

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Folding box (100 ml)**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Buscopan Compositum Solution for Injection

Veterinary spasmolytic and analgesic

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Each ml contains:

butylscopolamine bromide 4 mg

metamizole 500 mg

phenol (as preservative) 5 mg

**3. PHARMACEUTICAL FORM**

Solution for injection

**4. PACKAGE SIZE**

100 ml

**5. TARGET SPECIES**

Cattle (adult), horses and dogs.

**6. INDICATION(S)**

Spasmolytic and analgesic for horses, cattle and dogs.

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Horses: 5 ml per 100 kg body weight i.v. only

Adult Cattle: 5 ml per 100 kg body weight i.v. or i.m.

Dogs: 0.1 ml per kg body weight i.v. or i.m.

Due to risk of local reaction, do not use the i.m. route in horses.

Do not use in cows producing milk for human consumption.

Do not use in pregnant animals.

## 8. WITHDRAWAL PERIOD

Horses - 12 days

Cattle - i.v. injection: 9 days

- i.m. injection: 28 days

## 9. SPECIAL WARNING(S), IF NECESSARY

For further information on uses, dosage, contra-indications and warnings, read the package leaflet before use.

Veterinary Medicinal Product authorised for use in UK and IE.

## 10. EXPIRY DATE

Expiry Date (Month/year)

## 11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Protect from light. Avoid introduction of contamination during use. Should any apparent growth or discolouration occur, discard the product. Shelf-life after first opening the immediate packaging: 28 days. Following withdrawal of the first dose, use the product within 28 days then discard unused material. Keep the container in the outer carton.

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

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

## 13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

*[Distribution category]*

UK

IE

To be supplied only on veterinary prescription.

For animal treatment only.

## 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**

UK: Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

IE: Boehringer Ingelheim Vetmedica GmbH, 55216 Ingelheim/Rhein, Germany

**16. MARKETING AUTHORISATION NUMBERS**

UK: Vm 08327/4292

IE: 10454/004/001

**17. MANUFACTURER'S BATCH NUMBER**

Batch No:

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

100ml

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Buscopan Compositum Solution for Injection

Veterinary spasmolytic and analgesic

Indications: Spasmolytic and analgesic for horses, cattle and dogs.

**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

Each ml contains:

butylscopolamine bromide 4 mg

metamizole 500 mg

phenol (as preservative) 5 mg

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

100 ml

**4. ROUTE(S) OF ADMINISTRATION**

Horses 5 ml per 100 kg body weight i.v. only

Adult Cattle 5 ml per 100 kg body weight i.v. or i.m.

Dogs 0.1 ml per kg body weight i.v. or i.m.

Due to risk of local reaction, do not use the i.m. route in horses. Do not use in cows producing milk for human consumption. Do not use in pregnant animals.

**5. WITHDRAWAL PERIOD**

Horses - 12 days

Cattle - i.v. injection: 9 days

- i.m. injection: 28 days

**6. BATCH NUMBER**

Batch no:

**7. EXPIRY DATE**

Expiry Date:

## **8. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only

## **9. Other information**

For further information on uses, dosage, contraindications, warnings and disposal advice, read the package leaflet before use. Do not store above 25°C. Protect from light.

Avoid introduction of contamination during use. Keep the container in the outer carton.

Should any apparent growth or discolouration occur, discard the product. Shelf-life after first opening the immediate packaging: 28 days.

Following withdrawal of the first dose, use the product within 28 days then discard unused material.

To be supplied only on veterinary prescription.

Keep out of the sight and reach of children.

MARKETING AUTHORISATION NUMBER(S):

UK: Vm 08327/4292

IE: VPA 10454/004/001

UK: Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

IE: Boehringer Ingelheim Vetmedica GmbH, 55216 Ingelheim/Rhein, Germany

## **PACKAGE LEAFLET**

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

Marketing Authorisation Holder:

UK: Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

Ireland: Boehringer Ingelheim Vetmedica GmbH, 55216 Ingelheim/Rhein, Germany

Manufacturer responsible for batch release:

Labiana Life Sciences

08228 Les Fonts de Terrassa

Barcelona, Spain

### **2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Buscopan Compositum Solution for Injection

Veterinary spasmolytic and analgesic

### **3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS**

Aqueous solution for injection.

Each ml contains:

butylscopolamine bromide 4 mg

metamizole 500 mg

phenol (as preservative) 5 mg

### **4. INDICATION(S)**

Actions: Butylscopolamine bromide is a spasmolytic agent with particular activity on the smooth muscle of the digestive and urinary systems. Metamizole is a non-steroidal anti-inflammatory drug of the pyrazolone group and also has analgesic and antipyretic effects.

- As an aid in the control of pain associated with simple equine colic and as a diagnostic aid in more severe equine colics.
- For the control of diarrhoea in cattle, horses and dogs particularly when pain or abdominal discomfort is present.
- For the control of pain associated with urinary obstruction in horses and dogs.

### **5. CONTRAINDICATIONS**

Due to a risk of local reactions do not use the intramuscular route in horses. Do not use in pregnant animals as safety during pregnancy in the target species has not

been established. Do not use in case of hypersensitivity to the active substance or to any of the excipients. Do not use in horses suffering from paralytic ileus.

## **6. ADVERSE REACTIONS**

In horses, a slight transient increase in heart rate may be observed due to the parasympatholytic activity of butylscopolaminiumbromide (hyoscine butylbromide). In very rare cases, cardiovascular shock may occur if the intravenous injection is administered too fast.

In horses, mild tachycardia may be observed occasionally due to the parasympatholytic activity of hyoscine butylbromide.

In very rare cases, anaphylactic reactions may occur and should be treated symptomatically.

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

## **7. TARGET SPECIES**

Cattle (adult), horses and dogs.

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

Horses: 5 ml per 100 kg body weight by intravenous injection only

Adult Cattle: 5 ml per 100 kg body weight by intravenous or intramuscular injection

Dogs: 0.1 ml per kg body weight by intravenous or intramuscular injection

## **9. ADVICE ON CORRECT ADMINISTRATION**

Use aseptic techniques.

## **10. WITHDRAWAL PERIOD(S)**

Animals should not be slaughtered for human consumption during treatment.

Horses: 12 days

Cattle: 9 days after i.v. injection

28 days after i.m. injection

Not to be used in cows producing milk for human consumption.

## 11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C. Protect from light.

Avoid introduction of contamination during use. Should any apparent growth or discolouration occur, discard the product.

Shelf-life after first opening the immediate packaging: 28 days.

Following withdrawal of the first dose use the product within 28 days, then discard unused material.

When the container is broached (opened) for the first time, the date on which any product remaining in the container should be discarded should be calculated. A statement of the in-use shelf life of the product is given on the package insert.

This discard date should be written in the space provided on the label. Keep the container in the outer carton.

Do not use after the stated expiry date.

## 12. SPECIAL WARNING(S)

Special warnings for each target species: Due to the risk of anaphylactic shock metamizole-containing solutions should be administered slowly when given intravenously.

Operator Warnings: Take care to avoid self-injection. In a very small number of people, metamizole can cause reversible, but potentially serious agranulocytosis and other reactions such as skin allergy. Avoid use of the product if you are known to be sensitive to pyrazolones, or are sensitive to aspirin. Wash any splashes from the skin. If accidental self-injection occurs, seek medical advice and show the Doctor the product packaging.

Interaction with other medicinal products and other forms of interaction: The effects of metamizole and/or butylscopolamine bromide may be potentiated by concurrent use of other anticholinergic or analgesic drugs.

Concomitant use of inducers of hepatic microsomal enzymes (e.g., barbiturates, phenylbutazone) reduces the half-life period and hence the duration of action of metamizole. Simultaneous administration of neuroleptics, especially phenothiazine derivatives, may lead to severe hypothermia. Furthermore, the risk of gastrointestinal bleeding is increased upon concurrent use of glucocorticoids. The diuretic effect of furosemide is attenuated.

Co-administration of other weak analgesics increases the effects and side-effects of metamizole.

The anticholinergic action of quinidine and antihistaminic as well as the tachycardic effects of  $\beta$  sympathomimetics may be enhanced by this veterinary medicinal product.

For Animal Treatment Only.

Keep out of the sight and reach of children.

Veterinary Medicinal Product authorised for use in IE and UK.

To be supplied only on veterinary prescription.

To be used in accordance with the directions of a veterinary surgeon.

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

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

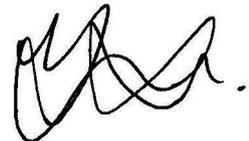
**14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

September 2022

**15. OTHER INFORMATION**

UK: Vm 08327/4292

IRELAND: VPA 10454/004/001

A handwritten signature in black ink, consisting of several loops and a final horizontal stroke.

Approved: 28 September 2022