Dorset Medicines Advisory Group

Shared Care Guideline for

Sustanon® 250

(Testosterone Decanoate, isocaproate, phenylpropionate & propionate in Arachis Oil)

INDICATION:

Induction and Progression through male puberty.

The aim of testosterone replacement therapy is to mimic the normal cadence of puberty and match requirements at different stages of pubertal development in patients with hypogonadotrophic hypogonadism, androgen deficiency secondary to testicular disease (hypergonadotrophic hypogonadism) and in CDGP (constitutional delay in growth and puberty). Testosterone replacement therapy is used to induce development of secondary sexual characteristics and promote linear growth, normal accrual of muscle mass and bone mineral density while avoiding mistimed epiphyseal plate closure.

AREAS OF RESPONSIBILITY FOR SHARED CARE

This shared care agreement outlines suggested ways in which the responsibilities for managing the prescribing of Sustanon® can be shared between the specialist setting and the patient's GP (if different). GPs are invited to participate. If the GP is not confident to undertake these roles, then he or she is under no obligation to do so. In such an event, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist. If a specialist asks the GP to prescribe this drug, the GP should reply to this request as soon as practicable.

Sharing of care assumes communication. The intention to share care is usually explained to the patient by the doctor initiating treatment. It is important that patients are consulted about treatment and agree with it.

The doctor who prescribes the medication legally assumes clinical responsibility for the drug and the consequences of its use.

REFERRAL AND INITIATION

Treatment with Sustanon 250 under the age of 16 years should always be initiated and monitored by a specialist (Consultant Paediatric Endocrinologist or Consultant Paediatrician with expertise in growth disorders) as recognised by the British Society for Paediatric Endocrinology and Diabetes (BSPED).

Specialist Responsibilities	
1	To undertake necessary clinical assessment and investigations to confirm diagnosis and need for pubertal induction
2	To arrange administration of the first injection in the hospital.
3	To provide GP with written information regarding the diagnosis and indication for Sustanon therapy along with dosage, preparation used and frequency of injections.
4	To liaise with GP about local arrangements necessary for instigation of therapy and identify any possible barriers to treatment.
5	To monitor patient's growth, pubertal development, assessment of any other on-going or evolving endocrinopathy and general condition at 4-6 monthly intervals following instigation of therapy and advise about change in dose, preparation or frequency of injections.

General Practitioner Responsibilities	
1	To prescribe Sustanon 250 as advised by the supervising Consultant and, where local practice dictates, discuss with the local Prescribing Advisor; feedback to the Consultant any concerns regarding Sustanon prescribing and/or shared care.
2	To facilitate the administration of subsequent injections at the surgery as appropriate. The injections should not be delayed beyond the recommended time period for any reason but can be brought forward by a few days if needed for practical or logistical reasons.
3	To monitor patient's overall health and well-being.
4	To report any adverse effects of therapy to the supervising Consultant or deputy.

Patient's role (or that of carer)	
1	To ensure they have clear understanding of the prescribed treatment.
2	To ensure that injections are administered as per the recommended time interval. Please notify the supervising Consultant and/or GP if the injection is delayed for any reason.
3	To share any concerns in relation to treatment with the supervising Consultant and/or GP.
4	To report any adverse effects to the supervising Consultant and/or GP whilst on treatment.

SUPPORTING INFORMATION

1. Patients started on Sustanon therapy require specialist supervision and review in a growth/endocrine clinic 2-3 times a year.

2. Sustanon has a good safety record. It is widely used throughout the UK for puberty induction (see BNFc) but does not have a licence for use.

3. Dose is commenced at 0.3ml by monthly intramuscular injection and increased every 6-12 months according to response. (may just be used for 3-6 month at 0.3ml dose for constitutional delay in growth and puberty)

4. Updates should be communicated with the GP by the supervising Consultant following every clinic visit, who will advise on dosage

Dosage Administration

a) Starting dose 0.3ml on a monthly basis

b) Increased initially to 0.6ml and then 1 ml every 6-12 months according to clinical response.

Administration

Deep intra-muscular injection. The manufacturer's recommended method of preparation and administration should be strictly followed.

Contraindications

There is a theoretical risk of allergic reaction in patients with peanut allergy, so either an alternative preparation should be used, or the first three injections given in the paediatric unit.

Cautions
Peanut allergy

Side effects
Prostatic cancer, Polycythaemia, Fluid retention, Weight increased, Depression, Nervousness, Mood altered, Libido increased, Libido decreased, Hypertension, Nausea, Hepatic function abnormal, Pruritus, Acne, Myalgia, Ejaculation disorder, Gynaecomastia, Oligospermia, Priapism, Benign prostatic hyperplasia, Lipids abnormal, PSA increased, Haematocrit increased, Red blood cell count increased, and Haemoglobin increased.

Interaction with other medicinal products and other forms of interaction
Sustanon 250, 250mg/ml solution for injection - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk) Date accessed: 28/04/2021

Enzyme-inducing agents may decrease, and enzyme-inhibiting drugs may increase testosterone levels. Therefore, adjustment of the dose of Sustanon 250 may be required.

Insulin and other anti-diabetic medicines:
Androgens may improve glucose tolerance and decrease the need for insulin or other anti-diabetic medicines in diabetic patients
Patients with diabetes mellitus should therefore be monitored especially at the beginning or end of treatment and at periodic intervals during Sustanon 250 treatment.

Anti-coagulant therapy:
High doses of androgens may enhance the anticoagulant action of coumarin type agents.
Therefore, close monitoring of prothrombin time and if necessary, a dose reduction of the anti-coagulant is required during therapy.

ACTH or Corticosteroids:
The concurrent administration of testosterone with ACTH or corticosteroids may enhance oedema formation therefore these active substances should be administered cautiously, particularly in patients with cardiac or hepatic disease or in patients predisposed to oedema

Laboratory test interactions:
Androgens may decrease levels of thyroxine-binding globulin, resulting in decreased total T4 serum levels and increased resin uptake of T3 and T4. Free thyroid hormone levels remain unchanged, and there is no clinical evidence of thyroid dysfunction.

This list is not exhaustive. The manufacturer's summary of product characteristics (SPC) and the most current edition of the British National Formulary should be consulted for full information on contra-indications, warnings, side-effects and drug interactions.

Drug costs: DM+d accessed April 2021
£2.45 per vial

References
1. BSPED Clinical Committee Clinical Guideline, Revised November 2016
Testosterone Replacement Therapy: R El-Khairi, N Shaw, EC Crowne
testosteronereplacementguideline.pdf (bsped.org.uk)

2. BNF online Digital Medicines Information Suite | Medicines Complete accessed April 2021

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