

This is a record of the informed consent process for:

Name:.....

Date of Birth:...../...../..... RiO:.....

Information about treatment with Estradiol (also known as Oestradiol)

(For the purpose of making a declaration of consent to treatment)

What is Estradiol?

Estradiol is a hormone medication which can help to feminise (develop a more female body type) and also help to reduce some male aspects of your body. This is a medicine that you will need to take regularly for changes to your body to take place. Most people take this medicine for the long term and some take it for the rest of their lives. Before taking the medicine, there are several things you need to know. These are the possible advantages, disadvantages, risks, and warning signs, as is the case with any medicine that you take. We have listed them here for you. It's important that you understand all of this information before you start taking the medicine so that you can make a decision about whether or not this is the right medicine for you. We are happy to answer any questions you have.

How is Estradiol taken?

Estradiol can be taken in different ways:

- A pill/ tablet (oral preparation)
- Skin patch or gel (transdermal application)
- Estradiol is not available in this service as an injection

Who is at higher risk of health problems if they take Estradiol?

Estradiol should not be used by anyone who has ever had an oestrogen-dependent cancer (*ie.* a cancer that grows more quickly when oestrogens are present), of which one of the commonest types is breast cancer.

It should be used with caution and only after a full discussion of risks by anyone who:

- has had blood clots that could or did travel to the lungs (pulmonary embolism) or other parts of their body
- has had a stroke or TIA (transient ischemic attack sometimes called a mini stroke)
- has a strong family history of breast cancer or other oestrogen-dependent cancer
- has diabetes
- has heart disease, heart valve problems, or a tendency to develop blood clots
- has hepatitis or other liver disease
- has high cholesterol
- has kidney disease
- has migraines or seizures
- is obese (body mass index, BMI greater than 30)
- uses nicotine, especially in the form of cigarettes
- is over 40 years old
- has a family history or a diagnosis of porphyria
- has been found to have high triglyceride levels (one of the fats in the blood)

This is a record of the informed consent process for:
 Name:.....
 Date of Birth:...../...../..... RiO:.....

People who have these risk factors are often able to take Estradiol but they may need to take other steps to manage the risks. This might be lifestyle changes such as stopping smoking or losing weight.

What Estradiol does to your body

I know that estradiol may be prescribed to help me appear less masculine and/or more feminine.

The effects of estradiol vary from person to person and any effects cannot be guaranteed. The table below shows a rough idea of timescales. The best effects of estradiol on your body might happen if you increase the amount of estradiol in your body slowly over time.

Effect of Estradiol	Expected start	Expected end of changes
Stop losing more hair from your head (<i>please note: scalp hair that has already been lost does not grow back</i>)	1-3 months	1-2 years
Lower libido (less interest in sex)	1-3 months	1-2 years
Fewer erections when not involved in sexual activity	1-3 months	3-6 months
Reduced level of haemoglobin (Oxygen-carrying pigment in red blood cells)	2-4 months	2-4 months
Difficulty in achieving an erection for use in sexual activity	Variable	Variable
Softer skin and less oiliness of your skin	3-6 months	Ongoing
Less muscle bulk and less strength	3-6 months	1-2 years
Body fat moves generally from tummy to hips and thighs	3-6 months	2-3 years
Breast growth	3-6 months	2-3 years
Smaller testicles	3-6 months	2-3 years
Fewer sperm are produced - affects fertility	Variable	Variable
Less hair on body and face	6-12 months	over 3 years

How permanent are the effects of Estradiol?

Most of the noticeable changes caused by taking estradiol cannot be reversed even if you stop taking estradiol, for example, most breast and nipple growth is usually permanent.

Infertility- The long term effects of estradiol on fertility are not fully understood. Your testicles might not be able to produce sperm or cause pregnancy even if you stop taking estradiol.

If you are unhappy with the effects of estradiol and decide that you no longer wish to take it, the NHS is unlikely to provide treatment to reverse any changes that it has already brought about.

It is important to recognise that for some people their current gender identity is not permanent. It may be that your gender identity changes in the future and you might not be happy with the permanent changes to your body caused by taking estradiol.

This is a record of the informed consent process for:

Name:.....

Date of Birth:...../...../..... RiO:.....

The permanent effect of estradiol on breasts

I know it can take several months or longer for the effects to become noticeable. I know that no one can predict how fast, or how much, change will happen.

I know that if I am taking estradiol I will probably experience noticeable breast growth.

- I know it can take several years for breasts to get to their full size.
- I know my larger breasts will remain, even if I stop taking my treatment.
- I know I should be “breast aware”, that is, be aware of what my breasts look and feel like as they start growing, check them regularly and attend breast screening as appropriate. If I continue to take estradiol after the age of 70 I should continue to attend breast screening. If I notice unusual changes in my breasts I should seek advice from my G.P. (family doctor).
- I know I might get a milky discharge from my nipples (called galactorrhoea). If I do, I know I should seek advice from my Gender Clinic or my GP.
- I know that there is some evidence that taking estradiol increases the risk of breast cancer. I know that the evidence to date is that the risk of breast cancer for trans people taking estradiol is much lower than in the general cisgender female population.

The effect of estradiol on fertility

I know that my body will make less testosterone when I take estradiol. This may affect my sex life in different ways and my fertility:

- I know that we do not know whether the changes to fertility are reversible or permanent.
- I know my sperm may not develop normally. This will make me less fertile. I also know I might never produce normal sperm again. The start of these changes is variable; no-one should start taking estradiol if they plan to store sperm.
- Taking estradiol is not a form of contraception. I know that I might get someone pregnant if we have vaginal intercourse or other intimate sexual contact and we don't use contraception.
- The options for storing of sperm, to preserve my fertility, have been explained to me
- Estradiol does not protect me from HIV, or sexual infections and I should practice safer sex as usual.
- I know that my sex drive may change and I may have less reliable and softer erections.
- I know that the effect of estradiol on my body can also include my testicles and penis becoming smaller and changes to the pre-cum and ejaculate that my body produces.

The reversible effects of estradiol on the body

I know that the following changes can happen and I know that these changes are not usually permanent and are likely to gradually go away if I stop taking estradiol.

- I know my face and body hair will become finer, less noticeable and will grow more slowly. I know that it won't stop completely, even if I take my treatment for years, and that almost all women have body hair.
- I know I will probably have less fat on my abdomen and more on my buttocks, hips, and thighs.
- I know that if I have head hair loss it may slow down, but may not stop completely. It is also very unlikely that hair that has been lost will grow back.

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Name:.....

Date of Birth:...../...../..... RiO:.....

- I know I may lose muscle and strength in my body
- I know that my skin may become softer and less oily.

What estradiol can't change

I know that some parts of my body and life will not change much by using my treatment.

- I know the pitch of my voice will not rise, and my speech patterns will not alter. I can be referred for voice and communication therapy if I wish.
- I know my "Adam's Apple" will not shrink. There is no NHS funded treatment available to change this.
- Estradiol will not make me entirely happy with my body.
- Taking estradiol will not make me into a different person or solve all of my problems.
- Although taking estradiol can reduce feelings of gender dysphoria for some people, it will not directly improve mental health problems such as depression.
- Taking estradiol will not mean that I will find a place in a community or am accepted by everyone.
- Taking estradiol will not remove all those parts of my body that I experience as male.

If you are experiencing difficulties with these areas you may wish to speak to your Gender Clinic or GP about them.

Risks of treatment

I know that the side-effects and safety of my treatment are not completely known. There may be long-term risks that are not yet known.

I know not to take more medicine than I am prescribed or add other hormones from other sources (such as the internet or friends). I know it increases health risks. I know that taking more than I am prescribed won't make changes happen more quickly or more effectively.

I know my treatment may cause changes that other people will notice; this may be an important goal for me but I understand that some transgender people have experienced harassment, discrimination, and violence because of this. Others have lost the support of loved ones. I know my clinician can help me find advocacy and support resources.

I know that for some people their current gender identity is not permanent. It may be that my gender identity changes in the future and I might not be happy with the permanent changes to my body caused by taking estradiol.

Risks of Estradiol

I know that taking estradiol increases the risk of blood clots that can result in:

- Deep vein thrombosis (DVT) and ongoing problems with veins in my legs
- Heart attack
- Blood clot in the lungs (pulmonary embolism, PE), which may cause permanent lung damage or death

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Name:.....

Date of Birth:...../...../..... RiO:.....

- Stroke, which may cause permanent brain damage or death

I know that the risk of blood clots is worse if I use nicotine. I know that the risk will reduce if I stop smoking. (If you would like help with stopping smoking, please ask your GP or practice nurse as soon as possible about the services that are available in your area).

I know that the risk of blood clots is worse if I am overweight or obese (BMI 25 or above). Being overweight also increases my risk for diabetes and heart disease.

I know that if I have high blood pressure and I take estradiol my overall combined risk of heart disease can be higher. However, blood pressure can be controlled by taking regular medication, exercise and changes to diet.

I know that taking estradiol can result in some weight gain. I know that if it goes up, I can work with my GP to try to control it with diet, lifestyle changes, and/or medication.

I know that taking estradiol increases my risk of getting gallstones. I know I should talk with my clinician and GP if I get severe, recurrent, or long-lasting pain in my abdomen, particularly after eating fatty food.

I know that estradiol can cause nausea and vomiting. I know I should talk with my clinician and GP if I have long-lasting nausea or vomiting.

I know that estradiol can cause or worsen headaches or migraines. I know I should talk with my clinician and GP if I have headaches or migraines often or if the pain is unusually severe, or if I develop unusual symptoms, such as weakness or tingling in other parts of my body. This is particularly important because worsening migraine can be a risk factor for stroke.

I know that treatment may rarely cause me to produce more of a hormone called prolactin, and this may need to be investigated further. One of the signs of this happening is a milky discharge from my nipples. It is not yet known if taking estradiol increases the risk of prolactinoma (non-cancerous tumours of the pituitary gland). I know they are not life-threatening, but they can occasionally damage vision and cause headaches

It is not known for sure whether estradiol increases the risk of breast cancer for people taking estradiol. Risks of breast cancer are increased if there is history in your family. All people with breasts should anyway examine them regularly for changes or early signs of breast cancer. It is important to check with your GP that you are enrolled in the national breast screening programme. If I continue to take estradiol after the age of 70 I should continue to attend breast screening.

I know that there is still a risk that I could develop prostate cancer even when taking estradiol. I know that, if I am registered as female at my GP, I may not be invited for prostate screening should the NHS ever start such a programme, in which case I would need to ask my GP to enrol me if appropriate. I understand that the current screening blood test for prostate cancer (PSA) may not be reliable if I am taking estradiol. I will need to ask my GP to undertake any necessary assessment of my prostate health.

I know that I am more likely to have dangerous side effects if:

- I smoke
- I am overweight
- I am over 40 years old
- I have a personal or family history of blood clots
- I have high blood pressure.

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Name:.....

Date of Birth:...../...../..... RiO:.....

- I have a strong family history of breast cancer (more than one person with breast cancer, from amongst my siblings or parents)

Prevention of Medical Complications

I know that I must use my treatment at the time and at the dose recommended by my doctor, and tell my clinician or GP if I have any problems, side-effects or am unhappy with the treatment. I know that if I do not take my medication regularly, there may be health consequences such as osteoporosis (weakened bones).

I know that the dose and type of medication that has been recommended and prescribed for me may not be the same as that used by someone else.

I know that I need to have my Body Mass Index (BMI), blood pressure and blood test checked every 4-6 months in the first year after starting treatment. I should then have these tested every 6 months for the next 2 years and, thereafter, annually for as long as I am taking estradiol to monitor the effectiveness of my treatment and check for any unwanted effects.

I know that my treatment can interact with some prescribed medications, alcohol, diet supplements, herbal products, other hormones, and street drugs. This kind of interaction can cause unwanted effects, some of which may be life-threatening. I agree to be honest with my clinician about whatever else I take. I also know that information that I share about using other substances will not necessarily result in my care being withdrawn.

I know that my risk of medical problems can increase if I have other medical conditions and take estradiol. I agree to discuss with my clinician if I know of any medical conditions and to tell them if I am given a new diagnosis.

I know that if I have a serious medical event, such as a heart attack, stroke or blood clot I must contact the NRGDS, or ask my GP to do so, so that I can be supported in conversations about how to get the hormone treatment that I need.

I know that I may have to stop taking estradiol six weeks before some surgical or dental procedures (I know that I should tell any surgeon that plans to operate on me that I take estradiol) or when I may be immobile for a prolonged period of time. This will lower the risk of getting blood clots. I know I can start taking it again when my doctor says it's safe

I know that using these drugs to promote feminising body changes is an off-license use. I know this means that it is not approved by the UK medicines regulatory authority for this purpose. I know that the medicine and dose that is recommended for me is based on currently available research evidence, clinical guidelines, and the judgment and experience of the clinician.

I know that I can choose to stop taking estradiol at any time. I know that if I decide to do that, I should do it with the help of my clinician or GP. This will help to reduce possible negative reactions. I also know my clinician may suggest that I reduce the dose, change the type of treatment or stop taking it if certain conditions develop. Such action is rare but may happen if the side effects are severe, the risks of treatment cannot be managed in other ways or there are potentially dangerous health consequences of continuing treatment at that time.

More information

I know that I can obtain clarification or more information about any aspect of my treatment from the clinical team at NRGDS.

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Statements

- I have read and understood this information sheet and have no other questions about my treatment
- I need help with losing weight
- I need help with stopping smoking
- I need help with alcohol or substance use
- I need advice about sexual health
- I need more information about...

Name:..... Date of Birth...../...../.....

I confirm that I have had the treatment fully explained to me and have had the opportunity to ask questions. My attention has been drawn to the potential side effects, and I understand that if I experience any of these side effects I must seek advice.

I have agreed that I will only take hormone treatment as prescribed by or recommended by the Northern Region Gender Dysphoria Service, and that I will avoid using any other hormone treatments.

I know that for some people their gender identity may change over time. It may be that my gender identity changes in the future and I am not satisfied with the irreversible changes to my body caused by estradiol. I understand that it is impossible for me, or anyone else, to predict the future wishes of others with total accuracy. I am willing to consent to taking estradiol under these circumstances.

I understand that I can withdraw from this treatment at any time. I will inform my GP and gender clinic if I do so.

Signed..... Date:.....

For staff to complete

I am satisfied that understands the nature of the proposed treatment and has a full appreciation of the consequences of both the treatment in terms of benefits and possible side-effects and also the possible consequences of not undergoing this treatment. I believe that this person has the capacity to make this decision and they were able to communicate their decision to me today.

Signed..... Date:.....

Print Name..... Role.....