BECORDIL®

BENAZEPRIL HYDROCHLORIDE

Angiotensin-Converting Enzyme (ACE) Inhibitor for Dogs.

VETERINARY USE

FORMULA

Each tablet of BECORDIL® 5,0 mg contains:

Benazepril hydrochloride ..... 5,0 mg

Excipients q.s.p ..... 180 mg

TECHNICAL INFORMATION

Benazepril hydrochloride is a prodrug that, when administered orally (PO), is hydrolyzed in the liver to its active metabolite, benazeprilat. Benazeprilat is a selective angiotensin-converting enzyme (ACE) inhibitor, which prevents the conversion of inactive angiotensin I into active angiotensin II. Thereby, it reduces aldosterone synthesis, preventing the vasoconstriction of arteries and veins and the retention of sodium and water by the kidneys. Following benazepril oral administration to dogs, peak levels are quickly achieved (Tmax 0.5 hour) and rapidly reduced as the drug is partially metabolized by liver enzymes to benazeprilat. Benazepril and benazeprilat are extensively bound to plasma proteins (85-90%) and no significant difference in the pharmacokinetics of benazeprilat is observed when benazepril is administered to fed or fasted dogs. Benazeprilat is excreted in dogs via the biliary and urinary routes.

INDICATIONS

BECORDIL® is indicated to inhibit the action of angiotensin-converting enzyme (ACE) in dogs.

THE EFFICACY OF THIS PRODUCT HAS NOT BEEN EVALUATED BY THE MINISTRY OF AGRICULTURE, LIVESTOCK AND SUPPLY.

DOSAGE AND HOW TO USE

BECORDIL® should only be administered by the oral route. The recommended dose is 0.5 mg/kg every 24 hours, according to the table below:

Animal weight in kg	BECORDIL® 5.0 mg 0.5 mg/kg dose every 24 hours
2,5	¼ co¼ tablet
5,0	½ tablet
7,5	¾ tablet
10	1 tablet
15	1 ½ tablet
20	2 tablets
25	2 ½ tablets
30	3 tablets

CONTINUOUS USE MEDICATION. TREATMENT DURATION MUST BE ASSESSED BY THE PET'S VETERINARIAN.

CONTRAINDICATIONS

Do not administer **BECORDIL®** in cases of hypersensitivity to benazepril or any of the components of the formula.

This drug is not recommended for use in hypotensive, hypovolemic dogs with hypernatremia or acute renal failure. Do not use in cases of low cardiac output in animals with aortic valve stenosis, nor in breeding animals, pregnant or lactating female dogs, and in animals under 1 year of age.

DRUG INTERACTIONS

In dogs with congestive heart failure, benazepril has been administered in combination with digoxin, diuretics, pimobendan, and antiarrhythmic agents, without evidence of related adverse reactions. The combination of benazepril with potassium-sparing diuretics (e.g., spironolactone) can cause hyperkalemia. Thus, monitoring of serum potassium is

recommended. The combination of ACE inhibitors and non-steroidal anti-inflammatory drugs (NSAIDs) should be avoided, as it may reduce antihypertensive efficacy or impair renal function. The combination of benazepril with other antihypertensives (e.g. calcium-channel blockers, beta-blockers or diuretics) may cause additive hypotensive effects. The monitoring of renal function, serum sodium and potassium, and systemic blood pressure is recommended in all dogs treated with angiotensin-converting enzyme (ACE) inhibitors and diuretics.

SIDE EFFECTS
The safety study conducted with **BECORDIL®** at the recommended dose for up to 60 days demonstrated that the product is safe for use in dogs. No abnormalities were observed in hematological, biochemical, urinalysis and electrolyte testing. No changes have been observed in electrocardiogram, echocardiogram, blood pressure and physical examination parameters throughout the treatment period. In animals receiving twice the recommended dose, a slight increase in serum urea levels was observed after the 58th day, an effect already predicted with overdose.

PRECAUTIONS
It is recommended to monitor systemic blood pressure and serum levels of sodium, potassium and creatinine in dogs receiving **BECORDIL®**, like with all other angiotensin-converting enzyme inhibitors (ACE).

POISONING AND OVERDOSE
In cases of poisoning or overdose, seek the advice of a veterinary doctor for supportive treatment and evaluation. Marked hypotension, vomiting, weakness, pale mucosa, tachycardia and secondary kidney failure may occur in cases of severe accidental overdose. When twice the recommended dose was administered for 60 days, a slight increase in serum urea levels was observed.

WARNINGS
Veterinary products must be kept out of the reach of children and pets. They should not be stored near food, drinks or personal hygiene products. This product should only be administered as recommended in the package leaflet and under the prescription of a veterinarian.
In case of accidental intake, seek the emergency service, taking the product package and leaflet with you. Pregnant women should take special care to avoid accidental oral exposure, as ACE inhibitors are known to be harmful to the unborn fetus.

HOW SUPPLIED
Cartridge with 1 aluminum blister containing 4 bisected tablets each (FREE SAMPLE).
Cartridge with 3 aluminum blisters containing 10 bisected tablets each.

STORAGE RECOMMENDATIONS
Store this product in a dry place at room temperature (15oC to 30oC) away from direct sunlight and out of the reach of children and pets. In case of accidental ingestion, seek medical attention and take the product package with you.

Lot, manufacturing and expiration date: see packaging.

SALE UNDER THE VETERINARY DOCTOR'S PRESCRIPTION AND APPLICATION.

Provisionally registered with the Ministry of Agriculture, Livestock and Food Supply under no 112/2021 on 5/03/2022.

Owner and manufacturer:
Biolab Sanus Farmacêutica Ltda.
Av. Francisco Samuel Lucchesi Filho, 1039 - Bragança Paulista - SP
CEP: 12929-600 - CNPJ: 49.475.833/0018-46 - SAC: 0800 941 5566

Responsible technician: Daniela Ziolkowski - CRF-SP 29.486

Expiry date: 24 months after the manufacturing date.

Avert