

Female Roaccutane Protocol

Blood tests to be provided to patient for test 2 weeks prior to initial appointment

Patients to be advised re contraception prior to appointment – ensure 2 methods 1 month before starting treatment

4 x Follow up appointments = 3 x 4 weeks and 5 weeks post treatment

Criteria for Roaccutane

- Inflammatory acne with early scarring, or if scarring highly likely
- Severe cystic Acne
- Resistant to adequate courses of standard therapy with systemic antibacterials and topical therapy e.g. 2 x 3 month courses of oral antibiotics.
- Causing major physical and/ or psychological co-morbidity

Contraindications

- Hypervitaminosis A
- Uncontrolled Hyperlipidaemia
- Pregnancy or lactation
- Hepatic insufficiency
- Airline pilot
- History of moderate/severe depression

Use with caution in patients with

- Renal disease – reduced and titrated dose suggested
- Diabetes
- History of low mood
- Dependency upon good night vision e.g. coach and taxi drivers
- Peanut allergies – some brands contain peanut oil
- History of low mood

Initial appointment

- 1) Take and record a full history appropriate to known side effects
- 2) Record outcomes of any previous Roaccutane treatment
- 3) Discuss general side effects – provide Female Roaccutane PIL
- 4) Discuss teratogenic risk – highlight information in Female Roaccutane PIL
- 5) Document site, nature and severity of acne
- 6) Check recent bloods (LFT, Fasting lipids, FBC)
- 7) Provide patient with Contraception PIL
- 8) Discuss and ensure understanding of both PILs
- 9) Assess risk of pregnancy:
 - a. 2 forms of contraception must be used 1 month before, during the course and 1 month after course
 - i. Hormonal (COC, injection, implant) should be used. Progesterone only pill may be less reliable and make acne worse
 - ii. Barrier method
 - b. Medically supervised pregnancy test (minimum sensitivity of 25mIU/ml)
 - c. Complete Pregnancy Prevention Programme Checklist – save in patient record
- 10) Counsel regarding depression:
 - a. Record previous and current psychiatric health

- b. Complete and document PHQ-9 score – completed PHQ-9 to be scanned to record
 - c. Specifically discuss potential for mood change
 - d. Advise friends/ family to comment if mood change occurs
- 11) Prescribing clinician and patient to sign Isotretinoin consent form (FEMALE)
 - 12) Initiate treatment based upon 0.5mg/kg for 4 weeks
 - 13) Provide blood test form for recheck prior to next appointment at 4 weeks
 - 14) ENSURE the following read codes are used: Roaccutane Course Started, Roaccutane Blood form provided, Roaccutane follow up required

Initial Script (based upon female weighing 0kg)

- 40mg Roaccutane for 4 weeks

1st Follow up appointments

- 1) Check and document effectiveness of treatment
- 2) Check compliance with Roaccutane and contraception
- 3) Specifically enquire about common side effects
- 4) Specifically enquire about mood change – (assess severity of any change and consider the need for expert opinion/ discontinue of medication)
- 5) Ask an open question about other side effects
- 6) Medically supervised pregnancy test (minimum sensitivity of 25mIU/ml) – document result
- 7) Confirm the importance of effective contraception measures incl emergency contraception
- 8) Complete possible Roaccutane side effect patient questionnaire (FEMALE) – patient to sign
- 9) Check blood tests - if abnormal decide to stop or reduce dose, issue further blood test form
- 10) Prescribe 4 weeks of Roaccutane at 1mg/kg (aim for cumulative dose of 120mg/kg)
- 11) ENSURE the following read codes are used: Roaccutane Blood form provided, Roaccutane follow up required

Follow up Script (based upon male weighing 60kg)

- 60mg Roaccutane for 4 weeks

Post treatment follow-up (5 weeks after dose)

- 1) Complete 1 – 8 as above
- 2) Check blood test results
- 3) Arrange repeat bloods if indicated
- 4) Remind patient about the need to inform clinician of any late complications
- 5) Ensure that any unused Roaccutane is returned
- 6) ENSURE the following read codes are used: Roaccutane Blood form provided