cloudy lens in the eye (cataract) or increased pressure in the eye (glaucoma)
- Increased blood sugar levels or sugar in the urine
- High blood pressure

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. By reporting side effects you can help provide more information on the safety of this medicine.
Clobetasol Propionate 0.05% Cream

Package Leaflet: Information for the User

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 of the side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

Your medicine is called Clobetasol propionate Cream, however throughout this leaflet it will be referred to as Clobetasol propionate.

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 thickness of certain skin problems. These skin problems include eczema, psoriasis, lichen planus, discoid lupus, 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 old
- to treat any of the following skin problems, it could make them worse:
  - acne
  - severe flushing of skin on and around your face
  - spotty red rash around your mouth
  - lichen planus
  - discoid lupus
  - dermatitis
- if the infection is being treated with an anti-infective medicine at the same time
- if you are using the cream on someone else to make sure you wash your hands after use or wear disposable plastic gloves.
- if your skin problem does not improve in 2 to 4 weeks, talk to your doctor.

Warning and precautions
Talk to your doctor or pharmacist before using Clobetasol propionate if:
- you have previously had an allergic reaction with another steroid
- if you are using 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.
- if you are using the cream on broken skin or on skin folds.
- you are using for a chronic leg ulcer as you may be at increased risk of local allergic reaction or infection.
- you are applying to a large surface area or within the skin folds.
- 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 or on children as their skin is thinner than adults and as a result they may absorb larger amounts. Use on children should be limited to 5 days and reviewed weekly. Use on the face should be limited to 5 days.

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 1 or 2 times a day. This may be reduced as your skin begins to get better, or stopped when better.
- This cream is for use on your skin only.
- Do not use on large areas of the body for a long time (such as every day for many weeks or months). If you need treatment for a long time, your doctor may decide you need to use a milder cream or ointment.
- The germs that cause infections like warm and moist conditions under dressings so always clean the skin before a fresh dressing is put on.
- If you are applying the cream on someone else make sure you wash your hands after use or wear disposable plastic gloves.
- Your skin problem may not improve in 2 to 4 weeks, talk to your doctor.

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 use with your fingertip. For children you will need to use less cream but still use an adult 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

Never use or wear disposable plastic gloves.

Do not worry if you find you need a little more or less than this. It is only a rough guide.
Rare (may affect up to 1 in 1,000 people)

Clobetasol propionate include:

Other side effects you may notice when using

Uncommon (may affect up to 1 in 100 people)

If you have psoriasis

If you apply Clobetasol propionate to your face

If you apply too much or if accidentally

If you use more Clobetasol propionate than you should

If you forget to use Clobetasol propionate

If you stop using Clobetasol propionate

If you use Clobetasol propionate regularly make sure

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 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. Do not let the cream get into your eyes. If it does, wash it out immediately.

If you have any questions or are not sure about anything, ask your doctor or pharmacist.

Important

Remember this medicine is for you. It can only be prescribed by a doctor. Never give your medicine to other people, it may harm them, even if their symptoms are the same. This leaflet does not tell you everything about your medicine. If you have any question or are not sure about anything, ask your doctor or pharmacist (chemist) He/she will have additional information about this medicine and will be able to advise you.

6. Contents of the pack and other information

What Clobetasol propionate looks like and contents of the pack

Clobetasol propionate Cream contains 0.05% w/w of clobetasol propionate as the active ingredient. Your cream also contains the following inactive ingredients: ceteosteryl alcohol, glyceryl monostearate, Arlacel 165, beeswax substitute 6621, propylene glycol, chlorocresol, sodium citrate, cotic acid monohydrate, purified water.

Who manufactured your medicine?

Clobetasol propionate Cream is manufactured by INDUSTRIAL FARMACEUTICA CANTABRIA, S.A. Ctra. Cazona-adarzo, s/n, 39011, Spain and is procured from within the EU and repackaged by the Product Licence Holder: Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE.

POM

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More information

If you have any questions or are not sure about anything, ask your doctor or pharmacist who will advise you. You may be able to find out more information from books in public libraries.

Blind or partially sighted?

Is this leaflet hard to see or read?

Phone Lexon (UK) Limited,
Tel: 01527 505414 for help.