▼BEYONTTRA® (acoramidis) 356 mg film-coated tablets

Prescribing Information: United-Kingdom

(Refer to full Summary of Product Characteristics (SmPC) before prescribing)

Presentation: 356mg acoramidis tablet. **Indication:** Beyonttra is indicated for the treatment of wild-type or variant transthyretin amyloidosis in adult patients with cardiomyopathy (ATTR-CM). **Posology & method of administration:** ***Adults*:** Treatment should be initiated by a physician knowledgeable in the management of patients with transthyretin amyloid cardiomyopathy (ATTR-CM). The recommended dose of acoramidis is 712 mg (two tablets, 356 mg) orally, twice daily, corresponding to a total daily dose of 1 424 mg. There are no efficacy data in patients with New York Heart Association (NYHA) Class IV. No double dose should be taken to make up for missed individual doses. Dosing should resume at the next scheduled time. ***Elderly:*** No dose adjustment is necessary in elderly patients (≥ 65 years). ***Renal impairment:*** Based on low renal clearance of acoramidis, no dose adjustment is required. Data in patients with severe renal impairment (CrCl < 30 mL/min) are limited and there are no data for patients on dialysis. Hence acoramidis should be used with caution in this population. ***Hepatic impairment:*** Acoramidis has not been studied in patients with hepatic impairment and therefore is not recommended for use in this population. ***Paediatric population:*** There is no relevant use of acoramidis in the paediatric population for the indication of "the treatment of wild-type or variant transthyretin amyloidosis with cardiomyopathy". ***Method of administration:*** Oral use. The film-coated tablets should be swallowed whole. Can be taken with water, with or without food. **Contra-indications:** Hypersensitivity to the active substance or to any of the excipients. **Warnings & precautions:** ***Hepatic impairment:*** Acoramidis has not been studied in patients with hepatic impairment and therefore is not recommended for use in this population. ***Renal impairment***: Data in patients with severe renal impairment (CrCl < 30 mL/min) are limited and there are no data for patients on dialysis. Hence acoramidis should be used with caution in this population. ***Renal haemodynamic parameters:*** Patients treated with acoramidis experienced an initial decrease in estimated glomerular filtration rate (eGFR) in the first month of treatment and a corresponding increase in measured serum creatinine. ***Information about excipients***: This medicinal product contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'. **Interactions:** Based on clinical study in healthy adult volunteers, inhibition of OAT-1 and OAT-3 is not expected to result in clinical relevant drug-drug interactions with OAT-1/OAT-3 substrates (e.g. NSAIDs, bumetamide, furosemide, lamivudine, methotrexate, oseltamivir, tenofovir, ganciclovir, adefovir, cidofovir, zidovudine, zalcitabine). Based on *in vitro* study, no drug-drug interaction with co-administered BCRP substrates is anticipated at clinically relevant concentrations. Based on in vitro studies, acoramidis is unlikely to cause any clinically relevant uridine 5'-diphospho (UDP)-glucuronosyl transferase-dependent or Cytochrome P450 dependent interactions. However, acoramidis was shown to be an inhibitor of CYP2C8 and CYP2C9 in vitro. No in vivo study has been performed. Therefore, concomitant CYP2C8 and CYP2C9 substrates with narrow therapeutic index should be used with caution. Based on population pharmacokinetic (PK) analysis, concomitant diuretic use in patients does not affect steady-state plasma acoramidis concentrations. No dedicated *in vivo* drug-drug interaction study with gastric acid reducing agents was performed. Thus, the effect of gastric acid reducing agents on the pharmacokinetics of acoramidis is unknown. Acoramidis may decrease serum concentrations of free thyroxine without an accompanying change in thyroid stimulating hormone (TSH). No corresponding clinical findings consistent with thyroid dysfunction have been observed. **Pregnancy & lactation:** There are no data from the use of acoramidis in pregnant women. Studies in animals have shown developmental toxicity at a dose which also caused maternal toxicity. Acoramidis is not recommended during pregnancy and in women of childbearing potential not using contraception. It is unknown whether acoramidis or its metabolites are excreted in human milk. A risk to the newborns/infants cannot be excluded. Acoramidis should not be used during breast-feeding. No human data on fertility is available. Impairment of fertility has not been observed in non-clinical studies in supratherapeutic exposures. **Undesirable effects:** *Very common*: Diarrhoea, gout. Prescribers should consult the SmPC in relation to other side effects. **Overdose:** There is no clinical experience with overdose. In case of suspected overdose, treatment should be symptomatic and supportive. **Legal Category:** POM. **Package Quantities & Basic NHS Costs:** 356mg x 120 tablets £8,547.60 **MA Number(s):** PL 00010/0763. **Further information available from:** Bayer plc,400 South Oak Way, Reading RG2 6AD, United Kingdom. Telephone: 0118 206 3000.

Date of preparation: April 2025

Beyonttra® is a trademark of the Bayer Group

Reporting adverse events and quality complaints

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. Adverse events should be reported. Reporting forms and information can be found at http://yellowcard.mhra.gov.uk/ or search MHRA Yellow Card in Google Play or Apple App Store.

Adverse events should also be reported to Bayer plc. If you want to report an adverse event or quality complaint, reports can be directed to: Tel: 0118 2063500 or Email: pvuk@bayer.com
Further information is available on the "contact" tab at www.bayer.co.uk