

PACKAGE LEAFLET: INFORMATION FOR THE USER

BritLofex TABLETS 0.2mg LOFEXIDINE HYDROCHLORIDE

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- This leaflet does not contain all the information about your medicine.
- If you have any further questions, ask your doctor or community drugs worker.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or community drugs worker.

In this leaflet:

1. What BritLofex is and what it is used for
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1. WHAT BRITLOFEX IS AND WHAT IT IS USED FOR

BritLofex belongs to a group of medicines called alpha₂ adrenergic agonists and is an imidazoline derivative.

The tablets are taken to relieve the symptoms such as chills, sweating, stomach cramps, muscle pain and runny nose which you experience when you stop taking an opiate (e.g. methadone, heroin, dihydrocodeine etc.)

BritLofex will not stop you from craving opiates.

2. BEFORE YOU TAKE BRITLOFEX

Do not take BritLofex if:

- you are allergic to Lofexidine or to other imidazoline derivatives or to any ingredients of BritLofex (see Section 6 for a full list of ingredients).

Take special care with BritLofex

Before taking BritLofex tablets, tell your doctor or community drugs worker if:

- you are, or think you might be, pregnant;
- you are breast-feeding;
- you have a heart condition (e.g. angina), or have had a recent heart attack;
- you have a low pulse rate;
- you have low blood pressure;
- you have a low potassium level
- you have kidney problems;
- you suffer from depression;
- you are taking tablets for depression;
- you are taking barbiturates or other sedatives;
- you have ever had a stroke;
- you have been diagnosed with the heart condition QT prolongation or have a family history of QT problems;
- you are elderly (aged 65 and over) and are receiving treatment for high blood pressure.

Taking other medicines

Certain medicines need to be used with caution whilst taking BritLofex. Please consult your doctor or community drugs worker if you are currently taking, or intend to take any other medication whilst taking BritLofex.

BritLofex may increase the effects of alcohol, medicines called barbiturates and other drugs that make you sleepy.

BritLofex may increase the effects of medicines used to lower high blood pressure and it could make your blood pressure drop too low.

Taking medicines known as tricyclic antidepressants may reduce the effects of BritLofex.

Other medicines known to change heart rhythm or alter the balance of electrolytes (e.g. sodium, potassium etc) should be avoided. Taking these drugs with BritLofex may increase the risk of QT prolongation.

Taking BritLofex with food and drink

It is recommended that you do not drink alcohol or take opiates while you are undergoing detoxification with BritLofex.

Pregnancy and breast-feeding

Ask your doctor or community drugs worker for advice before taking any medicine.

Driving and using machines

BritLofex tablets may make you feel light-headed or drowsy. You must not drive or operate machinery if you feel light-headed or drowsy.

Important information about some of the ingredients of BritLofex

- BritLofex tablets contain sunset yellow (E110) which can cause allergic reactions. If you have ever been told that you are allergic to sunset yellow (E110), contact your doctor **before** taking this medicine.
- BritLofex tablets contain lactose (a kind of sugar). If you have ever been told that you have intolerance to some sugars, contact your doctor **before** taking this medicine.

WARNING!

If you are unable to continue with your detoxification programme you should contact your doctor or community drugs worker as soon as possible.

3. HOW TO TAKE BRITLOFEX

Read the label on your medicine before you start to take it. Your doctor or community drugs worker will tell you when and how often to take the tablets.

Your doctor or community drugs worker will explain how to stop using opiates and the course of treatment to follow during the withdrawal stages. Please follow these instructions as closely as possible:

- On the first day the usual dose is 4 tablets.
- After that, the dose can then be increased gradually, depending on the severity of your symptoms, but any increase must not be more than 4 tablets a day.
- The maximum daily dose is 12 tablets.
- You must not take more than 4 tablets at a time.

Sometimes the dosage may differ from this. For example, you may be prescribed a higher starting dose. Your doctor or community drugs worker will tell you the number of tablets you need to take each day.

BritLofex is usually taken for 7–10 days. Sometimes, however, it may be taken for a longer or a shorter time. Your doctor or community drugs worker will tell you how long to take the tablets for.

When the withdrawal symptoms are less severe the daily dose of BritLofex can be reduced, **gradually**. **You should never stop taking these tablets suddenly**.

Swallow your tablets **whole**, with a drink of water.

BritLofex tablets are not suitable for children (aged under 18).

If you take more BritLofex than you should

If you take more tablets than you have been told to, tell your doctor or community drugs worker or contact your nearest hospital emergency department **immediately**. Always take the tablets as your doctor or community worker has told you to.

If you forget to take BritLofex

If you forget to take a dose, take another as soon as you remember, but do not take more than 4 tablets at a time.

How to stop taking BritLofex

Never stop your tablets suddenly because your blood pressure might rise if you do so. The dose should be lowered **gradually**, over several days. Your doctor or community drugs worker will tell you how to do this.

After finishing your tablets

After completing the course of BritLofex tablets you should be detoxified from opiates and no longer have withdrawal symptoms. However, if you are still having withdrawal symptoms after you have finished your tablets, tell your doctor or community drugs worker.

Your doctor or community drugs worker will offer advice on how to remain opiate free.

4. POSSIBLE SIDE EFFECTS

If you experience an allergic reaction **stop** taking BritLofex and contact a doctor or your nearest hospital emergency department **immediately**. The signs of an allergic reaction may include:

- Rash
- Breathing difficulties
- Swelling of the face, lips, throat or tongue

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

BritLofex tablets may sometimes cause the following:

Very common side effects (more than 1 user in 10):

- light-headedness or dizziness
- feeling sleepy or falling asleep
- drop in blood pressure
- slow heart beat
- dry mouth or throat
- dry nose

Side effects with unknown frequency:

- an allergic reaction which may include:
 - Rash
 - Breathing difficulties
 - Swelling of the face, lips, throat or tongue
- changes in heart rhythm

If you think you have any of these or any other side effects not mentioned in the leaflet, contact your doctor or community drugs worker.

When you stop taking opiates, the withdrawal symptoms can make you feel unwell. If you think, however, that it is the BritLofex tablets which are making you feel unwell, tell your doctor or community drugs worker.

5. HOW TO STORE BRITLOFEX

- Always keep BritLofex and all other medicines out of the reach and sight of children.
- Do not use BritLofex after the expiry date which is printed on the pack. The expiry date refers to the last day of that month.
- Store your tablets below 25°C. Store them in the original package.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the safety of others and the environment.

Remember: this medicine is for you. Do not give it to others, even if they have the same symptoms as you.

You may want to read this leaflet again. Do not throw it away until you have finished your medicine.

6. FURTHER INFORMATION

If you are not already doing so, you may wish to contact your local drug addiction service. They will be able to offer you advice and support on how to come off drugs. You will find their address in the 'Yellow Pages' telephone directory under 'Counselling & Advice'.

What BritLofex contains

The **active** ingredient of each peach coloured BritLofex tablet is Lofexidine hydrochloride. Each tablet contains 0.2mg of Lofexidine hydrochloride.

The **other** ingredients are: lactose, citric acid, povidone, microcrystalline cellulose, calcium stearate, sodium lauryl sulphate, Opadry OY-S-9480 Brown (which contains sunset yellow-E110). These are included to help make the tablets.

What BritLofex looks like and contents of the pack

BritLofex tablets are round and peach coloured. They are supplied in packs of 60 tablets.

Marketing Authorisation Holder

The Marketing Authorisation is held by:-
Britannia Pharmaceuticals Ltd
Park View House, 65 London Road, Newbury
Berkshire, RG14 1JN, United Kingdom

Manufacturers

Stada Production Ireland Limited
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