Patient Risk Assessment and Consent Form

Please read this section carefully before completing the consent form

Norethisterone 5mg tablets are used for adult females of 18 to 50 years to postpone menstruation (period delay). This treatment is intended for non-regular use and only one supply is allowed every 6 months. You should contact your GP if you required a more frequent treatment regimen.

Patient Name:_____

Address :_____

Tel :_____

Email :_____

GP Name :_____

GP Address :_____

1. Communication between doctors involved in your treatment helps provide the safest and most effective healthcare. Do you want your GP to be notified for this consultation?

Yes No
(please circle)

Medicines and their possible side effects can affect individual people in different ways. The following are some of the side effects that are known to be associated with Norethisterone.

Just because a side effect is stated here does not mean that all people using this medicine will experience that or any side effect.

Warnings

Patient / Applicants may experience a rise in blood pressure, jaundice (yellowing of the skin or whites of the eyes), migraine-type headaches, signs of sever hypersensitivity (anaphylaxis): e.g. swelling of the mouth, tongue, face, throat, difficulty breathing, wheezing, severe skin rash, itch, redness, if you become pregnant unusually bad headache, sever itching (pruritus), other liver problems and signs e.g. abdominal pain, nausea, vomiting, tiredness, dark brown urine, any sudden changes in eyesight, hearing or speech, any changes in sense of smell or touch. If you are concerned with the side effects, you may talk to the pharmacist who oversee this treatment or your GP for further information before proceeding with treatment.

Drowsiness is rare with this medication, but may occur and interfere with performance of skilled tasks e.g driving Excess alcohol should be avoided when taking Norethisterone.

Applicant (or parent/guardian in the case of children/adolescents) must answer the following questions comprising the applicant Risk Assessment Consent form.

General Questions

	Yes	No
2. Please confirm you are 18 to 50 years old.		
3. Please confirm you would like to postpone menstruation (period delay) for non-regular use and that you understood that only one supply is allowed every 6 months and that you should contact your GP if you required a more frequent treatment regimen.		

BMI Question:

4. What is your height (in meters)? _____

5. What is your body weight (in kilogram)? _____

Clinical Questions

	Yes	No
6. Are you aware of any hypersensitivity (allergy), or any undesirable side effects to Norethisterone or any of its ingredients? *(See the Product Information Leaflet Section 4 for further information).*		
7. Are you pregnant or breast feeding or actively trying for a baby?		
8. Do you have severe liver impairment?		
9. Do you have severe kidney disease, or end stage renal disease requiring dialysis?		
10. Are you taking any other medication either prescribed or over the counter? *(If so you must show your pharmacist all your medication as certain medicines can interact with Norethisterone. Please list them in relevant section below).*		
11. Do you have any other questions you would like to ask your pharmacist about this product?		

12. Are you currently using regular contraception? Yes No

If you are taking regular pill/patch, a better way of delaying your period is taking your combined pill pack or your contraceptive patches back to back without a seven day break. We do not advise taking Norethisterone and your combined pill together.

13. Are you currently using mini pill/implant/injection? Yes No

If you are using the mini pill, a contraceptive implant or a contraceptive injection and norethisterone

together, it can result in a higher risk of having side effects from the hormones such as blood clots. We do not advise taking Norethisterone and your current treatment together.

14. Do you suffer from irregular bleeding or spotting between your periods?
Yes No

15. Are you allergic to any medicines or other substances (e.g peanuts/soya)?
Yes No

16. Are you planning to take Norethisterone and fly at the same time?
Yes No

If you are planning to take Norethisterone and fly at the same time that increase your risk for a blood clot. recommend that you take extra precautions such as wearing flying stockings and exercising. Please confirm you understand this by choosing the appropriate option which reflects your understanding.

Yes No

17. Do you understand noresthisterone is not contraceptive?
Yes No

Past and Current Medical History

18. High blood pressure	Yes	No
19. Angina / chest pain	Yes	No
20. Cardiac dysfunction	Yes	No
21. Myocardial infarction	Yes	No
22. Migraine		
23. Liver Disease	Yes	No
24. Jaundice in pregnancy	Yes	No
25. Severe itching or severe blistering rash in pregnancy (rare)	Yes	No
26. Liver disease	Yes	No
27. Epilepsy	Yes	No
28. Asthma	Yes	No
29. Diabetes	Yes	No
30. Renal dysfunction	Yes	No
31. Asthma	Yes	No
32. Porphyria (a rare metabolic disorder)	Yes	No

33. Please list any current and past medical problems you have:

1._____

2._____

3._____

4._____

5._____

(Continue on a separate sheet if necessary)

Past and Current Medications History
(Included all prescribed, over-the-counter, herbal, internet or recreational medications)

34. Please list your current medication. Include prescription and over the counter medications/drugs

1._____

2._____

3._____

4._____

5._____

(Continue on a separate sheet if necessary)

35. Have you had another supply of Norethisterone tablet (in any strength or formulation) within the pas 6 months from this pharmacy or another healthcare provider? (important)

Yes No

36. I have and will read manufacturer's patient information leaflet supplied again with my Norethisterone tablets and stop and report any adverse effect immediately to relevant healthcare profession.

Yes No

37. Are you aware the side effects of norethisterone listed on page one of this consent form and on section 4 of the patient information leaflet (PIL)?

Yes No

38. I understand norethisterone may worsen migraine, epilepsy and asthma

Yes No

39. I understand I should stop Norethisterone if unexpected side effects occur

Yes No

40. I understand Norethisterone supplied used for postponement of menstruation (not intended for long term use: only 57 tablets supplied over 16 days period, including 3 days initiation period.) It is not intended for regular or long term use

Yes No

I have read and understood the information provided regarding Norethisterone including the Patient Information Leaflet (PIL) supplied by my pharmacist. I understand the benefits and possible risks of taking Norethisterone, and confirm I am satisfied that my pharmacist has satisfactorily explained any questions I may have had about taking this product. I hereby give my informed consent to be supplied with Norethisterone. I confirm I will take Norethisterone as directed, and that I will stop taking it and notify my pharmacist if I develop any significant side effects.

Patient / Applicant Name;_____

Signature;_____ Date;_____

I confirm and agree that any treatment prescribed for me is for my personal use only.

Pharmacist Use Only

In all cases to be completed by the Pharmacist reviewing the applicant consent form who must be authorized by Voyager Medical to supply Norethisterone under this PGD

Notes to Pharmacist on risk assessment form;

Please ensure the applicant has read and understood the PIL prior to supplying Norethisterone. (the applicant should ideally be given this prior to completing the consent form)

General questions are usually confirmatory i.e. a YES answer is expected to continue with the application (see section 2 of the PGD if clarification is required).

BMI question
BMI = weight (in kilogram) / (height in meters)^2
BMI calculated by responsible pharmacist = _____
(Period delay PGD is not recommended for patient's BMI > or = 30 (Severe obesity) as stated in section 2.4 of PGD for higher risk of VTE.)

Clinical questions are usually to identify exclusions or pre-cautions/special warnings i.e. a NO answer is expected to continue the application (see sections 2.3 and 2.4 of PGD if clarification is required).

Medical history questions are usually to identify exclusions or precautions/special warnings i.e. a NO answer is expected to continue the application (see sections 2.3 and 2.4 of PGD if clarification is required).

Past and Current Medications History are used to identify any potential interactions with another medication(s) listed on section 2.7 of the PGD

FOR PHARMACIST USE ONLY – Please record here any details from the responses to the questions above that may affect your decision to supply the medication to the applicant named above: include details of all advice given

Voyager Medical Norethisterone Provision PGD
Patient Risk Assessment and consent Form

Have you reviewed the answers provided in the applicant consent form and followed the recommendations in; VOYAGER MEDICAL NORETHISTERONE PGD?

Yes No

Has the applicant met all the requirements to be supplied with Norethisterone?

Yes No

APPLICANTS NOT RECEIVING A SUPPLY OF MEDICATION. Record your reasons here why you chose not to supply medication on this occasion or why the applicant decided not to receive a supply on this occasion
Reschedule the appointment? YES / NO When?
Referred to: GP Medical Specialist/Consultant Other
Notified GP: (requested by patient) Via 1. Fax 2. Email 3.Letter 4.Letter/copy of consultation form for patient to carry to GP (circle for appropriate) Date of communication:_____
Additional Notes:

All records should be retained in the pharmacy in accordance with section 5.2 of the PGD

Pharmacist to sign below as a record of advice given (even if a medicine has not been supplied)

Name of authorised pharmacist (print):		Date:
GPhC/PSNI reg no.		Signature:
Product / Strength / Dosage: (Up to maximum 57 tablets is allowed under this PGD) Batch Number:		Expiry Date:
Supplied by;	Date Supplied	Pharmacy Stamp