

# Patient agreement to investigation or treatment

## Diphencyprone: topical immunotherapy

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### Brief description:

- 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.
- We want you to be informed about your choices to help you to be fully involved in making any decisions. Please ask about anything you do not fully understand or wish to have explained in more detail.
- If you would like this information in another format or language or would like help completing the form, please ask a member of our staff.

### Please bring this form with you to hospital

- You will be asked to read this form carefully, and you and your doctor (or other appropriate healthcare professional) will sign it to document your consent.
- All our consent forms are available on the Addenbrooke's website: <http://www.addenbrookes.org.uk/consent>
- Guidance for health professionals can be found on the Addenbrooke's intranet site <http://nww.addenbrookes.nhs.uk/consent>
- Remember, you can change your mind about having the treatment at any time.

### For staff use:

Does the patient have any special requirements? (eg requires an interpreter or other additional communication method)

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## About diphencyprone

- When diphencyprone is used as a treatment, the idea is to make the person allergic to diphencyprone and then to repeatedly paint it on to the skin in a controlled manner to make an allergic reaction happen at the site on the skin where the allergic reaction is wanted.
- 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 unlicensed for use as a skin treatment in the UK and so you will be asked to give your written consent to treatment if you decide to go ahead with the diphencyprone immunotherapy.

## Before you start 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 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.
- 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. Making an allergic reaction to diphencyprone develop.
  2. Testing to find a suitable strength of diphencyprone for treatment.
  3. Treatment with regular painting on to the skin of the correct strength of diphencyprone.
- **Stage one**

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 on to 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 two**

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 0.01%), 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 three**

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.

## 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 re-grown, the diphencyprone treatment is stopped.

### **Warts**

The duration of the treatment course 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 of the treatment

- 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

### Warts

There are a wide variety of topical preparations available for warts, or in some circumstances a course of tablets may be considered.

### Alopecia areata

Creams and lotions are used most commonly for this condition, or occasionally a short course of steroid tablets.

## Risks associated with 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.
- 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 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.

## Appointments and follow-ups

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.

## 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 Addenbrooke's Hospital 01223 245151 and ask to be put through to the on call Dermatologist.

### Self help groups

The following groups offer support to sufferers, publish journals and encourage research. Here are some useful addresses.

#### For alopecia:

- Hairline International  
[www.hairlineinternational.co.uk](http://www.hairlineinternational.co.uk)  
Telephone: 01564 775281
- Alopecia UK  
[www.alopeciaonline.org.uk](http://www.alopeciaonline.org.uk)  
Telephone: 0208 333 1661
- Patient UK  
[www.patient.co.uk/showdoc/23069060/](http://www.patient.co.uk/showdoc/23069060/)
- British Association for Dermatologists  
[www.bad.org.uk/](http://www.bad.org.uk/)



We are currently working towards a smoke free site. Smoking is only permitted in the designated smoking areas.

For advice and support in quitting, contact your GP or the free NHS stop smoking helpline on 0800 169 0 169

#### Help with this leaflet:



If you would like this information in another language, large print or audio format, please ask the department to contact

Patient Information: 01223 216032 or

[patient.information@addenbrookes.nhs.uk](mailto:patient.information@addenbrookes.nhs.uk)



#### Document history

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Consent form 1

# Patient agreement to investigation or treatment

<b>For staff use only:</b>
<b>Surname:</b>
<b>First names:</b>
<b>Date of birth:</b>
<b>Hospital no:</b>
<b>Male/Female:</b>
<b>(Use hospital identification label)</b>

Responsible health professional/job title  
 .....

Special requirements .....  
 (For example, other language/other communication method)

**Name of proposed procedure or course of treatment**

**Diphencyprone topical immunotherapy**

**Statement of health professional**

(To be filled in by a health professional with an **appropriate knowledge of the proposed procedure**, as specified in the Hospital's consent policy)

I have explained the procedure to the patient. In particular, I have explained:

- The intended benefits of the procedure: To help treat your skin disorder. Other (please specify): .....
- Any serious or frequently occurring risks from the procedures including those specific to the patient: 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; 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; More rarely, is a widespread nettle rash or urticaria can occur. 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 or if planning a pregnancy. This is because the effects or side effects of diphencyprone have not been studied during pregnancy.

I have discussed what the treatment / procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient.

- The following information leaflet has been provided: Diphencyprone topical immunotherapy. Version/Date/Ref: CF401 version 2, November 2010

Health professional's signature: .....Date: .....

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

Contact details (if patient wishes to discuss details later) 01223 216234

I have offered the patient information about the procedure but s/he has declined information.

**Statement of the interpreter (if appropriate)**

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

Interpreter's signature ..... Date: .....

Name (PRINT): .....

**Important notes: (tick if applicable)**

The patient has withdrawn consent (ask patient to sign/date here) .....

<b>For staff use only:</b> <b>Surname:</b> <b>First names:</b> <b>Date of birth:</b> <b>Hospital no:</b> <b>Male/Female:</b> <b>(Use hospital identification label)</b>
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**Statement of patient**

Please read this form carefully. If your treatment has been planned in advance, you should already have your own copy, which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. Do ask if you have any further questions. The staff at Addenbrooke's are here to help you.

**You have the right to change your mind at any time before the procedure is undertaken, including after you have signed this form.**

Training doctors and other health professionals is essential to the continuation of the Health Service and improving the quality of care. Your treatment may provide an important opportunity for such training, where necessary under the careful supervision of a senior doctor. You may, however, decline to be involved in the formal training of medical and other students without this adversely affecting your care and treatment.

**Please read the following:**

**I understand** that you cannot give me a guarantee that a particular person will perform the procedure. The person undertaking the procedure will, however, have appropriate experience.

**I understand** that any procedure in addition to those described on this form will only be carried out if it is necessary to save my life or to prevent serious harm to my health.

**I have been told** about additional procedures which may become necessary during my treatment. I have listed below any procedures that **I do not wish, without further discussion, to be carried out.**

**I understand** that all research will be approved by a research ethics committee and undertaken in accordance with appropriate ethical, legal and professional standards.

**I understand** that the research may be conducted within a hospital, university, not for profit organisation or a company laboratory.

**Please tick boxes to indicate you either agree/disagree to the three points below.**

- |   | Yes                      | No                       |
|---|--------------------------|--------------------------|
| <b>I agree</b> to the use of photography for the purpose of diagnosis and treatment.  | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>I agree</b> to anonymised photographs being used for medical teaching.   | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>I confirm</b> that the risks, benefits and alternatives of this procedure have been discussed with me and I have read and understood the above and agree to the procedure (or course of treatment) on this form. | <input type="checkbox"/> | <input type="checkbox"/> |

**Patient's signature:** ..... **Date:** .....

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

If the patient is unable to sign but has indicated his/her consent, a witness should sign below. Young people may also like a parent to sign here (see guidance notes).

**Witness' signature:** ..... **Date:** .....

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

**Confirmation of consent** (to be completed by a health professional when the patient is admitted for the procedure, if the patient has signed the form in advance)

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

Signature    Date: .....

Name (PRINT): ..... Job Title: .....

Copy accepted by patient: yes / no (please circle)