

# REGENESIS VET™ R.I.A.D™ INFORMATION FOR PRESCRIBERS



## INTRODUCTION

Regenesis Vet™ Recombinant Inflammatory Antagonist Diluent™ (R.I.A.D™) is a targeted cytokine therapy product developed through a proprietary, provisionally-patented system of processing autologous blood. Through this, a natural (non-doping) product is derived that leverages off the body's ability to heal itself. Please note, Regenesis Vet™ R.I.A.D™ is the first product of its kind worldwide and is fundamentally different to other commercially available orthobiologic products such as iRAP, PRP, Platelet Lysate, Stem Cells etc. Medical Device law restricts the use of Regenesis Vet™ R.I.A.D™ to licensed veterinarians only.

## THINGS TO NOTE

### PRIOR TO PROCESSING REGENESIS VET™ R.I.A.D™

- Ensure horse has not received NSAIDs for at least 3 days prior to the processing of Regenesis Vet™ R.I.A.D™. NSAIDs interfere with the cyclooxygenase of platelets that the related growth factors are harvested from and as such NSAIDs may affect the quality of the end product.
- Take caution when processing Regenesis Vet™ R.I.A.D™ if the horse has or is suspected to have an underlying infection and/or virus as this may contaminate treatments spun for later use.
- Horses temperatures should always be checked prior to the processing of Regenesis Vet™ R.I.A.D™.
- Ensure that there are no unwanted drugs in the horse's system when the product is processed as trace amounts may be present in processed treatments which could have unwanted doping-related consequences.
- Regenesis Vet must only be used on the same horse from which blood was drawn.

### PRIOR TO ADMINISTERING REGENESIS VET™ R.I.A.D™

- It is strongly recommended that horses receiving Regenesis Vet™ R.I.A.D™ for the first time, or horses that have proven to be sensitive to the product via intravenous administration, are premedicated with Buscopan prior to treatment.
- Ensure your horse is well hydrated prior to receiving Regenesis Vet™ R.I.A.D™ and has unrestricted access to water.
- Horses temperatures should always be checked prior to your vet administering Regenesis Vet™ R.I.A.D™.
- Where possible, Regenesis Vet™ R.I.A.D™ should be administered before the horse is exercised. Do not exercise the horse for at least 60 minutes after the administration of Regenesis Vet™ R.I.A.D™.
- Ideally, Regenesis Vet™ R.I.A.D™ should NOT be administered within 4 hours following exercise due to the possibility of increased Potassium levels following exercise.

Although autologous blood products are generally considered very safe, with any medical procedure, there is always the risk of side effects. As with many treatments, Regenesis Vet™ R.I.A.D™ can illicit an immune response within the horse's body and as such, although uncommon, minor side effects can occur. It is for this reason that it is imperative that your vet is involved in the administration of any and all treatments such that should any side effects occur, they can be appropriately managed. There are however various steps that can be taken to reduce the chance of side effects occurring which are outlined later in this document.

- Do NOT administer Regenesis Vet™ R.I.A.D™ if your horse has or is suspected to have an underlying infection or virus.
- Do not administer Regenesis Vet™ R.I.A.D™ to horses with conditions affecting mineral or electrolyte balance.
- Take caution when administering Regenesis Vet™ R.I.A.D™ to horses with diarrhea as this could affect their electrolyte balance.
- DO NOT ADMINISTER REGENESIS VET™ R.I.A.D™ WITHIN 21 DAYS OF AN AFRICAN HORSE SICKNESS (AHS) VACCINE OR WITHIN 14 DAYS OF ANY OTHER VACCINE.

### DURING THE ADMINISTRATION OF REGENESIS VET™ R.I.A.D™

- Ensure the horse is calm and well hydrated.
- Normal sterility standards should be adhered to when administering Regenesis Vet™ R.I.A.D™.
- Ensure that any and all Regenesis Vet™ R.I.A.D™ treatments are administered by a licensed veterinarian ONLY.
- Regenesis Vet™ R.I.A.D™ should be administered very slowly and evenly at a rate no faster than 1ml/4 seconds via intravenous route of administration. Faster injection rates increase the risk of an adverse event.
- Regenesis Vet™ R.I.A.D™ should be administered very slowly at a rate no faster than 1ml/2 seconds via intramuscular route of administration. The full treatment can be split evenly and injected at 2 different injection sites.

### FOLLOWING THE ADMINISTRATION OF REGENESIS VET™ R.I.A.D™

- Horses should be hand walked for 15-20 immediately following the administration of Regenesis Vet™ R.I.A.D™.
- Horses should be observed closely for at least 2 hours after the administration of Regenesis Vet™ R.I.A.D™ for signs of abdominal discomfort or abnormal behaviour.

- Contact your veterinarian if your horse displays any abnormal clinical signs following the administration of Regenesis Vet™ R.I.A.D.™ or if you suspect your horse may be having an adverse reaction.
- Do not exercise the horse for at least 60 minutes after the administration of Regenesis Vet™ R.I.A.D.™.
- If your horse appears uncomfortable, nervous, or experiences abdominal cramping post-treatment, hand walk the horse for 15-20 minutes. If signs do not resolve contact your veterinarian.
- Should a horse require medical treatment for any side effect or reaction following the administration of Regenesis Vet™ R.I.A.D.™, non-NSAID treatments should be administered as far possible due to the interference of NSAIDs with the cyclooxygenase of platelets and their related growth factors.
- Please note Regenesis Vet™ R.I.A.D.™ is not something that has an immediate effect. Improvement is most commonly reported from 7-10 days following the administration of Regenesis Vet™ R.I.A.D.™.
- Please avoid the administration of NSAIDs as far as possible for at least 3 days following the administration of Regenesis Vet™ R.I.A.D.™ as it may interfere with the efficacy of the product.

## WARNINGS & CONTRAINDICATIONS

- DO NOT ADMINISTER Regenesis Vet™ R.I.A.D.™ WITHIN 21 DAYS OF AN AFRICAN HORSE SICKNESS (AHS) VACCINE OR WITHIN 14 DAYS OF ANY OTHER VACCINE.
- TO BE ADMINISTERED BY A LICENSED VETERINARIAN ONLY.
- Do not administer Regenesis Vet™ R.I.A.D.™ to horses with a known hypersensitivity to anticoagulants.
- Do not exceed the recommended speed/rate of administration.
- Do not administer Regenesis Vet™ R.I.A.D.™ to horses that have or are suspected to have an underlying infection and/or virus.
- Do not administer Regenesis Vet™ R.I.A.D.™ to horses with conditions affecting mineral or electrolyte balance (Hyperkaemic periodic paralysis, hypocalcaemia etc.).
- Do not administer Regenesis Vet™ R.I.A.D.™ to horses with conditions that may be aggravated by hypocalcaemia (e.g. cardiac disease).
- Take caution when using Regenesis Vet™ R.I.A.D.™ in a horse with impaired renal function or with a history of renal disease.
- Do not administer Regenesis Vet™ R.I.A.D.™ to horses that have Hyperkaemic periodic paralysis (HYPP) or suspected HYPP.
- Do not administer Regenesis Vet™ R.I.A.D.™ to horses that are or are suspected to be Hypocalcaemic.
- Do not administer Regenesis Vet™ R.I.A.D.™ to horses that are or are suspected to be Hyperkaemic.
- Take caution when administering Regenesis Vet™ R.I.A.D.™ to horses that have underlying pathology (e.g. a tying-up predisposition).
- Do not administer a Regenesis Vet™ R.I.A.D.™ treatment that has or may have been defrosted and refrozen. A compromised cold chain may affect the quality and sterility of the product.
- Regenesis Vet™ R.I.A.D.™ should be used with caution in horses receiving concurrent administration of other drugs that may reduce serum calcium (such as tetracyclines) or whose toxicity may exacerbate a reduction in serum calcium (such as aminoglycosides).
- The safety of Regenesis Vet™ R.I.A.D.™ has not been established in pregnant or lactating mares.
- The safety of Regenesis Vet™ R.I.A.D.™ has not been established when administered concurrently with other medications.

## POSSIBLE SIDE EFFECTS & ADVERSE EVENTS

Although uncommon, adverse reactions can happen following the administration of Regenesis Vet™ R.I.A.D.™. Retrospective blood tests indicate that in majority of adverse events (>70%) the presence of a subclinical underlying virus and/or infection in the horse's body was

detected. The administration of Regenesis Vet™ R.I.A.D.™ may affect the plasma concentrations of various electrolytes such as potassium, calcium and magnesium. This can happen immediately following treatment or up to several hours post treatment. For this reason, caution should be used when administering Regenesis Vet™ R.I.A.D.™ to horses with conditions affecting electrolyte balance (Hypocalcaemia, Hyperkaemia, hyperkaemic periodic paralysis etc.). Resultantly, Adverse events can happen following intravenous and intramuscular administration. Typically, adverse events occur within 10-30 minutes following intravenous injection, whilst adverse events following intramuscular injections may take slightly longer for clinical signs to develop. For this reason it is strongly recommended that horses receiving Regenesis Vet™ R.I.A.D.™ for the first time, or horses that have proven to be sensitive to the product via intravenous administration, are premedicated with Buscopan prior to treatment. Horses should also be hand-walked for 15-20 minutes immediately following the administration Regenesis Vet™ R.I.A.D.™.

Horses may demonstrate transient signs consistent with abdominal discomfort/ cramping following the IV administration of Regenesis Vet™ R.I.A.D.™. This is believed to be due to a mild hypocalcaemic effect. Clinical signs usually occur shortly after the administration of Regenesis Vet™ R.I.A.D.™ and may be associated with a mild abdominal cramping. Horses should be observed closely for 2-4 hours post-treatment for the development of any of the abovementioned signs or other adverse reactions. Should any cramping or colic-like symptoms occur, they are usually mild in nature and resolve sporadically. More-often than not, hand-walking the horse for 15-20 minutes may improve or resolve such symptoms. Should a horse require medical treatment for any side effect or reaction, non-NSAID treatments should be administered where possible due to the potential interference of NSAIDs with the cyclooxygenase of platelets and their related growth factors. Please contact your vet immediately should your horse develop any abnormal clinical signs or behaviour.

Although uncommon, side effects following intramuscular injection have also been reported. These include but are not limited to; injection site swelling/hematoma, muscle fasciculation's, sweating, increased respiratory rate and heart rate, lethargy, mild ataxia and in rare cases tying-up-like reactions.

It is imperative that horses are closely monitored after the administration of Regenesis Vet™ R.I.A.D.™ for at least 2 hours. Should any side effects occur, they usually are very mild and can be resolved with proactive management such as hand walking or treated by your veterinarian if necessary. Side effects that are not detected from unmonitored horses may get progressively worse if left unnoticed. Should you notice any abnormal behaviour following the administration of Regenesis Vet™ R.I.A.D.™, please contact your vet immediately.

Avoiding injecting too close to a vaccine, slower injection rates and having a horse that is well-hydrated and free from underlying issues seem to significantly reduce the incidence of adverse reactions. Please familiarize yourself with the measures outlined above that can be taken prior to and following the administration of Regenesis Vet™ R.I.A.D.™ to reduce the chance of an adverse event.

## REPORTING OF ADVERSE EVENTS

To report suspected adverse events please contact Novita Biotechnology™ on [info@novita-biotech.com](mailto:info@novita-biotech.com) or [info@regenesisvet.com](mailto:info@regenesisvet.com)

## TERMS & CONDITIONS OF TRADE

Regenesis Vet™ R.I.A.D.™ is a product of Novita Biotechnology (Pty) Ltd. Novita Biotechnology's Terms & Conditions of Trade applies to all Regenesis Vet™ products and treatments. Terms & Conditions of trade available at [www.novita-biotech.com](http://www.novita-biotech.com) & [www.regenesisvet.com](http://www.regenesisvet.com)