

EQUIMOXIN 18.92 mg/g oral gel for horses

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder
and manufacturer:

Bioveta, a. s.
Komenského 212/12
683 23 Ivanovice na Hané
Czech Republic

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

EQUIMOXIN 18.92 mg/g oral gel for horses
Moxidectin

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

1 gram of the gel contains:

Active substance:	
Moxidectin	18.92 mg
Excipients:	
Benzyl alcohol (E 1519)	37.84 mg
Disodium edetate dihydrate	0.265 mg
Butylated hydroxytoluene (E 321)	max. 0.144 mg

Translucent, clear to yellow oral gel.

4. INDICATIONS

For the treatment of infestations
with moxidectin sensitive strains of:

Large strongyles:

Strongylus vulgaris (adults and arterial stages)
Strongylus edentatus
(adults and visceral stages)
Triodontophorus brevicauda (adults)
Triodontophorus serratus (adults)
Triodontophorus tenuicollis (adults)

Small strongyles

(adults and intraluminal larval stages):

Cyathostomum spp.
Cylicocyclus spp.
Cylicostephanus spp.
Cylicodontophorus spp.
Gyallocephalus spp.

Ascarids:

Parascaris equorum (adults and larval stages)

Other species:

Oxyuris equi (adults and larval stages)

Habronema muscae (adults)
Gasterophilus intestinalis (L2, L3)
Gasterophilus nasalis (L2, L3)
Strongyloides westeri (adults)
Trichostrongylus axei

The veterinary medicinal product has
a persistent efficacy of two weeks against
small strongyles.

The excretion of small strongyles eggs
is suppressed for 90 days.

The veterinary medicinal product is effective
against (developing) intramucosal L4 stages
of small strongyles. At 8 weeks after treatment,
early (hypobiotic) L3 stages of small strongyles
are eliminated.

5. CONTRAINDICATIONS

Do not use in foals less than 4 months of age.
Do not use in case of hypersensitivity to the
active substance or to any of the excipients.

6. ADVERSE REACTIONS

Flaccid lower lip and swelling of the upper
lip could be observed rarely in young animals.
These adverse effects are transient and
disappear spontaneously.

7. TARGET SPECIES

Non-food-producing horses.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Single oral administration.

The recommended dose is 0.4 mg
of moxidectin/kg bw, equivalent to a dose
of 1.056 g/50 kg bw.

One division on the applicator plunger scale
corresponds to a dose recommended for 50 kg
bw of a horse. The content of 1 applicator is
intended for a horse weighing 700 kg bw.

Use of a weight tape is recommended
to ensure accurate dosing. The applicator
should be adjusted to the calculated dose
by setting the ring to the corresponding mark
on the plunger.

9. ADVICE ON CORRECT ADMINISTRATION

While holding the syringe plunger, turn the
grooved dosing ring on the plunger so that
the bottom edge of the ring is aligned with
the mark of the desired weight.

Make sure that the horse has no feed residues
in its mouth. Remove the cap from the
applicator, insert the applicator into the horse's
mouth and apply the paste to the root of the
tongue. After application lift the horse's head
immediately for a few seconds and make sure
that the horse has swallowed the dose.

10. WITHDRAWAL PERIOD

Do not use in horses the meat and milk
of which is intended for human consumption.
The horse must be declared as a non-food-
producing horse in the horse passport.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach of children.

Protect from frost.

Store in the original container to protect
the product from light.

Do not use this veterinary medicinal product
after the expiry date which is stated on the
label and carton.

12. SPECIAL WARNING(S)

Do not use the same applicator to treat more
than one animal unless horses are running
together or in direct contact with each other on
the same premises.

To avoid overdosing, care should be taken to
accurately dose foals, especially low body
weight foals.

Special warnings for use in animals

Special warnings for use in animals

The product has been formulated specifically
for use in horses only. Dogs or cats may be
adversely affected by the concentration
of moxidectin in this veterinary medicinal
product if they are allowed to ingest spilled
gel or have access to used applicators.
Prevent access of these animals to the
product.

The following procedures that would increase
the risk of resistance and could ultimately
result in ineffective therapy should be avoided:

- too frequent and repeated use
of anthelmintics from the same group,
too long time of administration
- underdosing because of poor determination
of body weight, incorrect administration
or inadequate calibration of the dosing
device.

Using appropriate tests (e.g. Faecal Egg Count
Reduction Test – FECRT), suspected clinical
cases should be examined for resistance
to anthelmintics. Where test results confirm
the resistance to a certain anthelmintic,
an anthelmintic belonging to another group
and having a different mode of action should
be used.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

The product may cause skin and eye irritation.
Avoid therefore contact with skin and eyes.
When handling the veterinary medicinal
product, personal protective equipment
consisting of protective gloves should be used.
In case of contact with skin, wash immediately
with water and soap. In case of contact with
eyes, rinse immediately with plenty of clean
water. In case of irritation seek medical advice.
In case of accidental ingestion seek medical
advice immediately and show the package
leaflet or label to the practitioner.
Do not eat, drink or smoke while handling
the product.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

The product is toxic to fish and aquatic
organisms.

Any unused veterinary medicinal product
or waste materials derived from such
veterinary medicinal product should be
disposed of in accordance with local
requirements.

Avoid contamination of ponds, watercourses
or sewers with this product or used applicators.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED May 2016

15. OTHER INFORMATION

Overdose (symptoms, emergency procedures, antidotes), if necessary

Transient adverse reactions may occur
at 2 times the recommended dose in foals
and 3 times the recommended dose in adults.
The symptoms are depression, inappetence,
ataxia and flaccid lower lip within 8 to 24 hours
following treatment. Symptomatic treatment
is not usually necessary and the symptoms
subside completely within 24 to 72 hours.
There is no specific antidote.

Use during pregnancy and lactation

The product can be used during pregnancy
and lactation.

For animal treatment only.

Veterinary medicinal product subject
to prescription.

Pack size: 1 × 14.8 g, 10 × 14.8 g

Not all pack sizes may be marketed.

bioveta



Dimensions (mm):

Colours:

Prepared by:

Date:

A6 (105 × 148 mm) duplex printing

black

Vlková

13. 7. 2016

Approved by:

Date:

65x67 mm

18.92 mg/g oral gel for horses

EQUIMOXIN®

Moxidectin

14.8 g

1 gram of the gel contains:

Active substance: Moxidectin

18.92 mg

Excipients: Benzyl alcohol (E 1519)

37.84 mg

Disodium edetate dihydrate

0.265 mg

Butylated hydroxytoluene (E 321) max. 0.144 mg

Route of administration: Oral administration.

Withdrawal period: Do not use in horses the meat and milk of which is intended for human consumption.

The horse must be declared as a non-food-producing horse in the horse passport.

For animal treatment only.



Bioveta, a. s.

Czech Republic

Batch:

EXP:

481/E/14.8g/GBOH

platby za poskytnutí služby

18.92 mg/g oral gel for horses

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Bioveta, a. s.

Czech Republic

Batch:

EXP:

481/E/14.8g/GBO/1

P.č.:	minimální prostor pro dotisk šarže a expirace	11×5 mm	ANO		výjimku schválil:
			NE		
Dodavatel:	Dimensions (mm): 65×67				
	Colours: CMYK				
Prepared by:	Raška				
	Date: 14. 3. 2017				
Approved by:			Date:		

minimální prostor pro dotisk šarže a expirace	15x6 mm	ANO
		NE
místo pro dotisk je umístěno na největší (nejstabilnější) ploše krabičky		ANO
		NE

PRINTED SIDE

PČ.:	Rozměr š x h x v (mm):	190x40x30	
	Barevnost:	CMYK	
	Připravil:	Raška	
	Datum:	16. 3. 2017	
Dodavatel:			Schválil(a):
			Dne:

TT-06-16

481/K/1x14.8g/(EBC)/1



Name and address of the marketing authorisation holder:
Bioveta, a. s.
Komenského 212/12
683 23 Ivanovice na Hané
Czech Republic

For animal treatment only.
Subject to medical prescription.

EQUIMOXIN[®]

18.92 mg/g oral gel for horses

Moxidectin

1 x 14.8 g (1 applicator)





1 gram of the gel contains:

Active substance: Moxidectin	18.92 mg
Excipients: Benzyl alcohol (E 1519)	37.84 mg
Disodium edetate dihydrate	0.265 mg
Butylated hydroxytoluene (E 321)	max. 0.144 mg

Pharmaceutical form: Oral gel.
Target species: Non-food-producing horses.

Indications: For the treatment of infestations with moxidectin sensitive strains of:

Large strongyles: *Strongylus vulgaris*, *Strongylus edentatus*, *Triodontophorus brevicauda*, *Triodontophorus serratus*, *Triodontophorus tenuicollis*

Small strongyles: *Cyathostomum* spp., *Cylicocyclus* spp., *Cylicostephanus* spp., *Cylicodontophorus* spp., *Gyaloccephalus* spp.

Ascarids: *Parascaris equorum*

Other species: *Oxyuris equi* and others (see the package leaflet).

The veterinary medicinal product has a persistent efficacy of two weeks against small strongyles.
The excretion of small strongyles eggs is suppressed for 90 days.
The veterinary medicinal product is effective against (developing) intramucosal L4 stages of small strongyles. At 8 weeks after treatment, early (hypobiotic) L₃ stages of small strongyles are eliminated.

Method and route(s) of administration: Single oral administration.
The recommended dose is 0.4 mg of moxidectin/kg bw. 1 scale division corresponds to the recommended dose for 50 kg bw. The content of 1 applicator is intended for a horse weighing 700 kg bw.
Read the package leaflet before use.

Withdrawal period: Do not use in horses the meat and milk of which is intended for human consumption.
The horse must be declared as a non-food-producing horse in the horse passport.

Special warning(s), if necessary: Read the package leaflet before use.

Special storage conditions: Protect from frost.
Store in the original container to protect the product from light.
Keep out of the reach of children.

Waste disposal: Read the package leaflet.

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EQUIMOXIN[®]
18.92 mg/g oral gel for horses
1 x 14.8 g (1 applicator)

bioveta

Batch:

EXP:



8 594 004 860 651

1:1

18.92 mg/g oral gel for horses

EQUIMOXIN®

Moxidectin

 **EQUIMOXIN®**

Batch:

 **EQUIMOXIN®**

Batch:

481/OP/2/GB0/1

18.92 mg/g oral gel for horses

EQUIMOXIN®

Moxidectin

 **EQUIMOXIN®**

Batch:

 **EQUIMOXIN®**

Batch:

481/OP/2/GB0/1

PČ.:	minimální prostor pro dotisk šarže a expirace		11×5 mm	ANO NE	výjimku schválil:	
Dodavatel:	Dimensions (mm):		75×33			
	Colours:		Pantone 299 Pantone 7499 black Raška 14. 3. 2017			
Prepared by:			Approved by:			
Date:			Date:			