

Clofen

contains the active ingredient 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 benefits and risks. 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 your medicine.

You may need to read it again.

What Clofen is used for

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

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

Clofen belongs to a group of medicines called muscle relaxants. These medicines work by reducing excess muscle tension, thereby reducing pain and stiffness. This can help improve mobility and the management of daily activities.

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

Your doctor may have prescribed Clofen for another reason.

Clofen is available only with a doctor's prescription.

Before you take Clofen

When you must not take it

Do not take Clofen if you are allergic to:

- * **medicines containing baclofen (eg. Lioresal)**
- * **any of the ingredients listed at the end of this leaflet.**

Some of the symptoms of an allergic reaction may include skin rash, itching or hives; swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing; wheezing or shortness of breath.

Do not take Clofen if the expiry date (EXP) printed on the pack has passed.

If you take this medicine after the expiry date, it may not work as well.

Do not take Clofen if the packaging shows signs of tampering or the tablets do not look quite right.

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 are allergic to any other medicines, foods, dyes or preservatives.

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.

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

- * mental disorders such as schizophrenia or depression
- * epilepsy or any other condition that causes convulsions, fits or seizures
- * stomach or duodenal ulcers
- * stroke or other brain blood vessel problems
- * heart problems
- * liver problems
- * kidney problems
- * lung or breathing problems
- * porphyria, a disorder which can affect the liver and blood cell formation
- * alcohol dependence
- * diabetes
- * high blood pressure
- * Parkinson's disease
- * cerebral palsy
- * rheumatoid disorders.

Your doctor may want to take special care if you have any of these conditions.

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 if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may be affected by Clofen, or may affect how well it works. These include:

- * medicines that can cause sedation (makes you sleepy) such as some pain relievers; medicines for anxiety, travel sickness, hay fever or allergy, cough and cold, blocked nose; sleeping tablets or sedatives
- * some medicines used for depression such as tricyclic antidepressants and monoamine oxidase inhibitors (MAOIs)
- * lithium (eg. Lithicarb), a medicine used to treat mood swings and some types of depressions
- * levodopa and carbidopa combinations (eg. Sinemet, Kinson), medicines used for Parkinson's disease
- * medicines used for high blood pressure
- * insulin and medicines used to treat diabetes.

Your doctor can tell you what to do if you are taking any of these medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

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

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.

How much to take

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

The dose varies from person to person.

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

Your doctor may increase this 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 and those with kidney problems may need smaller doses.

How to take it

Swallow the tablets with a glass of water.

When to take it

Take Clofen during meals.

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.

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 the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

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

If you are not sure what to do or have any questions, ask your doctor or pharmacist for help.

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

How long to take it for

Keep taking Clofen for as long as your doctor recommends.

Your doctor will discuss with you how long treatment with Clofen should continue for, especially if you do not respond after 6 to 8 weeks of treatment at the maximum dosage.

Do not stop taking Clofen suddenly, even if you feel better after a few days, unless advised by your doctor.

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.

If you take too much Clofen, you may feel drowsy, have problems breathing or lose consciousness.

You may also feel confused, hallucinate, have blurred vision, feel sick (nausea), vomit, faint, have diarrhoea, increased saliva, a slow or irregular heart beat, muscle weakness or seizures (fits).

While you are taking Clofen

Things you must do

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

Before starting any new medicine, tell your doctor or pharmacist that you are taking Clofen.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Clofen.

If you plan to have surgery that needs a general anaesthetic, including dental surgery, tell your doctor or dentist that you are taking Clofen.

Visit your doctor regularly so 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 diabetes.

Things you must not do

Do not stop taking Clofen, or change the dose, without checking with your doctor. Do not let yourself run out of your medicine over weekends or during holidays.

Stopping Clofen suddenly may cause unwanted effects such as mood changes or mental disturbances, seizures (fits), a fast heart beat and worsening of muscle spasms.

Your doctor will tell you how to gradually reduce the amount of Clofen you are taking before stopping completely. This may take a few weeks.

Do not use Clofen to treat any other conditions unless your doctor tells you to.

Do not give Clofen 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.

Clofen may cause drowsiness, especially at the start of treatment, dizziness or lightheadedness in some people. 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.

Combining Clofen and alcohol can make you feel more sleepy, dizzy or lightheaded. Your doctor may suggest you avoid alcohol while you are taking Clofen.

Be careful taking other medicines that can cause drowsiness while you are taking Clofen.

Combining Clofen with medicines that can cause sedation (make you sleepy) can make you more drowsy or dizzy. Your doctor and pharmacist can give you more information.

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 treatment if you get some of these side effects.

Side effects to Clofen are usually short-lived and mainly occur at the start of treatment or if the dose of Clofen is too high or increased too quickly.

Do not suddenly stop taking Clofen. If unwanted side effects do occur, tell your doctor.

Your doctor may lower the dose to relieve any side effects.

If you are over 65 years of age or have brain blood vessel problems (eg. stroke) or a history of mental disorders, 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)
- * headache

- * nausea (feeling sick), vomiting, retching
- * dry mouth
- * change in sense of taste
- * stuffy or blocked nose
- * constipation, diarrhoea, stomach pain
- * weight gain
- * loss of appetite
- * difficulty sleeping, nightmares
- * excessive sweating
- * impotence or inability to ejaculate
- * blurred vision.

The above list includes the milder side effects of Clofen.

Tell your doctor as soon as possible if you notice any of the following:

- * confusion, depression or hallucinations (seeing or hearing things that are not there)
- * ringing in the ears
- * muscle weakness, spasms or pain
- * unsteadiness when walking, shaking
- * tingling or numbness of the hands or feet
- * swelling of ankles due to fluid buildup
- * difficulty or pain when urinating
- * frequent urination or bed-wetting
- * blood in the urine.

The above list includes serious side effects, which may require medical attention.

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; swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing; wheezing or shortness of breath
- * difficulty in breathing
- * uncontrollable severe muscle spasms of the body or eyes
- * fainting
- * seizures (fits)

- * fast or irregular heart beat
- * chest pain.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

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

This is not a complete list of all possible side effects.

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

After taking Clofen

Storage

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.

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 30 degrees C.

Do not store Clofen or any other medicine in the bathroom or near a sink.

Do not leave Clofen in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking Clofen, 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

Clofen is made in Australia by:

Alphapharm Pty Limited

(ABN 93 002 359 739)

Chase Building 2

Wentworth Park Road

Glebe NSW 2037

Phone: (02) 9298 3999

www.alphapharm.com.au

Medical Information

Phone: 1800 028 365

Australian registration numbers:

Clofen 10 - AUST R 42146

Clofen 25 - AUST R 42147

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