Caledonian Holdings Distribution Pty Ltd  
Section: 7(a) Central nervous system - Tranquillisers, psychotherapeutic agents  
PRODUCT NAME  
CaleSed  

GENERIC NAME  
Detomidine hydrochloride  

REGISTERED NAME  
CaleSed Injection  

COMPOSITION  
Detomidine hydrochloride 10 mg/mL  

ACTIONS  
CaleSed is an alpha-2 adrenerceptor agonist at central and peripheral sites. Its central depressive action produces a decrease in vigilance of the animal without any hypnotic effect. CaleSed is non-narcotic. It causes temporary blockage of pain impulses and reduces the level of consciousness resulting in heavy or deep sedation, but does not produce unconsciousness. Animals treated within the recommended range of doses remain standing, and seek a well-balanced footing. CaleSed exerts its analgesic effect by inhibition of CNS-mediated transmission of pain impulses and pain sensation. CaleSed alpha-adrenergic effects include increase in arterial blood pressure and bradycardia.  

Pharmacokinetics: CaleSed is evenly distributed in the body and rapidly penetrates the brain and CNS. The active constituent is rapidly absorbed from the injection site and evenly distributed. Site tolerance is high with minimal tissue irritation. CaleSed is extensively metabolised and the metabolites are excreted principally in urine, with an average elimination half-life of 1.2 hours. Therefore the retention of residues is very low, and 70 - 80% of the total dose is excreted from the body during two consecutive days.  

INDICATIONS  
Dose-dependent equine sedative and analgesic for all indications including visceral pain. CaleSed can be used to facilitate clinical examinations, radiography, minor surgical procedures, transport etc. and for the control of pain, including that of the uncomplicated colic case. CaleSed can provide prolonged analgesia (up to 12 hours) for example in trauma cases.  

CONTRAINDICATIONS  
This product is contraindicated for use in pregnant mares. Intravenous potentiated sulphonamides are contraindicated in sedated or anaesthetised horses as potentially fatal dysrhythmias may occur. Adverse reactions including deaths have been reported when used concomitantly with detomidine or halothane.  

PRECAUTIONS  
CaleSed may cause penile relaxation. Use with caution on male horses, particularly stallions during the breeding season. Clinicians should anticipate the occasional tendency of the horse’s head to drop under the influence of CaleSed and the animal should be accommodated appropriately to ensure that no respiratory obstruction occurs. Immediately following administration there may be a tendency to stagger, particularly if high dose rates are employed. The horse should not be fed until the effect of the drug has worn off. The safe handling of horses can be improved with CaleSed however normal restraint methods and precautions should still be used. Local anaesthetics can be used when required for painful procedures, particularly surgery, as the duration of analgesia from CaleSed may not equate with the duration of sedation.  

Safety Instructions: CaleSed is a potent preparation and any accidental spillage should be promptly washed off. Detomidine is a centrally acting alpha-2 adrenergic agonist, similar in its pharmacology to clonidine. Accidental administration to humans may produce hypertension of variable duration which may be followed by hypotension. First stage aid should include careful monitoring of the blood pressure with administration of phentolamine if dangerous levels of hypotension develop. Hypotension should be treated with fluid replacement and other supportive measures.  

First Aid: If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131126.  
Disposal: Dispose of empty vial by wrapping with paper and putting in garbage.  

WITHHOLDING PERIODS  
Not to be used in horses intended for human consumption.  

ADVERSE REACTIONS  
Sympathomimetic properties, particularly at higher doses, may include piloerection, sweating, diuresis and occasional slight tremors.
**Cardiovascular system:** Calesed causes an increase in arterial blood pressure and a decrease in heart rate at the recommended dose levels. Recovery to initial levels occurs at approximately the same time as the clinical effect has worn off. Slight and transitory arrhythmias may appear, and secondary A-V and S-A blocks may occur.

**Respiratory system:** Respiration is stimulated after a brief depression. Pauses in the breathing pattern may occur. The pH remains stable.

**Gastrointestinal system:** Under the influence of Calesed, gastrointestinal involuntary movements are reduced. In possible overdose cases the symptoms may be relieved by atropine or a specific alpha-2 antagonist.

**DOSAGE AND ADMINISTRATION**
Administer by intravenous or intramuscular injection.
Dosage is usually from 10 - 80 micrograms per kilogram of body weight (0.1 - 0.8 mL/100 kg) depending upon the desired depth and duration of effect.

- **MILD SEDATION (0.5 to 1 hour duration):** 10 - 20 μg/kg (0.1 - 0.2 mL per 100 kg)
- **MODERATE SEDATION (1 to 2 hour duration):** 20 - 40 μg/kg (0.2 - 0.4 mL per 100 kg)
- **HEAVY SEDATION (2 to 6 hour duration):** 40 - 80 μg/kg (0.4 - 0.8 mL per 100 kg)
- **ANALGESIA FOR COLIC (until diagnosis confirmed):** 20 - 40 μg/kg (0.2 - 0.4 mL per 100 kg).

The full analgesic effect is established within 5 - 15 minutes following administration.
If the desired level of sedation is not achieved following administration of a low dose, a further, additive, dose may be given.

**PRESENTATION**
Injection (multidose vial): 20 mL.

**STORAGE**
Store below 25°C (Air conditioning). Protect from light.
Use the contents within 5 days of first broaching the vial. Discard the unused portion.

**POISONS SCHEDULES**
54

**APVMA NUMBER**
63855