

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 20 mg, film-coated tablets for dogs (BE, CZ, DE, HU, LU, NL, PL, PT, SK)

BENADIL 20, film-coated tablets for dogs (FR)

KELAPRIL 20 mg, film-coated tablets for dogs (UK)

Benazepril hydrochloride

2. STATEMENT OF ACTIVE SUBSTANCES

One tablet contains:

Active substance:

18.4 mg of benazepril
(equivalent to 20 mg benazepril hydrochloride)

Excipients:

Titanium dioxide (E171) 0.52 mg

Iron oxide red (E172) 0.06 mg

3. PHARMACEUTICAL FORM

Film-coated tablets

4. PACKAGE SIZE

28 tablets – 98 tablets

5. TARGET SPECIES

Dogs

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
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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 30°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”
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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)
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17. MANUFACTURER’S BATCH NUMBER
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Lot:

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

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BENADIL 20, film-coated tablets for dogs (FR)

KELAPRIL 20 mg, film-coated tablets for dogs (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.