

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. There have been reports of reduction in brain function (encephalopathy) in some patients taking Lyflex at prescribed doses, which resolved after stopping the medication. Symptoms include increased sleepiness, new onset of drowsiness, confusion, muscle jerks or coma. If you experience any of these symptoms, seek medical attention immediately. Your physician will decide whether baclofen has to be discontinued.

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

Always take this medicine exactly as your doctor has told you. 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.

Increasing and final dose

Children (infants and children up to 18 years): the dosage should be gradually increased until it becomes sufficient for the child's individual requirements, this may be between 0.75 and 2 mg/kg body weight. The total dose should not exceed a maximum of 40 ml a day in children below 8 years of age. In children over 8 years of age a maximum dose of 60 ml a day may be given.

Adults: your doctor may advise you to increase the dose gradually - i.e. every 3 days, until the appropriate final dose is reached. Your doctor will decide on the final dose, this will usually be up to 20 ml three times a day. The maximum dose is 100 ml a day, although if you are in hospital a higher dose may be used. Although Lyflex is usually taken three times a day, some patients may take it only at night or an hour before doing a task, such as washing, dressing, shaving, etc.

Patients with kidney problems: a lower dose of 5 ml daily is used.

Blood tests may be carried out during treatment, especially in those with diabetes or liver diseases.

Taking Lyflex long term

Continue taking Lyflex for as long as the doctor tells you to. Do not stop taking Lyflex, or lower the dose, without first checking with your doctor.

Method and administration

Take the solution **with food** or a milk drink if you find that taking it makes you nauseous (sick).

If you take more Lyflex than you should

If you take too much Lyflex or someone else accidentally takes your medicine, contact your doctor or your nearest hospital casualty department immediately. Take the bottle and any remaining solution with you so that people can see what you have taken.

- Signs of overdose may be:**
- unusual muscle weakness (too little muscle tone) or sudden contraction of your muscles
 - drowsiness
 - excessive salivation
 - feeling sick (nausea), being sick (vomiting) or diarrhoea
 - difficulty in breathing
 - fits (convulsions)
 - loss of consciousness
 - abnormally low body temperature
 - feeling confused or agitated
 - hallucinations
 - blurred vision
 - poor or absent reflexes
 - high or low blood pressure
 - slow, fast or irregular heart beat
 - pain in muscles
 - fever and dark urine (rhabdomyolysis)
 - ringing in the ears.

If you have **kidney disease** and have accidentally taken more tablets or more syrup than **your doctor** has prescribed, you may experience neurological symptoms of overdose (e.g. drowsiness, feeling confused, hallucinations).

If you forget to take Lyflex

If you forget to take a dose take it as soon as you remember, but if it is almost time for your next dose, skip the forgotten dose and continue as usual.

Do not take a double dose to make up for a forgotten dose.

If you stop taking Lyflex

Stopping this medicine suddenly may cause unwanted effects such as muscle spasms and increased muscle rigidity, feeling anxious or confused, changes in mood and emotion, mental disorders, hallucinations, fast heart rate, fever or convulsions (fits).

Talk to your doctor if you want to stop taking Lyflex. Your doctor will advise you how to stop the medicine gradually.

Do not let yourself run out of medicine especially over the weekend or on holidays.

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.

STOP taking the solution and seek medical help immediately if you have any of the following symptoms:

- severe itching of the skin, with a red rash or raised lumps.

Seek immediate medical attention if you have any of the following symptoms:

- excessive weakness of the limbs or feeling tired and exhausted
- feeling dizzy, light-headed, or fainting

- hallucinations, confusion
- mood changes (e.g. excitement or depression)
- blurred or double vision
- slow or difficult breathing
- skin rash
- difficulty in passing urine
- seizures (fits)
- slurred or slow speech
- low body temperature (less than 35°C), feeling cold with pale-looking skin.

The side effects listed below have been reported:

Very common side effects (may affect more than 1 in 10 people):

- sleepiness
- feeling nauseous (sick).

Common side effects (may affect up to 1 in 10 people):

- headache
- repetitive uncontrolled movement of the eyes or other eye problems
- low blood pressure (fainting)
- stomach problems including vomiting, retching, constipation or diarrhoea
- unsteadiness, trembling or other problems with muscle control
- increased need to pass urine
- aching muscles, muscle pain
- dry mouth
- excessive sweating
- nightmares or sleeplessness.

Rare side effects (may affect up to 1 in 1000 people):

- stomach ache
- liver problems
- convulsions (particularly in epileptics)
- sexual problems in men, e.g. impotence
- disturbed sense of taste
- increased muscle spasm
- numbness or tingling in the hands or feet.

Not known: frequency cannot be estimated from the available data

- slow heart beat
- increase in blood sugar
- trouble breathing during sleep (sleep apnoea syndrome)
- symptoms caused by stopping treatment suddenly (see section 3. How to take Lyflex)
- reduction in brain function (encephalopathy).

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 at: www.mhra.gov.uk/yellowcard 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 Lyflex

- Keep this medicine out of the sight and reach of children.
- Do not take after the expiry date which is stated on the bottle label and on the carton after EXP. The expiry date refers to the last day of that month.
- Do not use after eight weeks from the date of first opening.
- Do not store above 25°C. Store in the original package.
- 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 Lyflex contains

- The active substance is baclofen (5 mg per 5 ml).
- The other ingredients are: sorbitol (E 420), methyl parahydroxybenzoate (E 218), propyl parahydroxybenzoate (E 216), carmellose sodium, raspberry flavour (containing propylene glycol (E 1520)) and water. (See end of section 2 for further information on sorbitol, methyl parahydroxybenzoate, propyl parahydroxybenzoate, propylene glycol and sodium).

What Lyflex looks like and contents of the pack

Lyflex is a clear, slightly yellow liquid with the smell and flavour of raspberry.

It is available in amber glass bottles of 300 ml.

Marketing Authorisation Holder

Rosemont Pharmaceuticals Ltd, Leeds, LS11 9XE, UK.

Manufacturer

Delpharm Bladel BV, Industrieweg 1, 5531 AD Bladel, the Netherlands.

This leaflet was last revised in July 2024