

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BENADIL 5 mg, film-coated tablets for dogs and cats (BE, CZ, DE, HU, LU, NL, PL, PT, SK)

BENADIL 5, film-coated tablets for dogs and cats (FR)

KELAPRIL 5 mg, film-coated tablets for dogs and cats (UK)

Benazepril hydrochloride

2. STATEMENT OF ACTIVE SUBSTANCES

One tablet contains:

Active substance:

4.6 mg benazepril

(equivalent to 5 mg benazepril hydrochloride)

Excipients:

Titanium dioxide (E171) 0.52 mg

Iron oxide yellow (E172) 0.06 mg

3. PHARMACEUTICAL FORM

Film-coated tablets

4. PACKAGE SIZE

28 tablets – 98 tablets

5. TARGET SPECIES

Dogs and cats

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNINGS, IF NECESSARY

User warnings

Pregnant women and women of child-bearing age should exercise caution when handling this product – read package leaflet before use.

10. EXPIRY DATE

EXP.:

Tablet halves should be used within 2 days.

11. SPECIAL STORAGE CONDITIONS

Store below 25°C in the original package.

Store in a dry place.

Each time an unused half tablet is stored, it should be returned to the open blister space inserted back into the cardboard box and used at the next administration.

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

Richter Pharma AG
Feldgasse 19
4600 Wels
Austria
regulatory.affairs@richter-pharma.at

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER’S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS
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Blister containing 14 film-coated tablets.

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BENADIL 5, film-coated tablets for dogs and cats (FR)

KELAPRIL 5 mg, film-coated tablets for dogs and cats (UK)

Benazepril hydrochloride

2. NAME OF THE MARKETING AUTHORISATION HOLDER
--

Richter Pharma AG

3. EXPIRY DATE

EXP:

4. BATCH NUMBER

Lot:

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.