

# Lyflex 5 mg/5 ml Oral Solution

## baclofen

**Read all of this leaflet carefully before you or your child starts 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 or pharmacist.
- This medicine has been prescribed for you. 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 of the side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet:**

1. What Lyflex is and what it is used for
2. What you need to know before you take Lyflex
3. How to take Lyflex
4. Possible side effects
5. How to store Lyflex
6. Contents of the pack and other information

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

Lyflex contains baclofen which is a muscle relaxant. Your doctor has decided that you or your child needs this medicine to help treat your condition. Baclofen is used to reduce and relieve the excessive tension in your muscles (spasms) occurring in various illnesses such as cerebral palsy, multiple sclerosis, cerebrovascular accidents, spinal cord diseases and other nervous system disorders. Because baclofen reduces spasms and the pain that goes with them, it helps to make you more mobile and better able to manage your daily activities.

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

**Do not take Lyflex:**

- if you are allergic to baclofen or to any of the other ingredients of this medicine (listed in section 6)
- if you have or have ever had stomach ulcers.

**Warnings and precautions**

Talk to your doctor before taking Lyflex

- if you have mental illness (e.g. schizophrenia, depression)
- if you have Parkinson's disease
- if you have epilepsy
- if you have high blood pressure or if you take any blood pressure medication
- if you have blood vessel disease or stroke
- if you have lung problems which make breathing difficult
- if you have liver or kidney problems
- if you have diabetes
- if you have difficulty in passing urine
- if you have a history of drug abuse or dependence

Some people being treated with baclofen have had thoughts of harming or killing themselves or have tried to kill themselves. Most of these people also had depression, had been using alcohol excessively or were prone to having thoughts of killing themselves. If you have thoughts of harming or killing yourself at any time, speak to your doctor straightaway or go to a hospital. Also, ask a relative or close friend to tell you if they are worried about any changes in your behaviour and ask them to read this leaflet.

If you are going to have an operation of any kind, make sure that the doctor knows that you are taking Lyflex.

**Other medicines and Lyflex**

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

Some medicines may be affected by Lyflex or they may affect how well Lyflex will work. Tell your doctor or pharmacist:

- if you are taking medicines which slow down the nervous system, e.g. anti-histamines such as promethazine, sedatives such as temazepam, opiates for pain relief such as morphine and anti-convulsants (anti-epileptic medicines such as carbamazepine), or medicines containing alcohol
- if you are taking other medicines to relax muscles e.g. tizanidine
- if you are taking medicines used to treat mood disorders and depression, such as lithium or tricyclic antidepressants such as amitriptyline
- if you are taking medicines for high blood pressure e.g. diltiazem

- if you are taking anti-inflammatory medicines for arthritis or pain, such as ibuprofen
- if you are taking medicines for Parkinson's disease e.g. levodopa or carbidopa.

**Lyflex with alcohol**

Lyflex may increase the effect of alcohol. Drinking alcohol while taking Lyflex may cause you to feel sleepy. If you feel that the alcohol is affecting you more than usual, do not drink alcoholic drinks.

**Pregnancy, breast-feeding and fertility**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Lyflex can be passed to your unborn or breast-fed baby. If you have to take Lyflex during pregnancy, your unborn baby will also be exposed to baclofen. After birth your baby may develop withdrawal symptoms such as convulsions (symptoms of withdrawal are described in the section "If you stop taking Lyflex").

**Driving and using machines**

Some people may feel drowsy and/or dizzy or have problems with their eyes while they are taking Lyflex. If this happens, you should not drive or do anything that requires you to be alert (such as operate tools or machinery) or perform any tasks that may require you to be alert until these effects have worn off.

**Lyflex contains:**

■ **sorbitol (E 420)**

This medicine contains 2.21 g sorbitol (E 420) in each 5 ml which is equivalent to 442.3 mg/ml.

Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

■ **methyl parahydroxybenzoate (E 218) and propyl parahydroxybenzoate (E 216)**

These may cause allergic reactions (possibly delayed).

■ **propylene glycol (E 1520)**

This medicine contains 5.25 mg propylene glycol (E 1520) in each 5 ml which is equivalent to 1.05 mg/ml. If your baby is less than 4 weeks old, talk to your doctor or pharmacist before giving them this medicine, in particular if the baby is given other medicines that contain propylene glycol or alcohol.

■ **sodium**

This medicine contains less than 1 mmol sodium (23 mg) in 5 ml, that is to say essentially 'sodium-free'. When the dose is greater than 30 ml it cannot be considered 'sodium free' and it should be taken into consideration by patients on a controlled sodium diet. At maximum daily dose (100 ml) this medicine contains 77 mg of sodium (main component of cooking/table salt). This is equivalent to 3.9% of the recommended maximum daily dietary intake of sodium for an adult.

### 3. How to take Lyflex

Check with your doctor or pharmacist if you are not sure.

**Starting doses**

**Children (infants and children up to 18 years):** the treatment is adjusted to their body weight. Children's treatment usually starts with very low dose (approximately 0.3 mg/kg/day), in 2-4 divided doses (preferably 4 doses).

**Adults:** the usual starting dose is 5 ml three times a day.

**Elderly and those with spasms from brain injury:** are more likely to get side effects, particularly at the start of treatment. Your doctor may lower the dose.

