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ADVANTAGE™ 40 FOR DOGS
ADVANTAGE™ 100 FOR DOGS
ADVANTAGE™ 250 FOR DOGS
ADVANTAGE™ 400 FOR DOGS
ADVANTAGE™ 40 FOR CATS
ADVANTAGE™ 80 FOR CATS
ADVANTAGE™ FOR SMALL CATS, SMALL DOGS
& PET RABBITS
ADVANTAGE™ FOR LARGE CATS & PET
RABBITS

Presentation A clear yellow to slightly brownish free-flowing non-aqueous solution containing 10 % w/v imidacloprid. The product is presented in a single use plastic tube for cutaneous (spot-on) treatment in dogs, cats and pet rabbits. Each tube contains 0.4 ml (40 mg imidacloprid), 1.0 ml (100 mg imidacloprid), 2.5 ml (250 mg imidacloprid), 4.0 ml (400 mg imidacloprid), 0.4 ml (40 mg imidacloprid), 0.8 ml (80 mg imidacloprid), 0.4 ml (40 mg imidacloprid) and 0.8 ml (80 mg imidacloprid) respectively as listed above.

Uses For the prevention and treatment of flea infestations on cats and dogs.

For the treatment of flea infestations on pet rabbits.

Fleas are killed within one day following treatment. One treatment prevents further flea infestation on dogs for up to four weeks, three to four weeks on cats and up to one week on pet rabbits. The treatment should be repeated after 4 weeks. The product can be used as part of a treatment strategy for flea allergy dermatitis in the cat and the dog.

Dosage and administration Please refer to Table 1 (overleaf).

Treatment of nursing bitches and queens controls flea infestation on both the dam and the offspring.

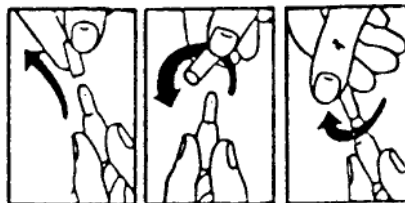
Re-infestation from emergence of new fleas in the environment may continue to occur for six weeks or longer after treatment is initiated. More than one treatment may therefore be required, depending on the level of fleas in the environment. To aid reduction in environmental challenge, the additional use of a suitable environmental treatment against adult fleas and developing stages is recommended. In order to reduce further the environmental challenge, it is

recommended that all cats, dogs and rabbits in the household are treated.

In recent studies, in addition to the adulticidal flea efficacy of imidacloprid, a larvicidal flea efficacy in the surroundings of the treated pet has been demonstrated. Larval stages in the pet's surroundings are killed following contact with a treated animal.

The product remains effective if the animal becomes wet, for example after exposure to heavy rain or after swimming (dogs). However, re-treatment may become necessary, depending on the presence of fleas in the environment. In these cases do not treat more frequently than once weekly.

Method of Administration: Remove one tube from the package. Hold tube in an upright position, twist and pull off cap. Use reversed cap to twist and remove seal from tube.



Administration to the Cat/Rabbit: Part the hair on the pet's neck at the base of the skull until the skin is visible. Place the tip of the tube on the skin and squeeze firmly several times to empty the contents directly onto the skin.



Dosage and Treatment Schedule

TABLE 1

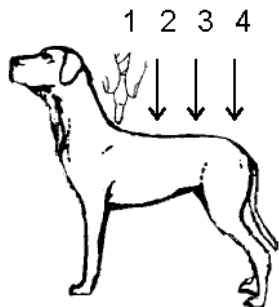
Species	Product	Number of Tubes
Cats		
Less than 4 kg bodyweight	Advantage for Small Cats, Small Dogs and Pet Rabbits or Advantage 40 for Cats	1 x 0.4 ml
4 kg and greater	Advantage 80 for Cats or Advantage for Large Cats and Pet Rabbits	1 x 0.8 ml
Dogs		
Less than 4 kg bodyweight	Advantage for Small Cats, Small Dogs and Pet Rabbits or Advantage 40 for Dogs	1 x 0.4 ml
4 kg to less than 10 kg	Advantage 100 for Dogs	1 x 1.0 ml
10 kg to less than 25 kg	Advantage 250 for Dogs	1 x 2.5 ml
25 kg to less than 40 kg	Advantage 400 for Dogs	1 x 4.0 ml
40 kg and greater	Advantage 400 for Dogs	2 x 4.0 ml
Rabbit		
Adult less than 4 kg bodyweight (older than 10 weeks)	Advantage for Small Cats, Small Dogs and Pet Rabbits	1 x 0.4 ml
Adult 4 kg and greater	Advantage for Large Cats and Pet Rabbits	1 x 0.8 ml

Administration to the Dog: With the dog in the standing position, part the coat between the shoulder blades until the skin is visible. Place the tip of the tube on the skin and squeeze firmly several times to empty the contents directly onto the skin.



Two tubes: (only for Advantage 400 on dogs weighing 40 kg and greater):

Apply the entire contents of the tubes evenly to 3 or 4 different application sites along the dog's backline from the shoulder to the base of the tail. Do not apply an excessive amount of solution to any one spot as this could cause some of the solution to run off the side of the dog.



All Species: Do not rub in.

It is particularly important to apply the dose to an area where it cannot be licked off. Correct application will minimise the opportunity for the animal to lick off the product.

Apply only to undamaged skin.

Use During Pregnancy and Lactation: No reproductive toxic effects have been observed in rats and no primary embryotoxic or teratogenic toxic effects have been observed during the studies on rats and rabbits. Studies on pregnant and lactating bitches, queens and does together with their offspring are limited. Evidence so far indicates that no adverse effects are to be expected in these animals.

Contra-indications, warnings, etc Do not use on rabbits intended for human consumption.

Do not use on pet rabbits of less than 10 weeks of age.

Do not use on unweaned puppies and kittens of less than 8 weeks of age.

Do not allow recently treated animals to groom each other.

Care should be taken to avoid the contents of the tube coming into contact with the eyes or mouth of the user or recipient animal.

The product is bitter tasting and salivation may occasionally occur if the animal licks the application site immediately after treatment. This is not a sign of intoxication and disappears after a short time without treatment.

Operator Safety: Wash hands thoroughly after use.

Wash off any skin contamination with soap and water.

After application do not stroke or groom animals until the application site is dry (typically within an hour or so).

People with known skin sensitivity may be particularly sensitive to the product.

This product contains benzyl alcohol and may cause skin sensitisation or transient skin reactions (for example allergy, irritation, tingling).

Avoid contact between the product and the eyes or mouth.

If the product gets into eyes accidentally, the eyes

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should be thoroughly flushed with water. If skin or eye irritation persists, obtain medical attention.

If the product is accidentally swallowed, obtain medical attention immediately.

Do not eat, drink or smoke during application.

Pharmaceutical precautions Store away from food, drink and animal feeding stuffs.

Do not use after expiry date.

Keep out of reach of children.

Unused product and containers should be disposed of in accordance with national requirements.

After use, replace cap on tube.

External packaging and empty tubes may be disposed of with domestic refuse.

For animal treatment only.

Legal category POM

Package quantities Blister pack, packed into a cardboard box with an instruction leaflet or onto a display card, containing 4 tubes filled as follows:

Advantage for Small Cats, 4 x 0.4 ml tubes

Small Dogs & Pet Rabbits

Advantage for Large Cats 4 x 0.8 ml tubes

and Pet Rabbits

Advantage 40 for Cats 4 x 0.4 ml tubes

Advantage 80 for Cats 4 x 0.8 ml tubes

Advantage 40 for Dogs 4 x 0.4 ml tubes

Advantage 100 for Dogs 4 x 1.0 ml tubes

Advantage 250 for Dogs 4 x 2.5 ml tubes

Advantage 400 for Dogs 4 x 4.0 ml tubes

Further information No incompatibility has been observed between this product at twice the recommended dose and the following commonly used veterinary products: febantel, pyrantel and praziquantel (dogs) and pyrantel and praziquantel (cats). The compatibility of the product was also demonstrated with a range of routine treatments including vaccination.

In cats, no adverse clinical signs were produced using doses of five times the therapeutic level for eight consecutive weeks.

In dogs, no adverse clinical signs were produced by individual doses of up to 200 mg/kg bodyweight (five to eight times the therapeutic dose). Daily treatments at 100 mg/kg bodyweight for five consecutive days or weekly treatments at five times the maximum dose rate for eight consecutive weeks were also tolerated without adverse effect.

In rabbits, no adverse clinical signs were seen using doses of up to 45 mg/kg bodyweight (4 times the therapeutic level) weekly for 4 consecutive weeks.

Poisoning following inadvertent oral uptake in either man or animals is unlikely. In this event, treatment should be symptomatic. There is no known specific antidote but administration of activated charcoal may be beneficial.

The solvent in Advantage may mark certain materials including leather, fabrics, plastics and finished surfaces. Allow application site to dry before permitting contact with such materials.

Marketing authorisation number

Advantage for Small Cats, Vm 00010/4134¹

Small Dogs & Pet Rabbits

Advantage for Large Cats & Vm 00010/4117¹

Pet Rabbits

Advantage 40 for Dogs Vm 04895/4002²

Advantage 100 for Dogs Vm 04895/4004²

Advantage 250 for Dogs Vm 04895/4005²

Advantage 400 for Dogs Vm 04895/4007²

Advantage 40 for Cats Vm 04895/4003²

Advantage 80 for Cats Vm 04895/4006²

1: MA Holder Bayer plc

2: MA Holder Bayer AG

ADVANTIX™ SPOT-ON SOLUTION FOR DOGS UP TO 4 KG

ADVANTIX™ SPOT-ON SOLUTION FOR DOGS OF 4 KG UP TO 10 KG

ADVANTIX™ SPOT-ON SOLUTION FOR DOGS OF 10 KG UP TO 25 KG

ADVANTIX™ SPOT-ON SOLUTION FOR DOGS OF 25 KG AND OVER

Presentation A clear yellowish to brownish, non-aqueous solution containing imidacloprid and permethrin. The product is presented in a single use plastic tube for dermal (spot-on) treatment in dogs. Each tube contains 0.4ml (40 mg imidacloprid, 200 mg permethrin), 1.0 ml (100 mg imidacloprid, 500 mg permethrin), 2.5 ml (250 mg imidacloprid, 1250 mg permethrin) and 4 ml (400 mg imidacloprid, 2000 mg permethrin) respectively, as listed above. The product also contains 0.1% w/v butylated hydroxytoluene (Ph Eur) as a preservative

Uses For the treatment and prevention of flea (*Ctenocephalides canis*, *Ctenocephalides felis*) infestations in dogs only.

Fleas on dogs are killed within one day following treatment. One treatment prevents further flea infestation for four weeks. The product can be used as part of a treatment strategy for flea allergy dermatitis (FAD).

The product has a persistent acaricidal and repellent effect for four weeks (*Rhipicephalus sanguineus*, *Ixodes ricinus*) or three weeks (*Dermacentor reticulatus*), respectively, against tick infestations.

One treatment provides repellent (anti-feeding) activity against sand flies (*Phlebotomus papatasi*) for two weeks and against mosquitoes for two (*Aedes aegypti*) or four (*Culex pipiens*) weeks, respectively.

Dosage and administration Please refer to Table 1 (overleaf).

The recommended minimum dose is:

10 mg/kg bodyweight (bw) imidacloprid and 50 mg/kg bw permethrin.

To reduce re-infestation from emergence of new fleas it is recommended that all dogs in a household be treated. Other pet animals living in the same household should also be treated with a suitable product. To further aid in reducing environmental challenge, the additional use of a suitable environmental treatment against adult fleas and their developmental stages is recommended.

The product remains effective if the animal becomes wet. However, prolonged, intense exposure to water should be avoided. In cases of frequent water exposure the duration of activity may be reduced. In these cases do not re-treat more frequently than once weekly. If the dog requires shampooing, it is better to do so before applying Advantix or at least two weeks after application so as to ensure satisfactory efficacy of the product.

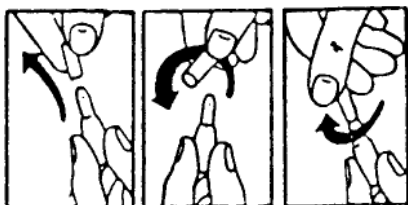
TABLE 1
Dosage and Treatment Schedule

Dogs (bw)	Trade name	Volume (ml)	Imidacloprid (mg/kg bw)	Permethrin (mg/kg bw)
≤ 4 kg	Advantix® Spot-on for dogs up to 4 kg	0.4 ml	minimum of 10	minimum of 50
>4 kg up to 10 kg	Advantix® Spot-on for dogs of 4 up to 10 kg	1.0 ml	10 - 25	50 - 125
>10 kg up to 25 kg	Advantix® Spot-on for dogs of 10 up to 25 kg	2.5 ml	10 - 25	50 - 125
>25 kg up to 40 kg	Advantix® Spot-on for dogs of 25 kg and over	4.0 ml	10 - 16	50 - 80

For dogs > 40 kg the appropriate combination of pipettes should be used.

Method of Administration: For dermal use only.

Remove one pipette from the package. Hold pipette in an upright position, twist and pull cap off. Turn the cap around and place the other end of the cap back on the pipette. Twist cap to break seal, then remove cap from pipette.



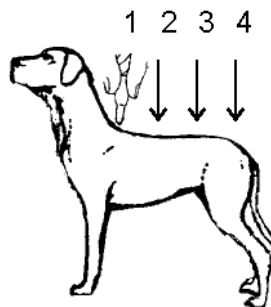
The dog should be standing for easy application. Apply only to intact skin.

Administration to dogs weighing under 10 kg: Part the coat between the shoulder blades until the skin is visible. Place the tip of the pipette on the skin and squeeze firmly several times to empty the contents directly onto the skin.



Administration to dogs weighing 10 kg and over: The entire contents of the Advantix® pipette(s) should be applied evenly to four spots on the midline of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the pipette on the skin and gently squeeze to expel a

portion of the solution onto the skin. Do not apply an excessive amount of solution at any one spot that could cause some of the solution to run off the side of the dog.



Contra-indications, warnings, etc Do not use on cats.



This product is extremely poisonous to cats and could be fatal due to the unique physiology of this species which is unable to metabolise certain compounds, including permethrin. To prevent cats from being accidentally exposed to the product, keep cats away from treated dogs until the application site is dry. It is important to ensure that cats do not groom the site of application on a dog which has been treated with this product. Seek veterinary advice immediately if this occurs.

In the absence of available data, the product should not be used on puppies of less than 7 weeks of age. Each product also has a minimum weight limit :

Advantix® Spot-on solution
- for dogs up to 4 kg

Do not use in dogs of less than 1.5kg bw

- for dogs of 4 up to 10 kg Do not use in dogs less than 4kg bw
- for dogs of 10 up to 25 kg Do not use in dogs less than 10kg bw
- for dogs of 25 kg and over Do not use in dogs less than 25kg bw

Do not use in cases of known hypersensitivity to the active substances.

Care should be taken to avoid the contents of the pipette coming into contact with the eyes or mouth of the recipient dog.

Care should be taken to administer the product correctly as described above, under Method of Administration. In particular, oral uptake due to the licking of the application site by treated or in-contact animals should be avoided.

Consult your veterinary surgeon before using the product on sick and debilitated dogs.

On rare occasions, reactions in dogs may include transient skin sensitivity (including increased pruritus, alopecia and erythema at the application site) or lethargy.

Poisoning following inadvertent oral uptake in dogs is unlikely but may occur in very rare cases. In this event, neurological signs such as tremor and lethargy can occur. Treatment should be symptomatic under veterinary medical attention. There is no known specific antidote.

User Safety:: Avoid contact between the product and skin, eyes or mouth.

Do not eat, drink or smoke during application.

Wash hands thoroughly after use.

In case of accidental spillage on human skin, wash off immediately with soap and water.

People with known skin sensitivity may be particularly sensitive to this product.

If the product gets accidentally into the eyes, they should be thoroughly flushed with water. If skin or eye irritation persists, or if the product is accidentally swallowed, obtain medical attention immediately and show the package insert to the physician.

Treated dogs should not be handled, especially by children, until the application site is dry. This may be ensured by treating dogs when children are not present, eg in the evening after children have gone to bed. In this case, recently treated dogs should not be allowed to sleep together with their owner, especially children.

Environmental Safety:: After use, replace cap on tube. Any unused product or waste material should be disposed of in accordance with national requirements.

Advantix® Spot-on should not be allowed to enter water courses as this may be dangerous for fish and aquatic organisms.

The product is dangerous to aquatic organisms. Do not, under any circumstances, allow treated dogs to enter any type of surface water, such as ponds, for at least 48 hours after treatment.

Permethrin containing products are toxic to honey bees.

Pharmaceutical precautions Do not freeze.

After opening the foil pouch do not store above 30°C.

All pipettes should be used within one year after opening the foil pouch or before expiry date on the pipette, whichever is the earlier.

Legal category POM

Package quantities Heat-sealed blister packs containing 4 unit dose pipettes in a sealed aluminium pouch, packed with an instruction sheet into a cardboard box.

Further information Imidacloprid is effective against both adult and larval flea stages. Larvicidal flea efficacy in the surroundings of the treated pet has also been demonstrated. Larval stages in the dog's immediate surroundings are killed following contact with a treated animal.

Permethrin belongs to the type I class of pyrethroid acaricides and insecticides and also acts as a repellent.

The combination is synergistic. As an activator of arthropod ganglia, imidacloprid increases the efficacy of permethrin.

Ticks already on the dog may not be killed within the two days following treatment and may remain attached and visible. Therefore the removal of ticks already on the dog at the time of treatment is recommended, in order to prevent them from attaching and having a blood meal.

The product provides repellent (anti-feeding) activity against ticks, sand flies and mosquitoes. Preventing parasites from taking a blood meal reduces the risk of disease transmission (e.g. Borreliosis, Rickettsiosis, Ehrlichiosis, Leishmaniasis). However, there may be an attachment of single ticks or bites by single sand flies or mosquitoes. For this reason, a transmission of infectious diseases by these parasites cannot be completely excluded if conditions are unfavourable.

The product can be used during pregnancy and lactation.

There is no known interaction with other medications or other forms of interaction.

No adverse clinical signs were noted in healthy puppies and adult dogs exposed to 5 x overdosage, and for puppies whose mothers were treated with 3 x overdosage of the product.

The solvent in Advantix® Spot-on may stain certain materials including leather, fabrics, plastics and finished surfaces. Allow the application site to dry before permitting contact with such materials.

Marketing Authorisation Number

Product	MA Number
Advantix® Spot-on solution for dogs up to 4 kg	Vm 00010/4136
Advantix® Spot-on solution for dogs of 4 up to 10 kg	Vm 00010/4137
Advantix® Spot-on solution for dogs of 10 up to 25 kg	Vm 00010/4138
Advantix® Spot-on solution for dogs of 25 kg and over	Vm 00010/4139

BAYCOX™ 2.5% SOLUTION

Presentation A clear colourless to yellow brown solution containing as active ingredient 2.5% w/v (25 mg/ml) toltrazuril for dilution in drinking water and subsequent administration. The product also contains the following excipients, triethanolamine 30 mg/ml and polyethylene glycol 80.7 mg/ml.

Uses For the treatment of coccidiosis in Broiler Breeders. Baycox 2.5% Solution is effective against *Eimeria acervulina*, *E. brunetti*, *E. maxima*, *E. necatrix*, *E. tenella*, *E. mitis*.

BAYER plc

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Dosage and administration *Administration:* via the drinking water

Baycox is mixed in the drinking water before use. Gentle mixing is required. Proportioning systems may be used (see Pharmaceutical Precautions).

The recommended dose rate is 7 mg toltrazuril per kg bodyweight per day given for 2 consecutive days. This corresponds to:

28 ml Baycox 2.5% Solution (equivalent to 700 mg toltrazuril) per 100 kg of bodyweight per day for 2 consecutive days.

To calculate the volume of Baycox required to be added to the water supply over one day.

**Total liveweight in kg x 0.28 =
ml Baycox required for one day**

As a guide for usage this is normally equivalent to 25 ppm (equivalent to 1 ml Baycox 2.5% Solution) per litre of drinking water for continuous medication over 48 hours, or to 75 ppm (equivalent to 3 ml Baycox 2.5% Solution) per litre of drinking water given for 8 hours per day, on 2 consecutive days.

Treatment Regimen

Curative Treatment

Chicken: 1 medication period (over 2 days) which can be repeated after 5 days in case of severe infections.

Only make up sufficient drinking water for requirements.

After calculations of the required amount of product, this volume should be carefully dispensed from the container into a domestic measuring jug reserved and labeled specifically for the purpose. Measurement must be made carefully to ensure correct dosage. Product must not be stored in the jug.

Contra-indications, warnings etc Do not use in birds producing eggs for human consumption. A three to five fold overdosage is readily tolerated without any symptoms. If the recommended dose is exceeded beyond 3-5 times there is a decrease in water intake.

Baycox does not interfere with the development of immunity against coccidiosis. As with all anticoccidials, prolonged use may result in the development of resistant strains.

Consumer Safety:

Do not slaughter birds for human consumption during treatment or for a period of 18 days following last administration.

User Safety:

Baycox is an alkaline solution.

Wear synthetic rubber gloves when handling the product.

Wash any splashes from skin and eyes immediately with water.

Wash hands and exposed skin after use.

Do not eat, drink or smoke whilst using the product.

Environmental Safety:

Only make up sufficient drinking water for requirements. Wash out empty container with water 3 times when medicating birds and add washings to drinking water.

Store litter from treated houses as long as possible. Do not apply to agricultural land at a rate greater than 2 tonnes/hectare/year. If spreading within an NVZ ensure that the NVZ action program rules are complied with

The principle metabolite of toltrazuril is persistent and mobile in groundwater. Disposal of manure from treated birds of all species is therefore likely to require

prior authorisation from the local environmental regulatory authority. The local office of the Environment Agency, SEPA or Environment and Heritage Service of Northern Ireland should be contacted in good time before disposing of manure from treated birds.

Any unused product or waste material should be disposed of in accordance with national requirements.

Pharmaceutical precautions Dilutions more concentrated than 1:1,000 (1 ml Baycox 2.5% to 1 litre drinking water) may result in precipitation. Predilution is not recommended. Do not store above 25°C.

Legal category POM

Package quantities 1 litre high density polyethylene bottles, containing solution for dilution in water.

Further information Anticoccidial, active against all intracellular stages but the mode of action is unknown.

In poultry toltrazuril is absorbed at a rate of at least 50%. The highest equivalent concentrations are found in liver. The active substance is rapidly metabolised in poultry. The main metabolite is characterised as a sulfone-derivative. About 1 week after the last dose this metabolite represents by far the most relevant residue in the animal.

Marketing authorisation number Vm 00010/4084.

BAYTRIL™ 2.5% INJECTION

Presentation A ready to use sterile aqueous injectable solution containing 25 mg/ml enrofloxacin and 30 mg/ml n-butyl alcohol as a preservative.

Uses Enrofloxacin is a synthetic, broad spectrum antimicrobial substance, belonging to the fluoroquinolone group of antibiotics. It is bactericidal in action and effective against many gram positive and gram negative bacteria and mycoplasmas.

Baytril 2.5% Injection is indicated for use in dogs and cats in the treatment of bacterial infections of the alimentary, respiratory and urogenital tracts, skin, secondary wound infections and Otitis externa where clinical experience, supported where possible by sensitivity testing of the causal organism indicates enrofloxacin as the drug of choice.

Baytril 2.5% Injection may also be used in exotic animals (small mammals, reptiles and birds) for the treatment of bacterial infections of the alimentary and respiratory tracts where clinical experience, supported where possible by sensitivity testing of the causal organism, indicates enrofloxacin as the drug of choice.

Dosage and administration

Dogs and cats: 1 ml per 5 kg bodyweight (5 mg enrofloxacin per kg bodyweight) by subcutaneous injection once daily for 3 to 5 days. Treatment may be initiated with the injection and maintained orally with Baytril Tablets.

Exotic animals: The dose rates given below are for guidance only. Veterinary surgeons are advised to contact the company prior to use to discuss the particulars of each individual case. The use of a 0.5 ml (100 unit) insulin syringe should be considered for administration of the very small volumes required by some species of small mammals (mice, gerbils etc).

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Species	Dosage	Route	Dose Frequency	Treatment period
Small mammals	5 mg/kg bw (0.2 ml/kg)	s.c.	Twice daily	7 days
Reptiles	5 mg/kg bw (0.2 ml/kg)	i.m.	24-48 hour intervals	6 days
Birds	10 mg/kg bw (0.4 ml/kg)	i.m.	Twice daily	7 days

Treatment may be initiated with the injection and maintained with Baytril 2.5% Oral Solution.

Use during pregnancy and lactation: There is no restriction on the use of this product during pregnancy and lactation of the bitch and queen.

Contra-indications, warnings, etc Do not exceed the recommended dose. In accidental overdosage there is no antidote and treatment should be symptomatic.

Retinotoxic effects including blindness can occur when the recommended dose is exceeded in cats.

For animal treatment only.

Not for use in dogs less than 1 year of age or in exceptionally large breeds of dog with a longer growth period under 18 months of age, as articular cartilage may be affected during the period of rapid growth.

Not recommended for use in cats less than 8 weeks of age.

Normal sterile precautions should be taken. Local tissue reactions may occasionally occur at the injection site.

Not for use in exotic animals and birds intended for human consumption.

Baytril 2.5% Injection should not be used for prophylaxis.

Pharmaceutical precautions Do not store above 25°C.

Keep out of the reach of children.

Following withdrawal of the first dose, use the product within 28 days. Discard unused material.

Any unused product or waste material should be disposed of in accordance with national requirements.

Further information The pharmacokinetics of enrofloxacin in dogs and cats are such that both oral and parenteral administration lead to similar serum levels. Enrofloxacin possesses a high distribution volume. Tissue levels 2-3 times higher than that found in the serum have been demonstrated in laboratory animals and target species. Organs in which high levels can be expected are the lungs, liver, kidney, skin, bone, and lymphatic system.

Enrofloxacin also distributes into the C.S.F., the aqueous humour, and the foetus in pregnant animals.

In target animal studies, cats have been shown to suffer ocular damage after receiving doses of more than 15 mg/kg once daily for 21 consecutive days. Doses of 30 mg/kg given once daily for 21 consecutive days have been shown to cause irreversible ocular damage. At 50 mg/kg given once daily for 21 consecutive days, blindness can occur.

Occasionally skin reactions have been seen after administration in kennelled greyhounds. Muscle bruising in reptiles and birds after injection has been reported occasionally. There is no restriction on the use of this product during pregnancy and lactation of the bitch and queen. In the absence of data on use of this product during pregnancy and lactation in some exotic species, caution should be used when prescribing during these periods and a careful risk/benefit assessment made.

Legal category POM.

Package quantities Individually packed multi dose bottles of 50 ml.

Marketing authorisation number Vm 00010/4075.

BAYTRIL™ 5% INJECTION

Presentation A ready to use sterile solution for injection containing as active ingredient 50 mg/ml enrofloxacin, and 30 mg/ml n-butyl alcohol as a preservative

Uses Enrofloxacin is a synthetic, broad spectrum antimicrobial substance, belonging to the fluoroquinolone group of antibiotics. It is bactericidal in action and effective against many gram positive and gram negative bacteria and mycoplasmas.

Dogs and Cats: Baytril 5% Injection is indicated in the treatment of bacterial infections of the alimentary, respiratory and urogenital tracts, skin, secondary wound infections and Otitis externa where clinical experience, supported where possible by sensitivity testing of the causal organism, indicates enrofloxacin as the drug of choice.

Cattle: Diseases of the respiratory and alimentary tract of bacterial or mycoplasmal origin (e.g. pasteurellosis, mycoplasmosis, coli-bacillosis, coli-septicaemia and salmonellosis) and secondary bacterial infections subsequent to viral conditions (e.g. viral pneumonia) where clinical experience, supported where possible by sensitivity testing of the causal organism, indicates enrofloxacin as the drug of choice.

Pigs: Diseases of the respiratory and alimentary tract of bacterial or mycoplasmal origin (e.g. pasteurellosis, actinobacillosis, mycoplasmosis, coli-bacillosis, coli-septicaemia and salmonellosis) and multifactorial diseases such as atrophic rhinitis and enzootic pneumonia, where clinical experience, supported where possible by sensitivity testing of the causal organism, indicates enrofloxacin as the drug of choice.

Dosage and administration

Dogs and Cats: 1 ml per 10 kg bodyweight (5 mg enrofloxacin per kg bodyweight) by subcutaneous injection once daily for up to 5 days. Treatment may be initiated with the injection and maintained orally with Baytril Tablets.

Cattle: 0.5 ml per 10 kg bodyweight (2.5 mg enrofloxacin per kg bodyweight) daily by subcutaneous injection for 3 days. This rate may be doubled (1 ml per 10 kg; 5 mg/kg) for 5 days for salmonellosis and complicated respiratory disease. Not more than 10 ml should be administered at one subcutaneous injection site.

Pigs: 0.5 ml per 10 kg bodyweight (2.5 mg enrofloxacin per kg bodyweight) daily by intramuscular injection for 3 days. This rate may be doubled (1 ml per 10 kg; 5 mg/kg) for 5 days for salmonellosis and complicated respiratory disease. Not more than 2.5 ml should be administered at one subcutaneous injection site.

Use during pregnancy and lactation: There is no restriction on the use of this product during pregnancy and lactation.

Contra-indications, warnings, etc Do not exceed the recommended dose. In accidental overdosage there is no antidote and treatment should be symptomatic. Retinotoxic effects including blindness can occur when the recommended dose is exceeded in cats.

Not for use in dogs less than 1 year of age or in exceptionally large breeds with a longer growth period under 18 months of age, as articular cartilage may be affected during the period of rapid growth.

Not recommended for use in cats less than 8 weeks of age.

Only administer by the routes outlined above under dosage and administration.

Repeat injections should be made at different sites.

Normal sterile precautions should be taken. Local tissue reactions may occasionally occur at the injection site.

For animal treatment only.

Keep out of the reach of children.

Baytril 5% Injection should not be used for prophylaxis.

Withdrawal Periods MEAT

Cattle: Animals must not be slaughtered for human consumption during treatment. Animals may be slaughtered for human consumption only after 14 days from the last treatment.

Pigs: Animals must not be slaughtered for human consumption during treatment. Animals may be slaughtered for human consumption only after 10 days from the last treatment.

MILK

Not to be used in animals producing milk for human consumption.

Pharmaceutical precautions Do not store below 25°C.

Store in a dry place.

Following withdrawal of the first dose, use the product within 28 days. Discard unused material.

Any unused product or waste material should be disposed of in accordance with national requirements.

Further information The pharmacokinetics of enrofloxacin are such that both oral and parenteral administration lead to similar serum levels. Enrofloxacin possesses a high distribution volume. Tissue levels 2–3 times higher than that found in the serum have been demonstrated in laboratory animals and target species. Organs in which high levels can be expected are the lungs, liver, kidney, bone and lymphatic system.

Enrofloxacin also distributes into the C.S.F., the aqueous humour, and the foetus in pregnant animals.

In target animal studies, cats have been shown to suffer ocular damage after receiving doses of more than 15 mg/kg once daily for 21 consecutive days. Doses of 30 mg/kg given once daily for 21 consecutive days have been shown to cause irreversible ocular damage. At 50 mg/kg given once daily for 21 consecutive days, blindness can occur.

Occasionally skin reactions have been seen after administration in kennelled greyhounds.

Legal category POM.

Package quantities Individually packed multi dose bottles of 100 ml.

Marketing authorisation number Vm 00010/4076.

BAYTRIL™ 10% INJECTION

Presentation A ready to use sterile aqueous solution for injection containing as active ingredient 100 mg/ml enrofloxacin, and 30 mg/ml n-butyl alcohol as a preservative.

Uses Enrofloxacin is a synthetic, broad spectrum antimicrobial substance, belonging to the fluoroquinolone group of antibiotics. It is bactericidal in action and effective against many gram positive and gram negative bacteria and mycoplasmas.

Cattle: Diseases of the respiratory and alimentary tract of bacterial or mycoplasmal origin (e.g. pasteurellosis, mycoplasmosis, coli-bacillosis, coli-septicaemia and salmonellosis) and secondary bacterial infections subsequent to viral conditions (e.g. viral pneumonia) where clinical experience, supported where possible by sensitivity testing of the causal organism, indicates enrofloxacin as the drug of choice.

Pigs: Diseases of the respiratory and alimentary tract of bacterial or mycoplasmal origin (e.g. pasteurellosis, actinobacillosis, mycoplasmosis, coli-bacillosis, colisepticaemia and salmonellosis), and multifactorial diseases such as atrophic rhinitis and enzootic pneumonia, where clinical experience, supported where possible by sensitivity testing of the causal organism, indicates enrofloxacin as the drug of choice.

Dosage and administration For subcutaneous injection in cattle.

For intramuscular injection in pigs.

Cattle: 2.5 ml per 100 kg bodyweight (2.5 mg enrofloxacin per kg bodyweight) daily by subcutaneous injection for 3 days. This rate may be doubled (5 ml per 100 kg; 5 mg/kg) for 5 days for salmonellosis and complicated respiratory disease. Not more than 10 ml should be administered at any one injection site.

Pigs: 2.5 ml per 100 kg bodyweight (2.5 mg enrofloxacin per kg bodyweight) daily by intramuscular injection for 3 days. This rate may be doubled (5 ml per 100 kg; 5 mg/kg) for 5 days for salmonellosis and complicated respiratory disease. Not more than 2.5 ml should be administered at any one injection site in store pigs or 5 ml at any one site in sows.

Use during pregnancy and lactation: There is no restriction on the use of this product during pregnancy and lactation.

Contra-indications, warnings, etc Do not exceed the recommended dose. In accidental overdosage there is no antidote and treatment should be symptomatic.

Only administer by the routes outlined above under dosage and administration.

Normal sterile precautions should be taken.

Avoid the introduction of contamination during use.

Discard the product if any apparent growth or discoloration occurs.

Local tissue reactions may occasionally occur at the injection site.

For animal treatment only.

Keep out of the reach of children.

Baytril 10% Injection should not be used for prophylaxis.

Any spillage onto the skin should be washed off immediately with water.

Withdrawal Periods MEAT

Cattle: Animals must not be slaughtered for human consumption during treatment. Cattle may be slaugh-

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tered for human consumption only after 14 days from the last treatment.

Pigs: Animals must not be slaughtered for human consumption during treatment. Pigs may be slaughtered for human consumption only after 10 days from the last treatment.

MILK

Milk for human consumption must not be taken during treatment. Milk for human consumption may only be taken from cattle after 84 hours (i.e. 7 milkings) from the last treatment.

Pharmaceutical precautions Do not store above 25°C.

Store in a dry place.

Following withdrawal of the first dose use the product within 28 days. Discard unused material.

Unused product or waste material should be disposed of in accordance with national requirements.

Further information The pharmacokinetics of enrofloxacin are such that both oral and parental administration lead to similar serum levels. Enrofloxacin possesses a high distribution volume. Tissue levels 2–3 times higher than that found in the serum have been demonstrated in laboratory animals and target species. Organs in which high levels can be expected are the lungs, liver, kidney, bone and lymphatic system.

Enrofloxacin also distributes into the C.S.F., the aqueous humour, and the foetus in pregnant animals.

Legal category POM.

Package quantities Individually packed multi dose bottles of 100 ml.

Marketing authorisation number Vm 00010/4080.

BAYTRIL MAX™

Presentation A ready to use sterile aqueous injectable solution containing as active ingredient 100 mg/ml enrofloxacin, with 20 mg/ml benzyl alcohol and 30 mg/ml butyl alcohol as preservatives.

Uses Enrofloxacin is a synthetic, broad spectrum antimicrobial, bactericidal in action and effective against a wide range of gram positive and gram negative bacteria and mycoplasmas.

Cattle: Baytril Max is indicated for the treatment of bovine respiratory disease associated with *Pasteurella haemolytica*, *Pasteurella multocida*, *Haemophilus somnus* and *Mycoplasma species*.

Dosage and administration

Dosage rate: A single dose of 7.5 mg enrofloxacin per kg bodyweight (7.5 ml per 100 kg bodyweight)

Method of administration

Baytril® Max is administered subcutaneously.

Not more than 15 ml should be administered at one subcutaneous injection site.

Use during pregnancy and lactation

Not restricted

Contra-indications, warnings, etc Not for use in animals other than the target species.

Do not exceed the recommended dose.

Use aseptic precautions.

Transient local tissue reactions may occasionally occur at the injection site.

Baytril Max is an alkaline solution. Wash any splashes from skin or eyes immediately with water. Wash hands and exposed skin after use. Do not eat, drink or smoke whilst using the product.

For animal treatment only.

Keep out of the reach of children.

Withdrawal Periods Animals must not be slaughtered for human consumption during treatment. Cattle may be slaughtered for human consumption only after 14 days from the injection. Milk for human consumption must not be taken during treatment. Milk for human consumption may only be taken from cattle after 84 hours (i.e. 7 milkings) from the last treatment.

Pharmaceutical precautions Store below 25°C. Do not freeze. Following withdrawal of the first dose, use product within 28 days. Discard unused material.

Unused product and containers should be disposed of in accordance with any guidance from an appropriate waste regulation authority.

Legal category POM.

Package quantities Individually packed multi-dose bottles of 100 ml.

Further information Overdose: A dose of 25 mg/kg bodyweight administered for 15 consecutive days is tolerated without any clinical symptoms.

Clinical signs seen in gross overdose include diarrhoea, ataxia, lameness and muscle tremors. Treatment should be symptomatic.

The pharmacokinetics of enrofloxacin are such that oral and parenteral administration leads to similar serum levels. Enrofloxacin is lipid soluble and amphoteric and possesses a high distribution volume. Tissue levels 2-3 higher than that found in the serum, have been demonstrated in laboratory animals and target species. Organs in which high levels can be expected are the lungs, liver, kidney, skin, bone and lymphatic system. Enrofloxacin also distributes into the cerebrospinal fluid, the aqueous humour and the foetus in pregnant animals.

The fluoroquinolones also possess activity against bacteria in the stationary phase by an alteration of the permeability of the outer membrane phospholipid cell wall but are inactive against strict anaerobes.

After subcutaneous administration of 7.5 mg/kg the mean peak plasma concentration is 0.8 g/ml within 5.75 hours. The mean elimination half-life is 6.44 hours; this may be longer in male animals. The bioavailability is about 83% and the mean volume of distribution is high. Antibacterial activities determined by bioassay were significantly higher than the values for enrofloxacin determined by HPLC. Mean peak plasma concentration of antibacterial activity was 1.7 g/ml and the AUC (0-infinity) was 21.77 g.h/ml. Enrofloxacin is partly metabolised in the liver. Approximately 45 per cent of the dose is excreted in the urine and 55 per cent in the faeces as active and metabolites. Young calves may show slower elimination rates.

Marketing authorisation number Vm 00010/4103.

BAYTRIL™ 2.5% ORAL SOLUTION

Presentation A ready to use clear aqueous oral solution containing as active ingredient 25 mg/ml

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enrofloxacin, and 14 mg/ml benzyl alcohol (Ph.Eur.) as a preservative.

Uses Enrofloxacin is a synthetic, broad spectrum antimicrobial, belonging to the fluoroquinolone group of antibiotics. It is bactericidal in action with activity against many gram positive and gram negative bacteria as well as mycoplasmas.

Baytril 2.5% Oral Solution is indicated for use in calves for the treatment of infections of the respiratory and alimentary tract of bacterial or mycoplasmal origin (e.g. pasteurellosis, mycoplasmosis, coli-bacillosis, coli-septicaemia and salmonellosis), where clinical experience, supported where possible by sensitivity testing of the causal organism, indicates enrofloxacin as the drug of choice.

Baytril 2.5% Oral Solution may also be used in exotic animals (small mammals, reptiles and birds) for the treatment of bacterial infections of the alimentary and respiratory tracts where clinical experience, supported where possible by sensitivity testing of the causal organism, indicates enrofloxacin as the drug of choice. Estimate dosage with care.

Dosage and administration

Calves: Baytril 2.5% Oral Solution is administered via the milk, milk replacer, electrolyte solution or water. The dose rate is 2.5 mg per kg body weight (5 ml per 50 kg) daily for 3 days. This rate may be doubled to 5 mg per kg (10 ml per 50 kg) for 5 days for salmonellosis and complicated respiratory disease. Medicated fluids should be made up immediately prior to provision on a daily basis.

Exotic animals: The dose rates given below are for guidance only. Veterinary surgeons are advised to contact the company prior to use to discuss the particulars of each individual case.

Species	Dosage	Route	Dose Frequency	Treatment period
Small mammals	5 mg enrofloxacin per kg bodyweight (0.2 ml/kg bw)	Orally diluted in water	Twice daily	7 days
Reptiles	5 mg enrofloxacin per kg bodyweight (0.2 ml/kg bw)	Orally diluted in water	24-48 hour intervals	6 days
Birds (excluding chickens and turkeys)	10 mg enrofloxacin per kg bodyweight (0.4 ml/kg bw)	Orally diluted in water	Twice daily	7 days

For direct administration by gavage, dilutions of 1 part Baytril 2.5% Oral Solution to 4 parts water are recommended. If the product is to be given via the drinking water, concentrations of between 50 and 200 ppm should be considered as suitable working dilutions. Concentrations in excess of 250 ppm should be avoided as precipitation may occur. The dilution should be made on a daily basis, immediately prior to provision, preferably in a glass container. The use of 0.5 ml (100 unit) insulin syringe should be considered for the withdrawal of the very small volumes of Baytril 2.5% Oral Solution required for dilution prior to administration. Treatment may be initiated with Baytril 2.5% Injection and maintained with Baytril 2.5% Oral Solution.

Contra-indications, warnings, etc Do not exceed the recommended dose. In accidental overdose there is no antidote and treatment should be symptomatic.

For animal treatment only.

This product should not be used for the treatment of poultry (chickens and turkeys). Baytril 10% Oral Solution is indicated for these animals.

Not for use in exotic animals or birds intended for human consumption.

Wear impervious gloves when handling the product.

Wash any splashes from skin or eyes immediately with water.

Wash hands and exposed skin after use.

Do not eat, drink or smoke whilst using the product.

Baytril 2.5% Oral Solution should not be used for prophylaxis.

During the period of rapid growth, enrofloxacin may affect articular cartilage.

Withdrawal periods Calves must not be slaughtered for human consumption during treatment. Calves may be slaughtered for human consumption only after 8 days from the last treatment.

Not for use in exotic animals or birds intended for human consumption.

Pharmaceutical precautions Do not store above 25°C.

Store in a dry place.

Keep out of reach of children.

Following withdrawal of the first dose use the product within 28 days.

Discard unused material.

Any medicated liquid which is not consumed within 24 hours must be discarded.

Unused product and containers should be disposed of in accordance with any guidance from an appropriate waste regulatory authority.

Further information The pharmacokinetics of enrofloxacin in cattle are such that both oral and parenteral administration lead to similar serum levels. Enrofloxacin possesses a high distribution volume. Tissue levels 2-3 times higher than that found in the serum have been demonstrated in laboratory animals and target species. Organs in which high levels can be expected are the lungs, liver, kidney, bone and lymphatic system.

Enrofloxacin also distributes into the C.S.F., the aqueous humour, and the foetus in pregnant animals.

Legal category POM.

Package quantities Polyethylene bottles containing 100 ml.

Marketing authorisation number Vm 00010/4078.

BAYTRIL™ 10% ORAL SOLUTION

Presentation A ready to use clear aqueous oral solution containing as active ingredient 100 mg/ml enrofloxacin, and 14 mg/ml benzyl alcohol as a preservative.

Uses Enrofloxacin is a synthetic, broad spectrum antimicrobial substance, belonging to the fluoroquinolone group of antibiotics. It is bactericidal in action with activity against many gram positive and gram negative bacteria as well as mycoplasmas.