**Package leaflet: Information for the patient**

**BEYONTTRA 356 mg film-coated tablets**
acoramidis

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**



## 1. What BEYONTTRA is and what it is used for

BEYONTTRA contains the active substance acoramidis (as hydrochloride). It belongs to a group of medicines called transthyretin (TTR) stabilisers. A stabiliser prevents the TTR protein from breaking apart, which slows down the progression of your disease.

It is used to treat adults with cardiomyopathy (a disease that affects the heart muscle) resulting from transthyretin amyloidosis (ATTR-CM).

In people with transthyretin amyloidosis, a protein called transthyretin (TTR) does not work properly, causing it to break up and form fibrous clusters called amyloids. When amyloids form in the heart, the heart muscle stiffens, and the heart can no longer work normally. BEYONTTRA stabilises TTR, which can prevent it from breaking up and forming amyloids. This helps people whose heart has been affected by transthyretin amyloidosis cardiomyopathy.

## 2. What you need to know before you take BEYONTTRA

**Do not take BEYONTTRA**

If you are allergic to acoramidis or any of the other ingredients of this medicine (listed in section 6).

**Warnings and precautions**

Talk to your doctor, pharmacist or nurse before taking BEYONTTRA, especially if you have liver or severe kidney problems.

When starting your treatment you may experience changes in your kidney function blood tests, but these changes should not be harmful to your kidneys.

**Children and adolescents**

BEYONTTRA is not used in children and adolescents. Its use has not been studied in this population.

**Other medicines and BEYONTTRA**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

BEYONTTRA may change your thyroid blood tests, but these changes should not be harmful to your thyroid function.

**Pregnancy, breast-feeding and fertility**

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine as it is not known if BEYONTTRA may harm the unborn baby.

It is not known whether this medicine passes into breast milk. If you are breast-feeding or plan to breast feed, ask your doctor or pharmacist for advice before taking this medicine. There are no data on the use of BEYONTTRA in pregnant women.

**Driving and using machines**

BEYONTTRA has no or negligible influence on your ability to drive and use machines.

**Sodium**

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

## 3. How to take BEYONTTRA

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is two film-coated tablets (712 mg) taken by mouth twice a day. The total daily dose is 1 424 mg acoramidis.

BEYONTTRA tablets should be swallowed whole. You can take them with water, with or without food. Take 2 tablets in the morning (sun symbol on the blister) and 2 tablets in the evening (moon symbol on the blister).

**If you take more BEYONTTRA than you should**

Do not take more tablets than your doctor told you to take. Contact your doctor if you think you have taken too much of this medicine.

**If you forget to take BEYONTTRA**

If you forgot to take your tablets, take them at the next usual time. Do not take a double dose to make up for a forgotten dose.

**If you stop taking BEYONTTRA**

Do not stop taking BEYONTTRA without first speaking to your doctor. Your disease may progress if you stop taking BEYONTTRA.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The possible side effects are:

Very common (may affect more than 1 in 10 people)
- diarrhoea
- painful inflammation in the joints (gout)

**Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, Website: https://yellowcard.mhra.gov.uk or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

## 5. How to store BEYONTTRA

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 6. Contents of the pack and other information

**What BEYONTTRA contains**

- The active substance is acoramidis (as hydrochloride). Each tablet contains acoramidis hydrochloride equivalent to 356 mg acoramidis.
- The other ingredients are: microcrystalline cellulose (E 460), croscarmellose sodium (E 468), colloidal hydrated silica (E 551), magnesium stearate (E 470b), macrogol poly(vinyl alcohol) grafted copolymer (E 1209), talc (E 553b), titanium dioxide (E 171), glyceryl monocaprylocaprate Type I (E 471), poly(vinyl alcohol) (E 1203), iron oxide black (E 172), propylene glycol (E 1520), hypromellose 2910 (E 464).

See section 2 for information regarding sodium.

**What BEYONTTRA looks like and contents of the pack**

BEYONTTRA 356 mg film-coated tablets (tablets) are white and oval, approximately 15 mm long × 7.5 mm wide, printed with “BEYONTTRA” in black ink on one side.

BEYONTTRA is available in dual-cavity blisters of PVC/PCTFE with aluminium foil lidding in a pack containing 120 tablets.

**Marketing Authorisation Holder**
Bayer plc
400 South Oak Way
Reading
RG2 6AD, UK

**Manufacturer**
Rottendorf Pharma GmbH
Ostenfelder Strasse 51-61
Ennigerloh, 59320
Germany

For any information about this medicine, please contact the Marketing Authorisation Holder:

Bayer plc
Tel: +44-(0)118 206 3000

**This leaflet was last revised in July 2025**