Information for Veterinary Surgeons:

BCG Treatment Guidelines
Treatment of Sarcoids with BCG
Guidelines from Equine Medical Solutions Ltd

• Please find enclosed BCG Vaccine as prescribed by Equine Medical Solutions Ltd.
• Please make sure you follow the BCG protocol below. These guidelines should provide you with all the relevant information regarding the administration of this vaccine. If you are in ANY doubt about the method, risks or the prognosis, please contact Equine Medical Solutions IMMEDIATELY.

❖ NB Please note that although no actual powder can be seen in the vial, it is there! It is stored in the “bung” in the neck of the vial, and will dissolve in the diluent when that is added!
❖ *BCG vials should be stored in the fridge until they are needed!
❖ DO NOT SHAKE THE VIALS – just keep them turning over at body temperature for 15 minutes or so after reconstitution (a pocket is good!) and prior to use.

• In order to satisfy our requirements, you are requested to make a careful assessment of the lesion at each injection procedure.
  o ALL horses subjected to this procedure must be signed out of the food chain.
  o The material MUST be used solely for the animal prescribed.
  o The vaccine contains live freeze-dried BCG (Sofia strain). The vaccine must NOT be handled by any person with any immunocompromising state including those on systemic corticosteroids or other immunosuppressive drugs, those with malignant conditions and those with secondary immunocompromise since the reaction to self-injection with these conditions may be greater than otherwise and generalised BCG infection is possible.
  o In case of accidental self-injection please contact your doctor immediately and take the bottle with you. Safety information is available at Public Health England website.
  o This product does not have full authorisation in the country of origin and therefore has not been subjected to quality, safety and efficacy by a regulator. The benefit of it should be weighed against the risks (see below)
  o Unused material must be disposed in clinical waste.
  o THE MATERIAL SHOULD BE KEPT REFRIGERATED AS FAR AS POSSIBLE

• Photographs MUST be taken at defined intervals, & at six months post treatment. The intervals between photographs can be varied, but are ideal at each injection.

• This information will be used to support a possible licence application for equine use in the future!
• ANY untoward / unusual responses should be discussed immediately with Equine Medical Solutions Ltd!

Useful Tips:
1. It is best to divide the dose into several syringes – so that if one “bursts” the whole dose is not lost!
2. Remember sarcoids are dense & it may be helpful to create a small amount of intra-lesional “damage” with the needle tip to make the injection easier.
3. One vial can be divided between several lesions. It is the volume that matters, not the weight of the BCG - but it cannot be diluted beyond 1 ml in each vial.
   INSTRUCTIONS WILL BE GIVEN ON THE CASE CARD AND SHOULD BE FOLLOWED
4. Significant reactions can develop over 3-5 injections & this may REQUIRE CESSATION of the treatment protocol. Localised abscessation can develop and can be alarming in extent, with a persistent discharging sinus developing over 12 months; usually this resolves with time.
5. BCG treatment results in a very acceptable cosmetic effect and is safe for both operator and patient. It has much to commend it, but it is far from being the perfect treatment with a significant number of failures! The best results are achieved in nodular (TYPE A and TYPE B) sarcoids and fibroblastic sarcoids (both TYPE 1 and 2) around the eye. However, it is important to note that there is no detectable effect on untreated sarcoids on a horse with which, one or more individual lesions are treated with BCG.

Professor Knottenbelt advises the following treatment protocol for nodular (& some fibroblastic) sarcoids:

1. Evaluation of the size of the tumour to be treated
2. Sedation & restraint of the patient, & preparation of the material
   It is best to dissolve the BCG into the diluent approximately 15- 30 minutes before you are due to give the injection. Once the BCG has been diluted, it needs to be kept in a warm place – a trouser pocket would be ideal.
3. Dilution of one vial of lyophylised BCG viable bacillus into an appropriate volume of diluent; for small tumours <0.5cm the vial contents are diluted into 0.5ml of diluent and injected intra-lesionally. For larger lesions the vial can be diluted into a correspondingly larger volume up to 1 ml of diluent and injected intra-lesionally.
   ✓ It is important that the entire contents are injected INTRA-LESIONALLY!
   Subcutaneous injection in the vicinity of a sarcoid is to be avoided as far as possible – there is a much greater risk of ANAPHYLAXIS and it does not work therapeutically either!
4. The patient MUST be premedicated with corticosteroid (e.g dexamethasone IV at 0.01-0.04mg/kg) & flunixin (at 1.1mg/kg) for all treatments including the first injection. Antihistamines are of dubious value & are therefore not used routinely.
5. Use a pressure 1-2 ml Tuberculin-test type syringe and a 21-22G needle of appropriate length. Finer needles may seem to be attractive, but the BCG suspension is slightly viscous and can be hard to deliver through very fine needles.

6. Careful surgical preparation of site of first injection (Day 0)
7. Second injection should be given a week later (Day 7)
8. Third injection should be given two weeks later (Day 21)
9. Fourth injection should be given three weeks later (Day 42)
10. Fifth injection should be given a further four weeks later (Day 70)- subsequent injections are given at 4 weeks interval.

✓ THIS IS THE EXPANDING WEEK PROTOCOL and maximizes the benefit and minimises both the risks and the costs.

11. Up to 8-9 injections may be required. Dosing should not stop until a suitable response is evident. After 7 – 8 injections the case may be regarded as “non-responsive”.

12. The attending veterinary surgeon should remain with the horse for 30 mins after the injection with adrenaline at the ready. In the event of anaphylactic collapse, a dose of 3-5 ml 1:1000 iu (1mg/ml) adrenaline (per 450kg) should be given INTRAMUSCULARLY. DO NOT USE THE IV ROUTE!

13. NB. Check the concentration of the adrenaline solution you have!
14. ONLY leave the horse when YOU are satisfied it is safe!
15. The dose can be repeated if needed after 10-15 mins. Concurrent dexamethasone should be given IV.

EMERGENCY CONTACT INFORMATION

Professor Derek Knottenbelt
Email: knotty@equinesarcoid.co.uk

EQUINE MEDICAL SOLUTIONS
Email: office@equinesarcoid.co.uk
Tel: 01786 236380