LENS

Lowering Events in Non-proliferative retinopathy in Scotland

This leaflet contains important information relating to your LENS trial treatment. Please read all the information contained in this leaflet very carefully. If you have any questions about your treatment feel free to call the LENS research team: **Freephone 0808 164 5090**

Please keep this information leaflet in a safe place for future reference.

Initial Run-in phase

After your screening visit if you are suitable to take part, you will enter the "Run-in phase". You will be sent a 10 week supply of **fenofibrate tablets and a letter, separately,** by post. The letter will inform you how often to take the tablets, either one tablet daily OR one tablet every second day. It is preferable that you take the fenofibrate tablets in the morning.

Main trial

At your second visit, called the Randomisation visit, the research nurse will check how well you have managed during the Run-in phase and further blood tests will be taken. After your blood results have been checked, you will be sent a letter to confirm if you may continue in the trial. You will be randomly allocated to receive tablets containing either fenofibrate 145 mg, or placebo. Nobody in the research team to whom you might speak will know which treatment you have been allocated.

The letter will also explain how often to take the tablets, as in the Run-in, you will be asked to take either one tablet each day OR one tablet every second day. This information will be printed on the pack label of study tablets. You will be sent packs of study treatment by post, once every 6 months.

About your trial treatment

Fenofibrate 145mg or matching placebo tablets

- Oral use
- Store below 30°C
- Protect from moisture
- Keep out of the sight and reach of children
- For clinical trial use only
- Do not take study medication beyond its expiry

- You will receive an email or text alert each time your treatment supplies have been dispatched.
- During the Run-in phase, following your screening visit, you should either take one fenofibrate 145mg tablet each day or one fenofibrate 145mg tablet every second day. You will receive a letter to tell you which of these options is right for you.
- Please bring back all remaining Run-in tablets when you return for your Randomisation visit.
- During the main trial, you will be instructed to take either one study tablet each day or one study tablet every second day, just like in the Run-in period. You will receive another letter to tell you which of these options is right for you.
- When you receive a new study treatment pack, please continue to take the study medication you already have until it is finished before starting the new pack (unless the expiry date has passed).
- If you forget to take a tablet at your usual time, you may still take it later the same day. However, if you miss a whole day or more, do not try to make up for the missed tablets. Instead, leave them in the pack and continue from the day you restart.
- If you lose your study treatment, please call the LENS office and we will arrange for replacement treatment to be sent to you.
- For women: if you become pregnant while taking the study tablets please stop them immediately and call the research team at **Freephone 0808 164 5090** as soon as possible.

Possible side effects

Fenofibrate treatment is typically well tolerated and fenofibrate can be safely taken by patients who already take statins.

Taking fenofibrate is known to modestly increase the levels of a substance in the blood called *creatinine*. Creatinine is a marker of your kidney function. However, levels of creatinine go back to your normal level as soon as fenofibrate is stopped so there is no evidence that fenofibrate harms the kidney. Importantly, however, your kidney function determines whether you should take fenofibrate every day or every second day. The Run-in phase will therefore allow us to choose the best treatment strategy for you and will allow us to see if you have any side-effects while taking fenofibrate. In addition, we will monitor all blood tests that you may have taken at your GP practice or at hospital. If these suggest that you need to take the study tablets less often or that you need to stop taking the study tablets, the research team will contact you. Similarly, if any doctor looking after you has any queries or concerns related to the study, they can contact the research team at any time.

Further information about fenofibrate is given in your **LENS Participant Information Leaflet**. If any important new information about fenofibrate arises during the course of the study, the research team will contact you. Updated information will also be available on the study website (www.ctsu.ox.ac.uk/lens).

Should you feel that any side-effect of the study tablets becomes intolerable for you, you are of course free to stop taking them at any time.

You will be asked to complete a LENS questionnaire, either by phone or on your computer, every 6 months. You will also have the opportunity to mention any major problems on these questionnaires.

Other medications

Fenofibrate can be taken along with most other medicines including statins. There are certain medicines which should not be taken along with fenofibrate and these are listed below. Apart from warfarin, most of these are seldom used.

It is important that any doctor treating you (including your GP) knows that you are taking part in LENS so any prescription they give you will also be compatible. We will write to your GP to confirm your participation so that they are aware of this but you should also remind them that you are taking part when you attend for any reason. They may also call **Freephone 0808 164 5090** with any queries.

Specific medicines to be avoided during LENS:

Type of treatment	**Name of drug**
A specific group of blood thinning medicines (called Vitamin K antagonists)	wafarin acenocoumarol phenindione
Immunosuppressant	cyclosporin
Gout medication	colchicine
Anti-inflammatory medication	ketoprofen
Antibiotic	daptomycin
Other fibrates or similar drugs	bezafibrate Ciprofibrate
Lipid modification	rosuvastatin (40mg)

Questions about the study treatments may be directed to:
LENS, Clinical Trial Service Unit (CTSU)
Richard Doll Building, University of Oxford
Roosevelt Drive, OXFORD, OX3 7LF

Tel: 0808 164 5090 (Freephone)
Email: lens@ndph.ox.ac.uk Website: www.ctsu.ox.ac.uk/lens