

CLOFEN

baclofen

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about CLOFEN. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking CLOFEN against the benefits expected for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What CLOFEN is used for

CLOFEN belongs to a group of medicines called muscle relaxants.

This medicine is used to reduce stiffness and/or spasms in your muscles.

CLOFEN is used to control muscle spasms in conditions such as:

- multiple sclerosis
- spinal cord damage resulting from disease or physical injury

As this medicine reduces muscle spasms, it can help improve mobility and the management of daily activities.

CLOFEN may be used alone, or in combination with other medicines, to treat your condition.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

Before you take CLOFEN

When you must not take it

Do not take CLOFEN if you have an allergy to:

- any medicine containing baclofen
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not give this medicine to a child under the age of 16 years.

Safety and effectiveness in children younger than 16 years have not been established.

CLOFEN tablets are not suitable for use in children with a body weight below 33 kg.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you are pregnant or plan to become pregnant, or are breastfeeding or wish to breastfeed.

There is very little information on the use of this medicine in pregnancy or breastfeeding. Your doctor will discuss the risks and benefits of taking CLOFEN in pregnancy or when breastfeeding.

If you have to take CLOFEN when you are pregnant, your baby may have convulsions and other symptoms related to sudden discontinuation of the medicine following birth.

Tell your doctor if you have or have had any of the following medical conditions:

- a mental illness such as schizophrenia or depression
- Parkinson's disease
- epilepsy or any other condition that causes convulsions, fits or seizures
- stiffness and restriction of movement in a group of muscles
- stomach ulcers
- stroke or other blood vessel problems
- heart disease
- kidney disease
- liver disease
- lung or breathing problems
- diabetes

- porphyria, a rare disorder which can affect the liver and formation of blood cells
- alcoholism
- high blood pressure
- cerebral palsy
- rheumatoid disorders

If you have not told your doctor about any of the above, tell them before you start taking CLOFEN.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from a pharmacy, supermarket or health food shop.

Some medicines and CLOFEN may interfere with each other. These include:

- medicines that can make you sleepy, such as medicines used to help you sleep or calm you down (sleeping tablets or sedatives), pain relievers and medicines for hay fever or allergy, cough and cold, blocked nose
- some medicines used for depression such as tricyclic antidepressants, lithium and monoamine oxidase inhibitors (MAOIs)
- insulin and medicines used to treat diabetes
- medicines used to treat high blood pressure
- medicines used to treat Parkinson's disease, including selegiline, levodopa and carbidopa

You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take CLOFEN

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the bottle, ask your doctor or pharmacist for help.

How much to take

Treatment with CLOFEN is usually started in hospital using low doses.

The usual starting dose is 5 mg three times a day (15 mg per day).

Your doctor may increase the dose slowly depending on how you respond to CLOFEN.

Doses can range from 30 mg to 75 mg per day.

The maximum dose is 100 mg per day.

Your doctor will tell you how many tablets you need to take each day and when to take them.

People over 65 or below 16 years of age or have kidney problems your doctor may start you on a lower dose and increase it more gradually to prevent unwanted side effects.

How to take it

Swallow the tablets with a glass of water.

When to take it

Take CLOFEN at meal times.

This will lessen the chance of a stomach upset.

CLOFEN is usually taken as 3 divided doses throughout the day. However, your doctor may advise you differently depending on your situation.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

Your doctor will check your progress to make sure the medicine is working

for you and will discuss with you how long your treatment should continue for

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much CLOFEN.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

The main symptoms of overdose are: drowsiness, breathing difficulties, consciousness disorders and losing consciousness.

Other symptoms may include: feeling confused, hallucinations, being agitated, convulsing, blurred vision, unusual muscle slackness, sudden contraction of the muscles, poor or absent reflexes, fast or irregular heartbeat, low body temperature, feeling sick (nausea) or vomiting, , diarrhoea, increased saliva, trouble breathing when asleep (sleep apnoea), pain in your muscles, fever and dark urine (rhabdomyolysis).

If you have kidney disease and have accidentally taken more tablets than your doctor has prescribed, you may experience some neurological symptoms of overdose such as drowsiness, feeling confused or hallucinations.

While you are taking CLOFEN

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking CLOFEN.

Tell any other doctors, dentists and pharmacists who treat you that you are taking CLOFEN.

If you become pregnant while taking CLOFEN, tell your doctor immediately.

Keep all of your doctor's appointments so that they can check on your progress.

Your doctor may order some blood tests to prevent unwanted side effects, especially for people with liver problems or who have diabetes.

If your muscle spasms come back, tell your doctor.

Your doctor may change the dose of CLOFEN to make it work better for you.

Things you must not do

Do not stop taking CLOFEN, or change the dose, without checking with your doctor.

Stopping CLOFEN suddenly may cause unwanted effects such as severe muscle spasms, nervousness, feeling confused, hallucinations, abnormal thinking or behaviour, convulsions, uncontrollable twitching, jerking or writing movements, fast heartbeat, increased body temperature (fever), muscle pain and dark urine. The muscle spasms may get worse.

If you need to stop taking CLOFEN, your doctor will reduce the dose gradually over a period of 1 to 2 weeks so that these unwanted effects can be avoided.

Do not take CLOFEN to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful driving or operating machinery until you know how CLOFEN affects you.

This medicine may cause drowsiness or reduced alertness in some people, especially at the start of treatment. If any of these occur, do not drive, operate machinery or do anything else that could be dangerous.

Be careful when drinking alcohol while taking CLOFEN.

The combination of CLOFEN and alcohol may make you feel sleepy and less alert than usual.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking CLOFEN.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of these side effects.

Side effects occur mainly at the start of treatment or if the dose is too high or increased too quickly. They can often be relieved by lowering the dose.

If you are over 65 years of age, you should be careful while taking this medicine as the chance of side effects may be increased.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- daytime sleepiness or drowsiness
 - tiredness, lack of energy
 - dizziness, lightheadedness
 - spinning sensation (vertigo)
 - mental confusion
 - headache
 - difficulty sleeping, nightmares
 - nausea (feeling sick), vomiting, retching
 - constipation, diarrhoea, stomach pain
 - loss of appetite
 - stuffy or blocked nose
 - dry mouth
 - change in sense of taste
 - numbness or tingling in hands and feet
 - muscle weakness, spasms or pain
 - problems with coordination and balance
 - difficulty in speaking
 - swelling of ankles due to fluid build-up
 - blurred vision or double
 - ringing in the ears
 - frequent urination or bed-wetting
 - excessive sweating
 - weight gain
 - impotence or inability to ejaculate
 - low body temperature
- Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following:**
- signs of an allergic reaction such as skin rash, itching or hives on the skin; swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing; wheezing or shortness of breath
 - slow or difficulty breathing

- fast or irregular heart beat
- chest pain
- uncontrollable muscle spasms affecting the eyes, head, neck or body
- fainting or seizures (fits)
- depression or other severe mood or mental changes
- hallucinations (hearing or seeing things that are not there)
- being unable to urinate or pain upon urinating; blood in the urine
- symptoms following sudden discontinuation of the medicine (see Things you must not do above)

The above side effects can be serious. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After taking CLOFEN

Storage

Keep your tablets in the bottle until it is time to take them.

If you take the tablets out of the bottle they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store CLOFEN or any other medicine in the bathroom or near a sink. Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep Clofen where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

CLOFEN tablets are available in 2 strengths:

- CLOFEN 10 - round, white, scored tablet, marked "BN" over "10" on one side and "G" on the other.
- CLOFEN 25 - round, white, scored tablet, marked "BN" over "25" on one side and "G" on the other.

Each bottle contains 100 tablets.

Ingredients

The active ingredient in CLOFEN is baclofen.

- Each CLOFEN 10 contains 10 mg of baclofen
- Each CLOFEN 25 contains 25 mg of baclofen

The tablets also contain the following inactive ingredients:

- lactose
- microcrystalline cellulose
- calcium hydrogen phosphate anhydrous
- sodium starch glycollate
- colloidal anhydrous silica
- magnesium stearate

The tablets are gluten free.

Manufacturer

Alphapharm Pty Limited

(ABN 93 002 359 739)

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Australian registration numbers:

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