FOR ANIMAL USE ONLY

EXITEL PLUS XL
Tablets for Dogs
Reg. No. G4227 (Act 36/1947)

INDICATIONS
For the treatment of mixed infections by nematodes and cestodes of the following species in adult dogs:
Nematodes
Ascarids: *Toxocara canis, Toxascaris leonina (*adult and late immature forms).
Hookworms: *Uncinaria stenocephala, Ancylostoma caninum* (adults).
Whipworms: *Trichuris vulpis (*adults).

Cestodes
Tapeworms: *Echinococcus* species, (*E. granulosis, E. multilocularis), Taenia* species (*T. hydatigena, T. pisiformis, T. taeniformis), Dipylidium caninum (*adult and immature forms).

COMPOSITION
Each **Exitel Plus XL** tablet contains:

Praziquantel	175 mg
Pyrantel	175 mg (equivalent to 504 mg pyrantel embonate)
Febantel	525 mg

STORAGE
- Store at or below 25 °C.
- Each time an unused half tablet is stored, it should be returned to the open blister space and inserted back into the original carton. Unused half tablets must be used within 14 days.

WARNINGS
Special warnings for each target species
- Fleas serve as intermediate hosts for one common type of tapeworm – *Dipylidium caninum*.
- Tapeworm infestation is certain to reoccur unless control of intermediate hosts such as fleas, mice, etc. is undertaken.
- Tapeworm infestation is unlikely in pups less than 6 weeks of age.
- Parasite resistance to any particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class.
- KEEP OUT OF REACH OF CHILDREN, UNINFORMED PERSONS AND ANIMALS.
- Although this remedy has been extensively tested under a large variety of conditions, failure thereof may ensue as a result of a wide range of reasons. If this is suspected, seek veterinary advice and notify the registration holder.

PRECAUTIONS
Special precautions for use in animals
- Any partially used tablet should be discarded according to local waste disposal regulations.
- To ensure administration of a correct dose, body weight should be determined as accurately as possible.

DIRECTIONS FOR USE – USE ONLY AS DIRECTED
For oral administration only.

Recommended dosage:
The recommended dose rates are 15 mg/kg body weight febantel, 5 mg/kg pyrantel (equivalent to 14,4 mg/kg pyrantel embonate) and 5 mg/kg praziquantel.
This is equivalent to 1 **Exitel Plus XL** tablet per 35 kg body weight.
Dogs of more than 35 kg body weight should be given 1 **Exitel Plus XL** tablet plus the appropriate quantity of Exitel Plus (G4226) tablets equivalent to one tablet per 10 kg body weight (please refer to below table).

Dosage table:

Body Weight (kg)	Tablets
Approx. 17,5 kg	½ tablet
31 to 35 kg	1 **Exitel Plus XL** tablet
36 to 40 kg	1 **Exitel Plus XL** tablet and ½ Exitel Plus tablet
41 to 45 kg	1 **Exitel Plus XL** tablet and 1 Exitel Plus tablet
46 to 50 kg	1 **Exitel Plus XL** tablet and 1½ Exitel Plus tablets
51 to 55 kg	1 **Exitel Plus XL** tablet and 2 Exitel Plus tablets
56 to 60 kg	1 **Exitel Plus XL** tablet and 2½ Exitel Plus tablets
61 to 65 kg	1 **Exitel Plus XL** tablet and 3 Exitel Plus tablets
66 to 70 kg	2 **Exitel Plus XL** tablets

The tablets can be given directly to the dog or disguised in food. No starvation is needed before or after treatment.
If there is a risk for reinfestation, the advice of a veterinarian should be sought regarding the need for and the frequency of repeat administration.

OVERDOSE
The combination of praziquantel, pyrantel embonate and febantel is well tolerated in dogs. In safety studies, a single dose of 5 times the recommended dose or greater gave rise to occasional vomiting.

CONTRA-INDICATIONS
Do not use simultaneously with piperazine compounds.
Do not use in animals with a known sensitivity to the active ingredients or to any of the excipients.

SIDE EFFECTS
None known.

PREGNANCY AND LACTATION
No studies have been performed in dogs during early pregnancy. Use of the product during pregnancy should be in accordance with a benefit-risk assessment done by the responsible veterinarian.
It is recommended that the product is not used in dogs during the first 4 weeks of pregnancy. Do not exceed the stated dose when treating pregnant bitches.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION
Do not use simultaneously with piperazine compounds as the anthelmintic effects of pyrantel and piperazine may be antagonised.
Concurrent use with other cholinergic compounds can lead to toxicity.

PRESENTATION
A yellow, uncoated, oblong, flavoured, tablet with a cross break-line on both sides.
The tablets can be divided into equal halves.
The tablets are packaged in blister packs made of PVC/PE/PCTFE with 20-micron aluminium foil with 10 or 20 tablets per blister. They are available in cartons of 20, 50, 100 and 1 000's. (Not all presentations may be marketed.)

REGISTRATION HOLDER
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MANUFACTURER
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SLEGS VIR DIEREGEBRUIK

Exitel Plus XL
Tablette vir Honde
Reg. Nr. G4227 (Wet 36/1947)

INDIKASIES
Vir die behandeling van gemengde infeksies deur die volgende nematode- en sestodespesies in volwasse honde:

Nematodes
Spoelwurms: *Toxocara canis, Toxascaris leonina (*volwasse- en laat onvolwasse vorms).
Haakwurms: *Uncinaria stenocephala, Ancylostoma caninum* (volwassenes).
Sambokwurm: *Trichuris vulpis (*volwassenes).

Sestodes
Lintwurms: *Echinococcus* spesies, (*E. granulosis, E. multilocularis), Taenia* spesies (*T. hydatigena, T pisiformis, T. taeniformis), Dipylidium caninum (*volwasse- en onvolwasse vorms).

SAMESTELLING
Elke **Exitel Plus XL** tablet bevat:
Prasikwantel 175 mg
Pirantiel 175 mg (ekwivalent aan 504 mg pirantielembonaat)
Febantiel 525 mg

BERGING
Berg teen of benede 25 °C.
Elke keer as 'n ongebruikte halwe tablet gestoor word, moet dit teruggeplaas word in die oop ruimte van die leë stolpverpakking en terug in die oorspronklike karton geplaas word. Ongebruikte halwe tablette moet binne 14 dae gebruik word.

WAARSKUWINGS
Spesiale waarskuwings vir elke teikenspesie
Vlooie dien as die tussengasheer vir ’n algemene tipe lintwurm – *Dipylidium caninum.*
Lintwurmbesmetting sal verseker terugkeer, tensy beheer op tussengashere soos vlooie, muise ens. toegepas word.
Lintwurmbesmettings is onwaarskynlik in hondjies jonger as ’n ouderdom van 6 weke.
Parasietweerstand teen enige bepaalde klas ontwurmingsmiddel mag ontwikkel ná gereelde, herhaalde gebruik van ’n ontwurmingsmiddel in daardie klas.
HOU BUITE BEREIK VAN KINDERS, ONINGELIGTE PERSONE EN DIERE.
Alhoewel hierdie middel breedvoerig onder ’n wye verskeidenheid toestande getoets is, mag dit faal as gevolg van verskeie redes. Indien dit vermoed word, raadpleeg ’n veearts en verwittig die registrasiehouer.

VOORSORGMAATREëLS
Spesiale voorsorgmaatreëls vir gebruik in diere
Om toediening van die korrekte dosis te verseker, moet die liggaamsmassa so akkuraat as moontlik bepaal word.

GEBRUIKSAANWYSINGS – GEBRUIK SLEGS SOOS AANGEDUI
Slegs vir orale toediening.

Aanbevole dosis:
Die aanbevole dosis is 15 mg/kg liggaamsmassa febantiel, 5 mg/kg pirantiel (gelykstaande aan 14,4 mg/kg pirantielembonaat) en 5 mg/kg prasikwantel.
Dit is gelykstaande aan een **Exitel Plus XL** tablet per 35 kg liggaamsmassa.
Honde wat meer as 35 kg weeg, moet een **Exitel Plus XL** tablet kry en ‘n korrekte hoeveelheid Exitel Plus (G4226) tablette gelykstaande aan een tablet per 10 kg liggaamsmassa (verwys na die onderstaande tabel).

Die tablet kan direk aan die hond gee word, of dit kan in die kos gemeng word. Uithongering is nie nodig voor of ná behandeling nie.

Doseringstabel:

Liggaamsmassa (kg)	Tablette
Omtrent 17,5 kg	½ **Exitel Plus XL** tablet
31 - 35 kg	1 **Exitel Plus XL** tablet
36 - 40 kg	1 **Exitel Plus XL** tablet en ½ Exitel Plus tablet
41 - 45 kg	1 **Exitel Plus XL** tablet en 1 Exitel Plus tablet
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Indien daar ‘n risiko van herbesmetting is, konsulteer ‘n veearts in verband met die behoefte aan, en die frekwensie van herhaalde dosering.

OORDOSIS
Die kombinasie van prasikwantel, pirantielembonaat en febantiel word goed verdra in honde. In die veiligheidstudies het ‘n enkeldosis van 5 keer die aanbevole dosis, of meer, soms aanleiding gegee tot braking.

KONTRA-INDIKASIES
Moenie saam met piperasienbevattende produkte gebruik nie.
Moenie in diere met ‘n hipersensitiwiteit vir die aktiewe bestanddele of enige van die hulpstowwe gebruik nie.

NEWE-EFFEKTE
Geen

DRAGTIGHEID EN LAKTASIE
Teratogeniese effekte wat toegeskryf kan word aan hoë dosisse febantiel, is al aangemeld in skape en rotte.
Geen studies is uitgevoer in honde tydens vroeë swangerskap nie. Die gebruik van hierdie produk tydens swangerskap behoort in oorstemming te wees met ‘n voordeel/risiko-assessering deur die verantwoordelike veearts.
Dit word aanbeveel dat die produk nie gebruik word in honde gedurende die eerste 4 weke van swangerskap nie. Moenie die voorgeskewe dosis oorskry wanneer dragtige tewe behandel word nie.

INTERAKSIE MET ANDER MEDISINALE PRODUKTE EN ANDER VORMS VAN INTERAKSIE
Moenie gelyktydig met piperasienbevattende middels gebruik nie, aangesien die anthelmintiese effek van pirantiel en piperasien geantagoniseer kan word.
Gelyktydige gebruik met ander cholinergiese middels kan tot vergiftiging lei.

AANBIEDING
‘n Geel onbedekte, langwerpige, gegeurde tablet met ‘n kruisbreeklyn aan beide kante.
Die tablet kan verdeel word in gelyke helftes.
Die tablette word verpak in stulpverpakkings, gemaak van aluminiumfoelie, verpak in kartonhouers wat 20 tablette per kartonhouer bevat.

REGISTRASIEHOUER
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