

Bezafibrate for Primary Biliary Cholangitis (PBC)

Information for patients



Abdominal Medicine
and Surgery

This leaflet aims to answer your questions about taking bezafibrate to treat your primary biliary cholangitis (PBC). If you have any questions or concerns, please speak to a doctor, pharmacist or nurse caring for you.

What is bezafibrate?

Bezafibrate is a medication licensed for the treatment of high cholesterol. It is used 'off licence' for treatment of primary biliary cholangitis (PBC). 'Off licence' means that the medication is used for a different condition than it is licensed for.

There is no cure for PBC, but for many people, licenced medicines such as ursodeoxycholic acid (UDCA) and obeticholic acid (OCA) are effective at controlling the disease; however, some people do not tolerate or are not suitable for these, or may need bezafibrate in addition.

Bezafibrate is generally well-tolerated and has few side-effects but does require monitoring with blood tests when it is first started. Some studies have also shown that bezafibrate can reduce itching, which can be very severe in some patients with PBC.

The information contained within this patient information leaflet should also be read alongside the patient information leaflet provided by the manufacturer.

How do I take the medicine?

Most patients will be prescribed a modified-release (MR) 400 mg tablet to be taken once a day. This may be changed to 200 mg standard release tablets depending on your kidney function.

You should swallow bezafibrate tablets whole with a glass of water. Take it either in the morning or evening, ideally, during or after a meal. Take it at the same time each day.

What should I do if I forget to take the medicine?

If you forget to take your bezafibrate tablet, take it as soon as you remember; however, if it is close to the time for your next dose, skip the missed dose and go back to your normal time. Do not take 2 doses at the same time or extra doses.

Are there any side-effects?

Like all medicines, bezafibrate may cause side-effects; however, most patients taking bezafibrate tablets have no side effects or they are only mild.

You must stop taking bezafibrate and contact the liver team or a doctor immediately if:

- you experience any signs of an allergic reaction (e.g. rash, hives, itching, wheezing, tightness in the chest or throat, trouble breathing, swallowing, or talking; or swelling of the mouth, face, lips, tongue or throat).

The most commonly reported side-effects include gastrointestinal problems (including stomach pain, heartburn, upset stomach, diarrhoea or constipation, or not feeling hungry). These side-effects are generally mild, and generally resolve themselves. Speak to the Liver team if you do experience side-effects.

Serious side-effects

If you develop any of the following side-effects or symptoms, seek medical advice:

- dark urine, feeling tired, not hungry, upset stomach or stomach pain, light-coloured stools, vomiting, or yellow skin or eyes;
- sudden pain in the upper right belly area, right shoulder area, or between the shoulder blades; yellow skin or eyes; or fever with chills; and
- muscle pain or weakness.

Our contact details are at the end of this leaflet.

Is there anything else I need to know?

You will have blood tests before starting treatment, then 3 and 6 months after starting treatment. After this, you will have blood tests every 6 months whilst on bezafibrate.

Other medications:

If you start on any new medicines while taking your bezafibrate tablets, ensure that the prescriber is aware that you are taking bezafibrate.

If you are already taking or start a statin medication (e.g. simvastatin, atorvastatin, rosuvastatin), you will need close monitoring (with blood tests) to ensure that the combination of bezafibrate and a statin is safe. You should also be aware of any muscle pain and contact a health professional if you experience this.

How do I get a repeat prescription?

The hospital will provide you with bezafibrate supply for 3 months. After this, we will ask your GP and community pharmacy to take over supply.

Useful sources of information

PBC Foundation

Tel: **0131 5566811**

website: www.pbcfoundation.org.uk

British Liver Trust

Tel: **0800 652 7330**

website: www.britishlivertrust.org.uk

UK-PBC - Stratified Medicine in Primary Biliary Cholangitis

website: www.uk-pbc.com

Contact details

If you have any questions or concerns about bezafibrate, please contact us using the details below:

Liver Secretaries:

Tel: **0113 2069275**

Specialist Nurse:

Tel: **0113 2069275**

Email: leedsth-tr.hepatologypatientadvice@nhs.net

Liver Pharmacy Team:

Tel: **0113 2066826**

Email: leedsth-tr.mmpsliverteam@nhs.net



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