



Dithrocream™

Available in five different strengths containing dithranol 0.1% w/w; 0.25% w/w; 0.5% w/w; 1% w/w and 2% w/w.

Read all of this leaflet carefully before using this product.

Keep this leaflet. You may need to read it again. Ask your doctor or pharmacist if you need more information or advice. This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours. If any of the side effects gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

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1. WHAT DITHROCREAM IS AND WHAT IT IS USED FOR

- Dithrocream is a treatment for careful application to localised areas of your skin and scalp affected by a particular type of psoriasis that doctors refer to as sub-acute or chronic psoriasis.
- This type of psoriasis involves areas of raised, red patches of skin, covered with silvery scales (without any blistering or tenderness). The patches often occur on the elbows, knees, lower back and scalp.
- Dithrocream is recommended for use by **adults, the elderly and children**.
- The **active ingredient** in this product is dithranol. It helps to clear patches of psoriasis by restoring normal skin development.
- Dithrocream is available in **five strengths** that have colour coded packs, as follows:
 - 0.1% - in a pale blue pack
 - 0.25% - in a red pack
 - 0.5% - in a purple pack
 - 1% - in a brown pack
 - 2% - in a yellow pack

2. BEFORE YOU USE DITHROCREAM

Do not use this product:

- on psoriasis that feels and looks sore and angry, or on pustular psoriasis (which is very tender, inflamed, and involves small blisters filled with pus);
- to treat areas of psoriasis on your face;
- if you are **allergic** (hypersensitive) to dithranol or any of the other ingredients of Dithrocream listed in section 6.

Take special care when using this product:

Dithranol can cause skin burning and excessive soreness if not used correctly. It is therefore very important that you:

- use the correct strength of Dithrocream for your particular requirements (see Section 3a below);
- apply it carefully, only to the patches of psoriasis (see Section 3b below), and;
- limit the contact time on your skin (see Section 3c below);
- only use the three highest strengths, Dithrocream 0.5% w/w, 1% w/w and 2% w/w, if recommended by a doctor and if you have failed to respond to the lower strengths;
- avoid using this product (unless advised by your doctor) to treat psoriasis on areas of folded skin, such as the groin or underneath the breasts. This is because the skin's response to Dithrocream tends to be stronger in these areas. If you have been given a high strength of Dithrocream (0.5% w/w, 1% w/w or 2% w/w) to use on areas of folded skin, return to your doctor for further advice;
- keep the cream away from your eyes, nose and mouth;
- always wash your hands thoroughly after use.

Dithranol causes staining:

- avoid contact with fabrics, plastics and other materials, such as bedclothes, furnishings and bath and shower fittings, because this is likely to cause permanent staining which cannot be removed;
- treated areas of skin may gradually become stained purple or brown. This is harmless, and will gradually disappear within a few days after the end of your treatment;
- blonde or fair hair may take on a pinkish tinge when treating the scalp. This will grow out after treatment stops.

For children, use with extra caution and with regular supervision.

Using other medicines

If you have been regularly using topical corticosteroids to treat your psoriasis it is important that you allow yourself a treatment-free interval of at least one week before starting to use Dithrocream. You can use a plain emollient (skin moisturiser) on your skin in the meantime.

Pregnancy and breast-feeding

Dithrocream can be used during pregnancy and whilst breast-feeding. The ingredients have been in widespread use in this and similar preparations for many years, without reports of problems. However, safety trials have not been conducted.

Driving and using machinery

Using this product is not known to affect your ability to drive or use machinery.

Important information about two of the ingredients of Dithrocream

This cream contains a small amount of cetostearyl alcohol. This ingredient may cause local skin reactions (e.g. contact dermatitis) in a small number of people who are sensitive to it.

The cream also contains chlorocresol. This ingredient may cause allergic reactions in rare cases. If you have been told by your doctor that you are sensitive to cetostearyl alcohol or chlorocresol, please talk to your doctor before using this product.

3. HOW TO USE DITHROCREAM

Use Dithrocream only on patches of skin affected by the particular type of psoriasis that it is recommended for. Before using this tube for the first time, open it as follows:

Unscrew the cap, turn it upside down and then use the sharp point of the cap to pierce the membrane in the neck of the tube.

To use the cream (for adults, the elderly and children):

Follow instructions a) to d) below carefully otherwise the cream may cause skin burning and excessive soreness:

a) Make sure that you start treatment with the correct strength of Dithrocream:

- If you have not used Dithrocream before, or if you are about to use it on patches of psoriasis on areas of your body where you have not used it previously, always start treatment with the lowest strength of Dithrocream, 0.1% w/w. Use this strength for at least a week and then, only if recommended by your doctor or pharmacist, increase at weekly intervals to the 0.25% w/w, followed by the 0.5% w/w, the 1% w/w, and possibly the 2% w/w strength.
- The aim is to start with the lowest strength and build up gradually over approximately 4 weeks to the highest, optimum strength that does not cause excessive sensation of skin warmth.
- This optimum strength differs for each of us, and may also depend upon the thickness and location of your psoriatic patches. Your doctor should help you decide which strength is best for your particular circumstances.

b) Make sure that you always apply Dithrocream carefully as follows:

- Apply it thinly and only to the patches of psoriasis.
- Rub the cream gently into the psoriasis patches until completely absorbed, otherwise any excess cream may spread onto normal skin areas (where the skin reaction is much stronger), or spread onto clothing or bedding, causing staining.
- Always wash your hands immediately after use.

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c) Make sure that you apply the cream only once a day, and always limit the 'contact' time with your skin, using one of the following methods to stop it working for too long:

either use 'short contact treatment', in which case:

- apply the cream at any convenient time of the day or evening;
- start with a contact time of 10 minutes, then;
- bathe or shower to wash the cream off;
- and over the following days, gradually increase the contact time to no more than one hour, washing off the cream as previously.

or after you have gradually built up the contact time as described above, use 'overnight treatment', in which case:

- apply the cream at night before going to bed, then;
- the following morning, bathe or shower to wash the cream off.

Because using it 'overnight' involves a longer contact time, this option is only advised when using Dithrocream 0.1%, Dithrocream 0.25% or Dithrocream 0.5%.

Always make sure you start treatment with the correct strength of Dithrocream (see Section 3a).

d) For use on scalp psoriasis:

- Before use on the scalp, read carefully the section below, headed "If the cream or rinse ... gets into your eyes ..."
- First comb the hair to remove any loose scales, then, after suitably parting the hair, massage the cream well into the affected areas.
- Use it only once a day, and stop the cream working after the required contact time on the scalp by shampooing the hair as normal (use either the 'short contact' or 'overnight' method, as described under section 3c above).
- Take great care when washing out the shampoo (which may contain some Dithrocream residue) to avoid getting it into the eyes or on the face. This is particularly important when using the higher strengths of Dithrocream.

To avoid unnecessary staining to clothing and bed linen etc, you could wear an old pair of pyjamas and / or dressing gown and, when treating the scalp, use an old pillowcase.

Carry on using Dithrocream for long enough:

- Continue this daily treatment, using the highest strength of Dithrocream that does not cause excessive sensation of skin warmth, until your skin is completely better, ie when there is nothing to feel with the fingers and the skin texture is normal.
- By gradually increasing the strength of Dithrocream applied, it should be possible to clear psoriasis patches within 4 to 6 weeks.

If the cream or rinse (e.g. when shampooing or washing it off) gets into your eyes, nose or mouth, it may be strongly irritant. If this happens, rinse the affected areas with plenty of water for several minutes. In the case of any eye contamination, take care not to wash the rinse from one eye to the other eye. We recommend that you then go without undue delay to a Hospital Accident & Emergency department for further assessment and possibly more thorough eye irrigation.

If the cream accidentally gets onto normal skin, wipe it off straight away with a tissue, and wash the area with soap and warm water.

If the cream is accidentally swallowed, go to a hospital Accident & Emergency department straight away because it is a strong laxative and you may need a stomach washout.

If you use too high a strength or leave it in contact with your skin for too long, it may cause skin burning and excessive soreness, in which case the dosage should be reviewed by your doctor.

If you occasionally forget to use this product, do not worry. Just carry on using it when you remember. If you have any further questions on the use of this product, ask your doctor or pharmacist.

Look after your bath or shower to prevent the possibility of staining, particularly where Dithrocream 1% or 2% has been used. Always rinse the bath or shower with hot water immediately after washing or showering, and then use a suitable detergent to remove any deposit from the surface of the bath or shower. Wear protective gloves to avoid irritating your hands.

4. POSSIBLE SIDE EFFECTS

While Dithrocream is working, some skin redness and a feeling of mild 'sunburn' at the site of application is quite normal, indicating that it is working. If excessive burning or soreness occurs, this usually means that the strength being used is too high or that the cream is being left in contact with the skin for too long. If this happens, treatment should be stopped at once and the dosage reviewed by your doctor. Your doctor may advise you to use a lower strength, to apply it for shorter contact periods or to apply it less often.

Like all medicines, Dithrocream can cause other side effects, although not everybody gets them:

- If you mistakenly allow the cream to spread onto, and remain in contact with, areas of normal skin (see precautions in section 3b), it is more likely to cause burning and soreness.
- Temporary staining of the skin or hair can occur. However, this will gradually go away after treatment has stopped.
- On very rare occasions allergic reactions to the ingredients can occur. These may result in local skin inflammation, itching and redness, in which case treatment with Dithrocream should be stopped.

Any staining caused by getting the cream on your clothes, bed linen, fabrics, plastics or other materials is likely to be permanent.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom

Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

Ireland

HPRa Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

5. HOW TO STORE DITHROCREAM

- Keep it out of the reach and sight of children.
- Always replace the cap tightly after use.
- Do not store the product above 25°C.
- Do not use after the expiry date shown on the fold of the tube and the carton. The expiry date refers to the last day of that month.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION ABOUT DITHROCREAM

What Dithrocream contains:

The active ingredient in the Dithrocream range is dithranol, at five different strengths comprising 0.1% w/w, 0.25% w/w, 0.5% w/w, 1% w/w and 2% w/w. The **other ingredients** are white soft paraffin, cetostearyl alcohol, salicylic acid, ascorbic acid, sodium laurilsulfate, chlorocresol and purified water. Dithrocream 2% w/w also contains liquid paraffin.

What Dithrocream looks like and contents of the pack

- The product is a pale yellow/yellow cream.
- The cream is available in tubes containing 50g.

The Marketing Authorisation holder is Dermal Laboratories, Tatmore Place, Gosmore, Hitchin, Herts, SG4 7QR, UK.

The Manufacturer is Fleet Laboratories Ltd, 94 Rickmansworth Road, Watford, Herts, WD18 7JJ, UK.

This leaflet was last revised in August 2014.

To listen to or request a copy of this leaflet in Braille, large print or audio, please call free of charge: 0800 198 5000 (UK only).

Please be ready to give the following information:

Dithrocream, 00173/0029.

This is a service provided by the Royal National Institute of Blind People (RNIB).