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