ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {CONTAINER LABEL} AND OUTER PACKAGE {CARTON}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tri-Solfen cutaneous solution for pigs
Lidocaine
Bupivacaine
Adrenaline/Epinephrine
Cetrimide

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Lidocaine	40.6 mg	(as 50 mg lidocaine hydrochloride monohydrate)
Bupivacaine	4.2 mg	(as 5 mg bupivacaine hydrochloride monohydrate)
Adrenaline/Epinephrine	0.025 mg	(as 0.045 mg adrenaline tartrate)
Cetrimide	5.0 mg	

3. PHARMACEUTICAL FORM

Cutaneous solution.

4. PACKAGE SIZE

250 ml
500 ml
1 l
5 l

5. TARGET SPECIES

Pig.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Cutaneous use only.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s): zero days

9. SPECIAL WARNING(S), IF NECESSARY

Wear disposable impermeable gloves when handling the product and treating animals.
Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf life after first opening: 3 months.
Once opened, use by: ____ /____ /____

11. SPECIAL STORAGE CONDITIONS

This veterinary medicinal product does not require any special temperature storage conditions.
Keep the container tightly closed in order to protect from light.

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

Disposal: read package leaflet.

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 SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Dechra Limited
Snaygill Industrial Estate
Keighley Road
Skipton
North Yorkshire
BD23 2RW
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

Vm 10434/4100

POM-V

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Tri-Solfen cutaneous solution for pigs

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

Marketing authorisation holder:
Dechra Limited
Snaygill Industrial Estate
Keighley Road
Skipton
North Yorkshire
BD23 2RW
United Kingdom

Manufacturer responsible for batch release:
Genera d.d.
Svetonedeljska cesta 2, Kalinovica
HR-10436 Rakov Potok
Croatia

Or

Argenta Dundee Limited,
Kinnoull Road,
Dunsinane Industrial Estate,
Dundee DD2 3XR, Scotland,
United Kingdom

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tri-Solfen cutaneous solution for pigs
Lidocaine
Bupivacaine
Adrenaline/Epinephrine
Cetrimide

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

Each ml contains:

Lidocaine	40.6 mg	(as 50 mg lidocaine hydrochloride monohydrate)
Bupivacaine	4.2 mg	(as 5 mg bupivacaine hydrochloride monohydrate)
Adrenaline/Epinephrine	0.025 mg	(as 0.045 mg adrenaline tartrate)
Cetrimide	5.0 mg	

Excipients:

Sodium metabisulfite	0.045 mg
Brilliant blue FCF (E133)	0.05 mg

Clear, blue, semi-viscous liquid with no visible particles.

4. INDICATION(S)

Local anaesthesia during and following castration of piglets, and provision of castration wound antisepsis.

5. CONTRAINDICATIONS

Do not administer in cases of hypersensitivity to any of the active substances or to any of the excipients.

6. ADVERSE REACTIONS

Mild, transient (5-11 days duration) application site inflammation was the most commonly reported adverse reaction in the clinical field trial. There was an isolated report of anaphylaxis in one piglet.

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 animal in 10,000 animals treated, including isolated reports).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

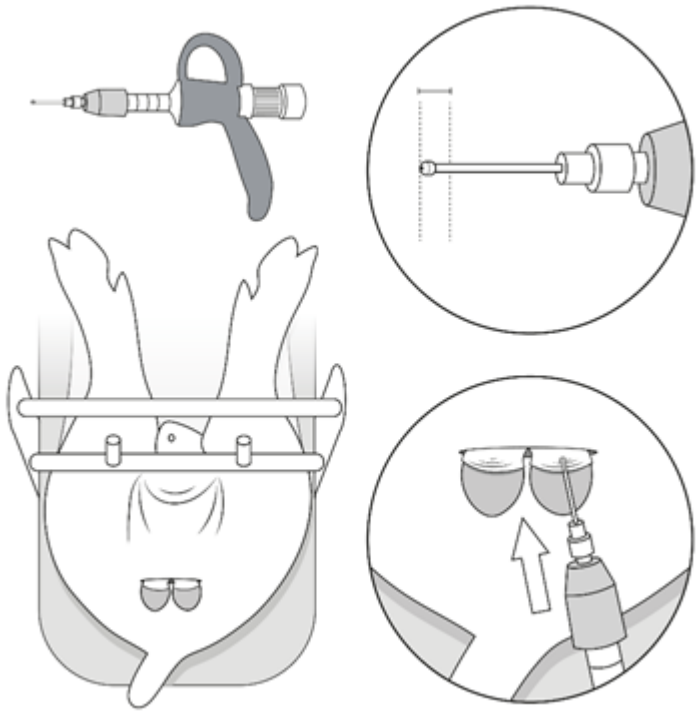
Pig.

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

For cutaneous use only.

<2 kg bw = 1 ml per piglet
2-4 kg bw = 2 ml per piglet

Assemble the applicator as directed below. Set the dose at 0.5 ml. Incise the scrotum and exteriorise the testis, exposing the spermatic cord. Instil 1 or 2 doses (depending on the bodyweight) of 0.5 ml to the opened scrotal sac, to fully coat the spermatic cord and the cut skin edge, then repeat for the other testicle. Wait 30 seconds before severing the spermatic cords.



Use of Applicator:
Connect the long nozzle to the dosing applicator. Connect the dosing applicator and draw-off tubing to the container as follows: Attach the tubing to the dosing applicator. Attach draw-off tubing to the spigot cap. Remove the screw cap and seal, replace with the spigot cap and draw-off tubing and check that they are firmly attached. Follow the dosing applicator manufacturer's directions for priming the application and for proper use and maintenance of the dosing applicator and draw-off tubing. The dosing applicator should be removed at the end of each day's use of the product. Remove the spigot cap and replace with screw cap, checking it is firmly attached. When the dosing gun is removed, expel any remaining product in it and clean according to the manufacturer's directions, before storage.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special temperature storage conditions.
Keep the container tightly closed in order to protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.
Shelf life after first opening the container: 3 months.

12. SPECIAL WARNING(S)

Special warnings for each target species:
For use in piglets up to 7 days of age.
The veterinary medicinal product will provide local anaesthesia within 30 seconds of application, with a duration of effect of approximately 1 hour. Additional analgesia or anaesthesia should be considered, according to recognised veterinary practice. No data are available on concurrent use with other products (see also 'Incompatibilities').

Special precautions for use in animals:
In the clinical field trial, the product was not tested on piglets less than 3 days of age or weighing less than 1 kg. Use only according to the benefit-risk assessment by the responsible veterinarian.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Contact with skin or eyes can cause irritation and repetitive exposure can lead to allergic reactions. Pharmacological effects (i.e. local anaesthesia) are also likely to occur in case of contact with the product.
Lidocaine and bupivacaine can form a metabolite (2,6-xylidine) in humans, which can induce carcinogenic effects at high doses in long-term toxicology studies in rats.
Avoid skin, eye or oral contact with the product.
Wear disposable impermeable gloves when handling the product and treating animals.
In case of accidental spillage onto skin, wash off immediately with soap and water.
Avoid ingestion of and do not smoke or eat while handling the veterinary medicinal product.
In case of accidental ingestion, seek medical advice and show the package insert to the physician.
People with known hypersensitivity to any of the active substances or to any of the excipients (e.g., sodium metabisulfite) should administer the product with caution.
Exposure to this product whilst using another medicinal product which also contains a locally acting amide anaesthetic may cause cross sensitivity.
Wash hands thoroughly after use.

Interaction with other medicinal products and other forms of interaction:
None known.

Overdose (symptoms, emergency procedures, antidotes):
In a laboratory safety study in piglets, transient application site inflammation was seen following 3-fold and 5-fold overdose, but this was similar to that seen at the normal dose

(see section 4.6). No other clinically relevant findings were seen after a five-fold overdose of Tri-Solfen was applied to the castration site.

Incompatibilities:
As no data are available on interactions, it is recommended not to apply other products to the castration site when using this product.

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

April 2022

15. OTHER INFORMATION

Pack sizes: 250 ml, 500 ml, 1 l, 5 l.
Not all pack sizes may be marketed.

Vm 10434/4100
POM-V

Approved 21 April 2022