Patient information and consent to diphencyprone: topical immunotherapy

**Key messages for patients**

- **Please bring with you all of your medications and its packaging (including inhalers, injections, creams, eye drops, patches, insulin and herbal remedies), a current repeat prescription from your GP, any cards about your treatment and any information that you have been given relevant to your care in hospital, such as x rays or test results.**

- **Take your medications as normal on the day of the procedure unless you have been specifically told not to take a drug or drugs before or on the day by a member of your medical team. If you have diabetes please ask for specific individual advice to be given on your medication at your pre-operative assessment appointment.**

- **Please read the precautions carefully before starting treatment.** You should not start treatment with diphencyprone if you are pregnant or planning to become pregnant in the next six months.

- **Please call the dermatology unit on 01223 216234 if you have any questions about your appointment. For all other enquiries please call the dermatology nurse answer phone on 01223 217391; please leave a message and we will return your call.**

Please read this information carefully, you and your health professional will sign it to document your consent.

After you have started the treatment we will file the consent form in your medical notes and you may take this information leaflet home with you.

**Important things you need to know**

Patient choice is an important part of your care. You have the right to change your mind at any time, even after you have given consent and the treatment has started.

We will also only carry out the treatment on your consent form unless, in the opinion of the responsible health professional, a further procedure is needed in order to save your life or prevent serious harm to your health.

We are unable to guarantee that a particular person will perform the whole course of treatment. However the person carrying out the treatment will have the relevant experience.

All information we hold about you is stored according to the Data Protection Act 1998.
About diphencyprone: topical immunotherapy

You have been recommended to have diphencyprone topical immunotherapy treatment for your skin condition - either alopecia areata or warts. Diphencyprone is a chemical to which it is easy to become allergic. The plan is to make an allergic skin reaction happen at the area of skin where an immune response is needed. The diphencyprone is painted onto the skin regularly to bring up the allergy which usually looks like mild redness and itching on the scalp and lasts for 24 to 48 hours. If warts on the hands or feet are being treated, no reaction may be visible.

Diphencyprone allergy can be used as a treatment for two skin conditions:
- hair loss due to alopecia areata (an auto-immune condition in which the body’s own immune system damages the hair follicles where the hair grows)
- skin warts.

Diphencyprone has been used as a skin treatment for 35 years. Diphencyprone is unlicenced for use as a skin treatment in the UK and so we will ask you for your written consent to treatment if you decide to go ahead with the diphencyprone immunotherapy.

Before your treatment

All patients attend a dermatology clinic, where you will meet a dermatology doctor or specialist nurse. At this clinic, we shall ask you for details of your medical history and carry out any necessary clinical examinations and investigations.

This is a good opportunity for you to ask us any questions about the treatment, but please feel free to discuss any concerns you might have at any time.

Precautions to take before each treatment

You should not start treatment with diphencyprone if you are pregnant, breastfeeding or planning to become pregnant in the next six months. The use of diphencyprone is not recommended in pregnancy or if planning a pregnancy. This is because the effects or side effects of diphencyprone have not been studied during pregnancy. Diphencyprone is not known to affect fertility.

Before treatment your skin should be clean and dry.

Please inform the doctor or nurse if you have started any new medication.

You should not sunbathe or use a sun bed while having treatment with diphencyprone.

The treated area should be protected from the sun. If you are having the scalp treated, you should bring a hat with you for wearing after the treatment has been applied. Ideally this should be a washable hat that can be washed after each treatment.

The treated area should be washed off the skin after 6 to 24 hours. It is probably most convenient to wash the area well just before bed on the day of treatment.
You should have a very strong steroid cream or ointment available for use. The doctor or nurse will prescribe this for you at the time of the first treatment. If you run out or lose the steroid treatment, you should inform the doctor or nurse so that a new tube can be prescribed for you.

**During the treatment**

There are three stages to treatment with diphencyprone:

1. creating an allergic reaction to diphencyprone
2. testing to find a suitable strength of diphencyprone for treatment
3. treatment with regular painting onto the skin of the correct strength of diphencyprone.

**Stage 1**

A strong solution of diphencyprone (usually a 2% solution) is painted on to a small area on the upper arm. An allergic reaction will often develop after a single application, but if not, a weaker solution (0.1%) is painted onto the same site two weeks later and repeated every two weeks until a reaction develops. An allergic reaction will be seen and felt as a red itchy change in the skin.

**Stage 2**

Once the allergy has developed, the next stage is to try to find the correct strength of diphencyprone solution that will give just enough, but not too much, of an allergic reaction. Starting with a very weak solution of diphencyprone (usually 0.001%), a small area of skin is painted with the diphencyprone. The strength of the solution used is increased every week until a moderate allergic reaction is produced. The ideal allergic reaction is pink and a bit itchy for about 36 hours.

**Stage 3**

Once the strength of diphencyprone solution that produces a moderate allergic reaction has been found, this solution can be applied to the target area of skin every week or every two weeks. Treatment is usually given once a week or once every two weeks.

**After the treatment**

After the diphencyprone has been applied, the skin becomes a bit pink and slightly itchy. This reaction should subside in 36 to 48 hours.

If the reaction to the diphencyprone is stronger than expected, the skin may be very itchy or even blister after the treatment. This over-reaction can be settled down with a cream which will be supplied by the clinic.

**Further treatment appointments**: if you are unable to keep an appointment please try to inform us so that your appointment time can be re-allocated.
Two consecutive failures to keep an appointment without notice will result in your treatment being discontinued. Appointments can be made in person at the clinic reception or by telephoning 01223 216234.

How long will I have treatment with diphencyprone?

Alopecia areata
The duration of treatment is usually for a minimum of six to eight months. If no response has occurred in that time, it is unlikely to happen with longer treatment. Usually once the hair has regrown, the diphencyprone treatment is stopped.

Warts
The duration of treatment is usually for a minimum of six to eight months. If no response has occurred in that time, it is unlikely to happen with a longer course of treatment.

Intended benefits
The intended benefit of the treatment is to help treat your skin disorder.

Will diphencyprone cure my skin condition?

Alopecia areata
If diphencyprone treatment works, it can stimulate hair to grow again. Of 100 people with alopecia treated with diphencyprone, about 30 will have very good regrowth, about 25 will have moderate regrowth, and 45 will have unsatisfactory or almost no regrowth. If the alopecia areata affects the whole head, the chances of successful treatment are lower with about 20% of people getting good hair growth.

However, alopecia is a very variable disease – sometimes once the hair has re-grown, it continues to grow, but in one half to three quarters of people it is lost again. The diphencyprone treatment does not ‘turn off’ the body’s own immune system attack on the hair follicles and this may continue for a long time.

Warts
If warts clear during treatment with diphencyprone, they usually stay clear. However, it is possible to catch warts again or for very small warts, that were not noticed during treatment, to grow and appear after treatment is finished.

Who will perform my treatment?
The treatment will be performed by a doctor or nurse in the dermatology clinic.

Alternative treatments that are available

Alopecia areata
Creams and lotions are used most commonly for this condition, or occasionally a short course of steroid tablets.
Warts
There are a wide variety of topical preparations available for warts, or in some circumstances a course of tablets may be considered.

Significant, unavoidable or frequently occurring risks of this treatment
The main side effects are the expected itch and slight discomfort of an allergic skin reaction, allergic dermatitis. If this is very vigorous, usually because too strong a solution of diphencyprone has been applied, then the dermatitis can blister, weep and be uncomfortable. As the skin recovers from the dermatitis, the surface may feel dry and flaky. A moisturising cream will make this feel more comfortable.

If the dermatitis is very strong, the treated skin may become swollen, oedematous and tender. This will settle after a few days. Sometimes, the intensity of the reaction can lead to a ‘flu-like feeling, which may last up to 48 hours.

A vigorous allergic reaction can also cause the lymph glands to swell and be painful. This would be in the neck (for scalp treatment), in the groin (for foot treatment) or under the arm (for hand treatment) and may take a few days to settle after the inflammation dies down.

Sometimes the inflammation settles to leave a temporary staining of the skin. Rarely, the skin can lose its pigment in the treated area and become pale. The may be more marked in people with darker skin and can be permanent, causing completely pale patches called vitiligo.

If the diphencyprone drips on to other areas of skin, rubs onto other areas (for instance by lying on a pillow) or is transferred to other areas of skin through touching or rubbing, then an allergic dermatitis can develop in those areas as well.

Your doctor will prescribe a strong steroid cream to use if you get a very vigorous reaction to the diphencyprone. This cream will help to settle it down more quickly.

Another side effect that can develop more rarely is a widespread nettle rash or urticaria. This is a very itchy, bumpy rash that can occur in about one in 10 people who have diphencyprone treatment. It will mean that the diphencyprone treatment cannot be continued. Urticaria can be treated with antihistamine tablets.

Sometimes during treatment, the reaction to the strength of diphencyprone that is being used can change, giving either a weaker or stronger than expected allergic dermatitis.

The use of diphencyprone is not recommended in pregnancy, during breastfeeding or if planning a pregnancy. This is because the effects or side effects of diphencyprone have not been studied during pregnancy. There is no reason to expect an adverse effect on male fertility.
Important information when having diphencyprone treatment

The diphencyprone treated area of skin should not touch other skin or other people. The treated area should also be protected from the sun as the sun’s rays break down the chemical and prevent it working. If a hat is worn during the day after the diphencyprone is applied to skin, remember that the chemical can remain on the inside of the hat.

Information about important questions on the consent form

1 Photography, Audio or Visual Recordings

As a leading teaching hospital we take great pride in our research and staff training. We ask for your permission to use images and recordings for your diagnosis and treatment, they will form part of your medical record. We also ask for your permission to use these images for audit and in training medical and other healthcare staff and UK medical students; you do not have to agree and if you prefer not to, this will not affect the care and treatment we provide. We will ask for your separate written permission to use any images or recordings in publications or research.

2 Students in training

Training doctors and other health professionals is essential to the NHS. Your treatment may provide an important opportunity for such training, where necessary under the careful supervision of a registered professional. You may, however, prefer not to take part in the formal training of medical and other students without this affecting your care and treatment.

Information and support

If you have any questions or anxieties or you experience any problems following treatment such as marked redness, soreness or blistering of the skin, please contact the dermatology unit, telephone 01223 216234. Outside of the centre’s normal working hours an answer machine will take messages or you can contact the hospital contact centre on 01223 245151 and ask to be put through to the on call dermatologist.

Self help groups

Hairline International
www.hairlineinternational.co.uk
Telephone: 01564 775281

Alopecia UK
www.alpeciaonline.org.uk
Telephone: 0208 333 1661

Patient UK
www.patient.co.uk/showdoc/23069060/

British Association for Dermatologists
www.bad.org.uk/
Privacy & Dignity
Same sex bays and bathrooms are offered in all wards except critical care and theatre recovery areas where the use of high-tech equipment and/or specialist one to one care is required.

We are a smoke-free site: smoking will not be allowed anywhere on the hospital site. For advice and support in quitting, contact your GP or the free NHS stop smoking helpline on 0800 169 0 169.

Other formats:
If you would like this information in another language or audio, please contact Interpreting services on telephone: 01223 256998, or email: interpreting@addenbrookes.nhs.uk For Large Print information please contact the patient information team: patient.info@addenbrookes.nhs.uk.
Diphencyprone: topical immunotherapy

To replace immunoglobulin that is not made by the patient

To prevent infections

Immunoglobulin replacement therapy

Treatment course of diphencyprone: topical immunotherapy

To treat the skin disorder

- allergic dermatitis (itch and discomfort of an allergic skin reaction) where skin has been touched by the diphencyprone liquid
- widespread nettle rash or urticaria (can occur in 1 in 10 people receiving the treatment)
- diphencyprone is not recommended for women if pregnant or planning a pregnancy.

b) the possible risks involved. Addenbrooke’s always ensures any risks are minimised. However all procedures/treatments carry some risk and I have set out below any significant, unavoidable or frequently occurring risks including those specific to the patient:

- allergic dermatitis (itch and discomfort of an allergic skin reaction) where skin has been touched by the diphencyprone liquid
- widespread nettle rash or urticaria (can occur in 1 in 10 people receiving the treatment)
- diphencyprone is not recommended for women if pregnant or planning a pregnancy.

c) what the procedure/treatment is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient:
Consent Form

Treatment course of diphencyprone: topical immunotherapy

d) any extra procedures/treatments that might become necessary during the procedure/treatment such as: □ Blood transfusion □ Other procedure/treatment (please state)

Treatment of intense allergic reaction; treatment of urticaria.

The following information leaflet has been provided:

Diphencyprone: topical immunotherapy

Version, reference and date: Version 5, CF401, February 2019

or □ I have offered the patient information about the procedure/treatment but this has been declined.

This procedure/treatment will involve:

□ General and/or regional anaesthesia □ Local anaesthesia □ Sedation □ None

Signed (Health professional): ................................................................. Date: D.D./M.M.Y.Y.Y.Y.

Name (PRINT): ........................................................................................................ Time (24hr): H.H.:M.M.

Designation: ........................................................................................................ Contact/bleep no:

C Consent of patient / person with parental responsibility

I confirm that the risks, benefits and alternatives of this procedure/treatment have been discussed with me and that my questions have been answered to my satisfaction and understanding.

Important: please read the patient information about this procedure/treatment and then put a tick in the relevant boxes for the following questions:

1 Photography, Audio or Visual Recording

a) I agree to the use of any of the above type of recordings for the purpose of diagnosis and treatment. □ Yes □ No

b) I agree to unidentified versions of any of the above recordings being used for audit and medical teaching in a healthcare setting. □ Yes □ No

2 Students in training

I agree to the involvement of medical and other students as part of their formal training. □ Yes □ No
I have listed below any procedures/treatments that **I do not wish to be carried out without further discussion.**


I have read and understood the Patient Information about this procedure/treatment and the above additional information. **I agree** to the procedure or treatment.

Signed (Patient): ................................................................. Date:   
Name of patient (PRINT): .............................................................

*If signing for a child or young person; delete if not applicable.*  
**I confirm** I am a person with **parental responsibility** for the patient named on this form.  
Signed: ................................................................. Date:   
Relationship to patient: .............................................................

*If the patient is unable to sign but has indicated his/her consent, a witness should sign below.*  
Signed (Witness): ................................................................. Date:   
Name of witness (PRINT): .............................................................
Address:  

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For staff use only:
Hospital number:  
Surname:  
First names:  
Date of birth:  
NHS no: _ _ _ / _ _ _ / _ _ _  
Use hospital identification label
Consent Form

Treatment course of diphencyprone: topical immunotherapy

D Confirmation of consent

Confirmation of consent (where the procedure/treatment has been discussed in advance)

On behalf of the team treating the patient, I have confirmed with the patient that she/he has no further questions and wishes the procedure/treatment to go ahead.

Signed (Health professional): ........................................... Date: ...D.../M..Y.Y.Y.Y.Y....

Name (PRINT): ................................................................. Job title: ..................................................

Please initial to confirm all sections have been completed:

E Interpreter's statement (if appropriate)

I have interpreted the information to the best of my ability, and in a way in which I believe the patient can understand:

Signed (Interpreter): ........................................... Date: ...D.../M..Y.Y.Y.Y.Y....

Name (PRINT): .................................................................

Or, please note the language line reference ID number:

F Withdrawal of patient consent

☐ The patient has withdrawn consent (ask patient to sign and date here)

Signed (Patient): ........................................... Date: ...D.../M..Y.Y.Y.Y.Y....

Signed (Health professional): ........................................... Date: ...D.../M..Y.Y.Y.Y.Y....

Name (PRINT): ................................................................. Job title: ..................................................