



Australian Pesticides &  
Veterinary Medicines Authority

Product Name: ADVOCATE ULTRA CHEW for Dogs 11.1 – 22 kg  
APVMA Approval No: 94907/144000

Label Name:	ADVOCATE ULTRA CHEW for Dogs 11.1 – 22 kg
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Signal Headings:	CAUTION KEEP OUT OF REACH OF CHILDREN FOR ANIMAL TREATMENT ONLY READ SAFETY DIRECTIONS
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Constituent Statements:	Each chew contains 450 mg LOTILANER, 114 mg PRAZIQUANTEL, 114 mg PYRANTEL (as embonate), 0.45 mg MOXIDECTIN
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Claims:	<p>[Summary claims statement for front claims]</p> <p>Ticks, fleas, heartworm and worms including tapeworms.</p> <p>[full claim statement]</p> <p><b>TICKS</b> For the treatment and control of:</p> <ul style="list-style-type: none"><li>• Paralysis ticks (<i>Ixodes holocyclus</i>),</li><li>• Brown Dog ticks (<i>Rhipicephalus sanguineus</i>) and</li><li>• Bush ticks (<i>Haemaphysalis longicornis</i>).</li></ul> <p><i>Ixodes holocyclus</i> ticks do not occur in Western Australia. As Advocate Ultra chew may not kill all ticks attached when dogs are first treated, any ticks present at the time of first treatment should be removed. In tick season, daily searching for, and removal of, any ticks found is recommended.</p> <p><b>FLEAS</b></p> <ul style="list-style-type: none"><li>• Provides immediate treatment and persistent killing activity for fleas (<i>Ctenocephalides felis</i>) for 5 weeks (35 days).</li><li>• Rapidly kills fleas before they have a chance to lay eggs.</li><li>• Controls flea allergy dermatitis (FAD) by controlling adult fleas.</li></ul> <p><b>MITES</b> For the treatment and control of demodex mites (<i>Demodex</i> spp.).</p> <p><b>HEARTWORM</b> For the prevention of heartworm (<i>Dirofilaria immitis</i>) disease.</p> <p><b>INTESTINAL WORMS</b> For the treatment and control of:</p>
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	<ul style="list-style-type: none"> <li>• Hookworms (adult, immature adult (L5), larval (L4) <i>Ancylostoma caninum</i>, <i>Ancylostoma braziliense</i>, adult <i>Ancylostoma ceylanicum</i>, adult <i>Uncinaria stenocephala</i>)</li> <li>• Roundworms (adult and immature adult (L5) <i>Toxocara canis</i>, adult <i>Toxascaris leonina</i>)</li> <li>• Tapeworms including hydatid tapeworm (<i>Echinococcus granulosus</i>), flea tapeworm (<i>Dipylidium caninum</i>), and <i>Taenia</i> spp.</li> </ul> <p>Advocate Ultra Chew contains lotilaner (an isoxazoline), praziquantel (a synthetic isoquinolone-pyrazine derivative), pyrantel embonate (a tetrahydropyrimidine) &amp; moxidectin (a macrocyclic lactone).</p> <p>If problems persist, consult your veterinarian.</p>
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Net Contents:	<p>1 Chew 3 Chews 6 Chews 50 Chews</p> <p>[3, 6 and 50 Chews] Illegal to sell individual chews separately</p>
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Directions for Use:	
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Restrictions:	
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Contraindications:	Not recommended for use in puppies under 8 weeks of age or weighing less than 2 kg.
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Precautions:	<p>Use with caution as the safety of the Advocate Ultra Chew has not been evaluated in breeding, pregnant, or lactating dogs.</p> <p>Safety of the product in dogs with high microfilaria worm burden has not been evaluated. It is recommended that all animals <math>\geq</math> 6 months of age be tested for existing heartworm infections before beginning medication with Advocate Ultra Chew.</p>
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Side Effects:	<p>Lotilaner is part of the isoxazoline family of chemicals. Adverse reactions to this family of chemicals are rarely observed but may include vomiting, diarrhoea, lethargy, inappetence, itching and very rarely, seizures. Most adverse reactions are self-limiting and of short duration. If you have any concerns, please speak to your veterinarian.</p> <p>Transient vomiting, drooling, salivation, diarrhoea and inappetence were among commonly occurring side effects during the safety and efficacy studies. These resolved without the need for treatment.</p>
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Dosage and Administration:	<p>Advocate Ultra Chew is given orally, once a month, to dogs. Administer Advocate Ultra Chew with or following food.</p> <p>Advocate Ultra Chew is a palatable chew and is readily consumed by dogs when offered by hand.</p> <p>Advocate Ultra Chew may be used all year round. Treat your dog on or about the same day each month.</p> <p>Regular monthly treatment prevents heartworm (<i>Dirofilaria immitis</i>) disease.</p>
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Advocate Ultra Chew contains lotilaner, moxidectin, pyrantel (as embonate) and praziquantel and is available in five strengths. The recommended dosing schedule indicates the strength of the chews to be used according to the body weight of the dog.

#### Recommended Dosing Schedule

[insert dosing table]

For dogs weighing above 45 kg bodyweight (or between 2 to 45 kg) an appropriate combination of chews matching the weight of the dog may be used, providing the minimum dose rate of 20 mg/kg lotilaner, 0.02 mg/kg moxidectin, 5 mg/kg pyrantel and 5 mg/kg praziquantel is met. Do not split chews.

This section contains file attachment.

#### General Directions:

##### Safety to Dogs

Advocate Ultra Chew was shown to be safe in dogs from 8 weeks of age and  $\geq 2$  kg bodyweight. Safety has been demonstrated in various breeds of dog, including avermectin sensitive Collies, when administered according to label instructions.

##### Dose monthly

Advocate Ultra Chew must be given every month, preferably on the same date, to ensure optimal protection for your dog. Most dogs will take Advocate Ultra Chew from your hand. If this is not the case, try hiding the chew in their food. Take the chew out from the blister immediately before dosing and be certain that the entire dose is consumed; watch your dog for several minutes after dosing to ensure that this is the case. If the entire dose is not consumed, redose as soon as possible with the full dose.

##### Fleas:

Advocate Ultra Chew starts to kill fleas within 2 hours from administration, with fleas being eliminated within 6-12 hours. For new infestations, fleas are eliminated within 4-6 hours for 5 weeks (35 days). Advocate Ultra Chew kills existing and newly emerged fleas on dogs before they can lay eggs due to its rapid onset of action and long-lasting efficacy. Therefore, Advocate Ultra Chew breaks the flea life cycle and prevents environmental contamination in areas to which the dog has access.

Advocate Ultra Chew can be used as part of a treatment strategy for flea allergy dermatitis (FAD).

##### Ticks:

Advocate Ultra Chew, demonstrated  $> 95\%$  efficacy for 5 weeks (35 days) against Brown Dog ticks and Bush ticks. In one of the Australian studies Advocate Ultra Chew was 92% effective at killing existing paralysis tick infestations within 48 hours of treatment administration. Advocate Ultra Chew was  $\geq 95.0\%$  efficacious for new paralysis tick infestations after 72 hours up to 35 days post-treatment.

##### Mites:

Monthly administration of Advocate Ultra Chew effectively treats and controls generalised demodectic mange caused by demodex mites. Dogs treated with lotilaner experienced a marked reduction of skin lesions and significant hair regrowth. Monthly treatment should be continued until the absence of mites is confirmed by two consecutive monthly skin scrapings. Demodectic mange is a multifactorial condition so consultation with a veterinarian is recommended.

##### Heartworm disease prevention:

Heartworm disease can make dogs very sick or even prove fatal. Monthly treatment with Advocate Ultra Chew prevents heartworm disease from threatening the health of your dog. Treatment with Advocate Ultra Chew should start one month before the first exposure to mosquitoes, which transmit heartworm (*Dirofilaria immitis*) between dogs.

When replacing another monthly heartworm preventative product, the first dose of Advocate Ultra Chew must be given within 1 month of the last dose of the previous monthly medication.

In a safety study conducted with heartworm positive dogs (with ~8700 microfilaria/mL) using a preclinical formulation for 56 days, no clinically relevant, long-term treatment-related abnormal health observations were made. Advocate Ultra Chew may be safely administered to heartworm infected animals, however, it is recommended, in accordance with good veterinary practice, that all animals  $\geq$  6 months of age be tested for existing heartworm infections before beginning medication with Advocate Ultra Chew. Advocate Ultra Chew is not effective against adult *D. immitis*.

Intestinal parasites:

Hookworms, roundworms and tapeworms are intestinal parasites of dogs throughout Australia. Most are zoonotic, so infection of dogs also poses a risk to human health.

Puppies can acquire hookworm infections through their mother's milk and dogs of all ages can become infected by ingestion or skin penetration of hookworm larvae in the environment. People can become infected and develop disease following ingestion or direct skin penetration of hookworm larvae passed in the faeces of infected dogs. Hookworms are bloodsucking parasites of the small intestine and in dogs can lead to lung infections, bloody diarrhoea, anaemia and even death if blood loss is severe. Advocate Ultra Chew kills hookworms (adult and immature *Ancylostoma* spp. and adult *Uncinaria stenocephala*) as stated in claims.

Roundworm infections can be acquired by puppies before they are born and later through their mother's milk, and dogs of all ages can become infected by ingestion of eggs from the environment. People can develop disease (toxocariasis) following ingestion of infective roundworm (*Toxocara* spp.) eggs passed in the faeces of infected dogs. In dogs, roundworms can lead to lung infections, vomiting and diarrhoea, abdominal discomfort, a pot-bellied appearance and general debilitation, which may be manifested by a dull hair coat and failure to thrive. The large worms can fill the small intestine, interfere with the absorption of nutrients and rarely, lead to death from intestinal blockage. Advocate Ultra Chew kills roundworms (adult and immature *Toxocara canis* and adult *Toxascaris leonina*).

Hydatid tapeworms (*Echinococcus granulosus*) can be transmitted from infected dogs to humans and pose a serious and deadly risk to human health (hydatidosis). Dogs can be infected with hydatid tapeworms when they eat raw offal (e.g. lungs, liver) of an infected animal (e.g. sheep, cattle, kangaroos, wallabies). Dogs infected with hydatid tapeworms are typically asymptomatic. Dogs at risk of hydatid tapeworm should be dosed monthly with Advocate Ultra Chew to ensure that newly acquired tapeworms are killed before reaching maturity. Do not feed dogs raw offal or allow access to offal from any source.

Dogs can be infected with taenia tapeworms (*Taenia* spp.) when they consume raw offal or meat of an infected animal (e.g. sheep, rabbit, horse, pig), and with the flea tapeworm (*Dipylidium caninum*) when they swallow infected adult fleas. Advocate Ultra Chew treats tapeworm infestations and prevents reinfestation with the flea tapeworm through effective flea control.

General Instructions

Advocate Ultra Chew should be administered at monthly intervals, preferably on the same date each month.

To protect families and minimise the risk of dogs becoming reinfested with fleas, ticks and worms, it is important to treat all animals within a household with an approved parasite protection product.

As Advocate Ultra Chew is an oral product, there are no restrictions with regards to swimming or washing after treatment. The dog can be treated while it is wet and can be exposed to water immediately after treatment.

**NOT TO BE USED FOR ANY PURPOSE, OR IN ANY MANNER, CONTRARY TO THIS LABEL UNLESS AUTHORISED UNDER APPROPRIATE LEGISLATION.**

Withholding Periods:	
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Trade Advice:	
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Safety Directions:	Repeated exposure may cause allergic disorders. Avoid contact with skin. Wash hands after use.
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First Aid Instructions:	If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 13 11 26.
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First Aid Warnings:	
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Additional User Safety:	Administer Advocate Ultra Chew to your dog immediately after taking out from the blister. Do not keep an open chew unattended.  Additional information is listed in the safety data sheet (SDS). For a copy phone 1800 995 709.
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Environmental Statements:	
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Disposal:	Dispose of blister packs by wrapping in paper and putting in garbage.
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Storage:	Store below 30 °C (room temperature).
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ADVOCATE ULTRA CHEW FOR DOGS – Dosage Table

Recommended Dosing Schedule

<b>Dog weight (kg)</b>	<b>Lotilaner</b>	<b>Moxidectin</b>	<b>Pyrantel*</b>	<b>Praziquantel</b>	<b>Chews administered</b>
	<b>mg / chew</b>				
2.0 – 2.8	56.25	0.05625	14.25	14.25	One
2.9 – 5.5	112.5	0.1125	28.5	28.5	One
5.6 – 11	225	0.225	57	57	One
11.1 – 22	450	0.45	114	114	One
22.1 – 45	900	0.9	228	228	One

\*as embonate