PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{NATURE/TYPE} 100, and 500 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

IVERTIN 10 mg/ml Solution for Injection for Cattle and Pigs
Ivermectin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml contains
Active substance:
Ivermectin .....10.0 mg

Excipients:
Propylene glycol .....613.6 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

Container of 100, and 500 ml

5. TARGET SPECIES

Cattle (beef and non-lactating dairy cattle) and pigs

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Cattle: Meat and offal: 49 days.
Milk: Do not use in lactating dairy cows producing milk for human consumption.
Do not use in non-lactating dairy cows including pregnant heifers within 60 days of calving.
Pigs: Meat and offal: 28 days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP.:
Once broached, use within 28 days
Once broached use by …….

11. SPECIAL STORAGE CONDITIONS

Keep vials in the outer carton.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Do not contaminate surface waters or ditches with the product or used containers.
Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.
To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Kela – Kempisch Laboratorium – Kela Laboratoria NV
St Lenaartseweg 48
2320 Hoogstraten
Belgium

16. MARKETING AUTHORISATION NUMBER

Vm 06126/4008

17. MANUFACTURER'S BATCH NUMBER

Batch:

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{NATURE/TYPE} 50, 100, 500 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

IVERTIN 10 mg/ml Solution for Injection for Cattle and Pigs
Ivermectin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml contains:
Active Substance:
Ivermectin .....10.0 mg

Excipients:
Propylene glycol .....613.6 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

Container of 50, 100 and 500 ml

5. TARGET SPECIES

Cattle (beef and non-lactating dairy cattle) and pigs

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Cattle: Meat and offal: 49 days.
Milk: Do not use in lactating dairy cows producing milk for human consumption.
Do not use in non-lactating dairy cows including pregnant heifers within 60 days of calving.
Pigs: Meat and offal: 28 days.

9. SPECIAL WARNING(S), IF NECESSARY

Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result in ineffective therapy:
_* Too frequent and repeated use of anthelmintics from the same class, over an extended period of time.

_* Underdosing, which may be due to underestimation of body weight, misadministration of the product, or lack of calibration of the dosing device (if any).
Suspected clinical cases of resistance to anthelmintics should be further investigated using appropriate tests (e.g. Faecal Egg Count Reduction Test). Where the results of the test(s) strongly suggest resistance to a particular anthelmintic, an anthelmintic belonging to another pharmacological class and having a different mode of action should be used".

Avermectins may not be well tolerated in all non target species. Cases of intolerance are reported in dogs, especially Collies, Old English Sheepdogs and related breeds or crosses, and also in turtles and tortoises.

Read the package leaflet before use.

10. EXPIRY DATE

EXP.:
Once broached, use within 28 days

11. SPECIAL STORAGE CONDITIONS

Keep vials in the outer carton.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Do not contaminate surface waters or ditches with the product or used containers.
Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.
To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Kela – Kempisch Laboratorium – Kela Laboratoria NV
St Lenaartseweg 48
2320 Hoogstraten
Belgium

16. MARKETING AUTHORISATION NUMBER

Vm 06126/4008

17. MANUFACTURER'S BATCH NUMBER

Batch:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{NATURE/TYPE} 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

IVERTIN 10 mg/ml Solution for Injection for Cattle and Pigs
Ivermectin

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

1 ml contains:
Active Substance:
Ivermectin .....10.0 mg

Excipients:
Propylene glycol .....613.6 mg

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

4. ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

5. WITHDRAWAL PERIOD(S)

Cattle: Meat and offal: 49 days.
Milk: Do not use in lactating dairy cows producing milk for human consumption.
Do not use in non-lactating dairy cows including pregnant heifers within 60 days of calving.
Pigs: Meat and offal: 28 days.

6. BATCH NUMBER

Batch:

7. EXPIRY DATE

EXP:
Once broached, use within 28 days.
Once broached use by …….

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PACKAGE LEAFLET

IVERTIN CATTLE and PIGS
10 mg/ml solution for injection
Ivermectin

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

Marketing authorisation holder:
Kela – Kempisch Laboratorium – Kela Laboratoria NV
St Lenaartseweg 48
2320 Hoogstraten
Belgium

Manufacturer responsible for batch release:
Laboratorios Calier SA
C/Barcelones 26 (Pla del Ramassa)
Les Franqueses del Valles
Barcelona
Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

IVERTIN 10 mg/ml Solution for Injection for Cattle and Pigs
Ivermectin

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

1 ml contains:
Active substance:
Ivermectin .....10.0 mg

Excipients:
Propylene glycol (E 1520)……613.6 mg

4. INDICATION(S)

Treatment of infections with the following parasites in beef and non-lactating dairy cattle or pigs:

Cattle

Round gastrointestinal worms
Ostertagia lyrata (Adult, L4)
Haemonchus placei (Adult, L3, L4)
Trichostrongylus axei (Adult,L4)
Trichostrongylus colubriformis (Adult,L4)
Cooperia oncophora (Adult,L4)
Cooperia punctata (Adult,L4)

Cooperia pectinata (Adult, L5)
Oesophagostomum radiatum (Adult,L3, L4)
Nematodirus helvetianus (Adult)
Nematodirus spathiger (Adult)
Bunostomum phlebotomum (Adult, L3, L4)
Adult and inhibited forms of *Ostertagia ostertagi*.

Lungworms
Dictyocaulus viviparus (Adult, L4)

Warble flies (all parasitic stages)
Hypoderma bovis, *H lineatum*

Sucking lice
Linognathus vituli
Haematopinus eurysternus
Solenopotes capillatus

Mange and other acariosis produced by:

Acari
Psoroptes ovis (syn. *P. communis* var. B*ovis*)
*Sarcoptes scabiei (*var. *bovis*)

The product injection helps in the control of the mange mite *Chorioptes bovis* but complete elimination may not occur.

Pigs

Gastrointestinal Roundworms
Ascaris suum
Hyostrongylus rubidus
Oesophagostomum spp.
Strongyloides ransom (adults)

Lungworms
Metastrongylus spp. (adults)

Lice
Haematopinus suis

Mange Mites
Sarcoptes scabiei var. *suis*

5. CONTRAINDICATIONS

Do not use in cats and dogs as severe adverse reactions may occur.
Do not use in cases of known hypersensitivity to the active substance or to any of the excipients.
Do not administer by intramuscular or intravenous route.

6. ADVERSE REACTIONS

Transient swelling at the injection site is commonly observed following treatment. These reactions can last up to 2 days and disappear without treatment.
Transient pain has been observed in very rare cases.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 in 10,000 animals treated, including isolated reports).

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle (beef and non-lactating dairy cattle) and pigs

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

For single subcutaneous injection.
To ensure administration of a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked.
If animals are to be treated collectively rather than individually, they should be grouped according to their bodyweight and dosed accordingly, in order to avoid under- or overdosing.

Cattle
Ivermectin should be administered at a dose of 200 µg/kg bodyweight (equivalent to 1ml/50 kg bodyweight).

Equivalent to:

Weight (kg)	Dose (ml)
Up to 50	1
51 – 100	2
101 – 150	3
151 – 200	4
201 – 250	5
251 – 300	6
301 – 350	7
351 – 400	8
401 – 450	9
451 – 500	10
501 – 550	11
551 - 600	12

Duration of the effect:
Ostertagia spp.: at least 7 days has been substantiated
Dictyocaulus viviparus: at least 14 days has been substantiated

Pigs
At the recommended dosage level of 300 µg ivermectin per kg of bodyweight, administer only subcutaneously in the neck in pigs.

Each ml contains 10 mg of ivermectin sufficient to treat 33 kg of bodyweight of pigs.

Use the following dosage table:

Weight (kg)	Dose (ml)
8	0.25
8 – 16	0.5
17 – 33	1.0
34 - 50	1.5
51 – 66	2.0
67 – 99	3.0
100 – 133	4.0
134 – 166	5.0
167 - 200	6.0

Over 200 kg bodyweight, give 1.0 ml per 33 kg bodyweight.

9. ADVICE ON CORRECT ADMINISTRATION

Cattle
It should be injected subcutaneously in front of or behind shoulder using aseptic technique. The use of a needle 16 gauge x 15 to 20 mm long is suggested. Use sterile equipment.

Pigs
The injection may be given with any standard automatic or single-dose or hypodermic syringe. Use of 1.4 x 15 mm (17 gauge x 1/2 inch) needle is suggested.. Injection of wet or dirty animals is not recommended.
. Vial stoppers must not be broached more than 20 times.
In young pigs, especially those weighing under 16kg for which less than 0.5ml of the product is indicated, dosing accuracy is important. The use of a syringe that can accurately deliver increments of 0.1ml is recommended. For piglets weighing less than 16kg give 0.1ml/3kg.

When treating pigs of less than 16kg seek veterinary advice regarding the use of 1ml disposable syringes graduated in increments of 0.1ml.

10. WITHDRAWAL PERIOD

Cattle: Meat and offal: 49 days.
Milk: Do not use in lactating dairy cows producing milk for human consumption.
Do not use in non-lactating dairy cows including pregnant heifers within 60 days of calving.
Pigs: Meat and offal: 28 days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Keep vials in the outer carton.
Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.
Shelf life after first opening the container: 28 days

12. SPECIAL WARNING(S)

Special warnings for each target species
Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result in ineffective therapy:
_* Too frequent and repeated use of anthelmintics from the same class, over an extended period of time.
_* Underdosing, which may be due to underestimation of body weight, misadministration of the product, or lack of calibration of the dosing device (if any).
Suspected clinical cases of resistance to anthelmintics should be further investigated using appropriate tests (e.g. Faecal Egg Count Reduction Test). Where the results of the test(s) strongly suggest resistance to a particular anthelmintic, an anthelmintic belonging to another pharmacological class and having a different mode of action should be used.
Resistance to ivermectin has been reported in *Cooperia spp.* and in *Ostertagia ostertagi* in cattle. Resistance has also been reported in *Haemonchus contortus* in cattle outside the EU. Therefore, the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of this helminth species and recommendations on how to limit further selection for resistance to anthelmintics.

Special precautions for use

Special precautions for use in animals
Contact with treated and non-treated infected herds must be avoided at least seven days after the treatment.

The product is effective in all hypodermosis stages, however, it is very important to treat on time (at the end of warble fly season). The elimination of *Hypoderma* larvae may cause negative reactions on the host, when they are found in vital areas. Killing *Hypoderma lineatum,* if found in perioesophageal tissue, may cause salivation and tympanism. Killing *Hypoderma bovis*, if found in the

vertebral canal, may cause unsteadiness or paralysis. Bovine should be treated before or after those stages of warble flies.

Avermectins may not be well tolerated in all non-target species (cases of intolerance with fatal outcome are reported in dogs - especially Collies, Old English Sheepdogs and related breeds or crosses, and also in turtles/tortoises).

In addition, care should be taken to avoid ingestion of spilled product or access to used containers by these other species.
Since ivermectin is highly bound to plasma proteins, special care should be taken in cases of sick animals or in nutritional conditions associated with low plasma protein levels.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
The product may cause local irritation and/or pain at the site of injection. Direct contact of the product with the skin should be avoided. Take care to avoid self-administration.
Do not smoke or eat while handling the product.
Wash hands after use. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Other precautions
The product is very toxic to aquatic organisms and dung insects. Treated cattle should not have direct access to ponds, streams or ditches for 14 days after treatment. Long term effects on dung insects caused by continuous or repeated use cannot be excluded. Therefore repeated treatments on a pasture within a season should only be given on the advice of a veterinarian.

Use during pregnancy and lactation
In pigs, the product can be used in breeding sows and boars.
The fertility of males is not affected by administration of the product.

Interaction with other medicinal products and other forms of interaction
Do not combine ivermectin treatment with vaccination against lungworms. If vaccinated animals are to be treated, treatment should not be carried out within a period of 28 days before or after vaccination.

Overdose (symptoms, emergency procedures, antidotes)
A single dose of 4.0 mg of ivermectin/kg given subcutaneously (20x recommended dose rate) to bovines caused ataxia and depression.
A dose of 30 mg ivermectin per Kg (100 x the recommended dose of 0.3 mg per kg) injected subcutaneously to pigs caused lethargy, ataxia, bilateral mydriasis, intermittent tremors, labored breathing and lateral recumbency.
If overdose occurs, apply symptomatic treatment.

Incompatibilities
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

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

EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Do not contaminate surface waters or ditches with the product or used containers.
Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2022

15. OTHER INFORMATION

Pack size:

Bottles of 50 ml, 100 ml, and 500 ml.
Clinical containers of 6, 10 and 12 units of 50 ml, 100 ml, and 500 ml.

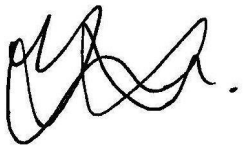
Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label.

For Animal Treatment Only

To be supplied only on veterinary prescription



Approved: 13 October 2022