

CLOFEN

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using CLOFEN?

CLOFEN contains the active ingredient baclofen. Baclofen belongs to a group of medicines called muscle relaxants.

CLOFEN is used to reduce the stiffness or spasms in your muscles to help make you more mobile and able to manage your daily activities.

For more information, see Section [1. Why am I using CLOFEN?](#) in the full CMI.

2. What should I know before I use CLOFEN?

Do not use if you have ever had an allergic reaction to baclofen or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use CLOFEN?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with CLOFEN and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use CLOFEN?

- Your doctor will tell you exactly how many tablets of CLOFEN to take.
- Do not exceed the recommended dose prescribed by your doctor.
- Treatment is usually started in hospital with small doses of CLOFEN. The dose is then gradually increased to an amount that works best for you.

More instructions can be found in Section [4. How do I use CLOFEN?](#) in the full CMI.

5. What should I know while using CLOFEN?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using CLOFEN.• Keep all doctor's appointments, so that your progress can be checked.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly, unless your doctor tells you to.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how CLOFEN affects you.• CLOFEN may cause sleepiness in some people, especially when you start taking it.
Drinking alcohol	<ul style="list-style-type: none">• Tell your doctor if you drink alcohol.
Looking after your medicine	<ul style="list-style-type: none">• Store the tablets in a cool dry place.

- Keep out of reach of children.

For more information, see Section [5. What should I know while using CLOFEN?](#) in the full CMI.

6. Are there any side effects?

Common side effects include daytime sleepiness, lack of energy, tiredness, dizziness or light-headedness, vertigo, confusion, headache, difficulty sleeping or nightmares, nausea, retching or vomiting, constipation, stomach cramps or diarrhoea, loss of appetite, stuffy nose, dry mouth, change in sense of taste, misuse, abuse and dependence, numbness, muscle weakness or spasms, swelling of ankles, blurred vision, ringing in the ears, frequent urination, excessive sweating, weight gain, impotence or inability to ejaculate, increased blood sugar, low body temperature. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

CLOFEN

Active ingredient: *Baclofen*

Consumer Medicine Information (CMI)

This leaflet provides important information about using CLOFEN. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using CLOFEN.**

Where to find information in this leaflet:

- [1. Why am I using CLOFEN?](#)
- [2. What should I know before I use CLOFEN?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use CLOFEN?](#)
- [5. What should I know while using CLOFEN?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using CLOFEN?

CLOFEN contains the active ingredient baclofen. Baclofen belongs to a group of medicines called muscle relaxants.

CLOFEN is used to reduce the stiffness or spasms in your muscles to help make you more mobile and able to manage your daily activities. These spasms

happen in various illnesses such as multiple sclerosis and diseases or physical injuries of the spinal cord.

Because this medicine 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 should I know before I use CLOFEN?

Warnings

Do not use CLOFEN if:

- you are allergic to baclofen, or 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

Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any other medical conditions including mental illness, Parkinson's disease, seizures (fits) from any cause, stiffness and restriction of movement in a group of muscles, stomach ulcers, stroke or blood

circulation problems, diabetes, a blood disorder known as porphyria (a rare disturbance in the production of porphyrin, a pigment important for liver function and blood formation), high blood pressure, difficulty urinating

- have problems with your heart, kidney, liver or lungs
- have a history of alcoholism, drink large amounts of alcohol, or have a history of drug abuse or dependence
- have had thoughts of self-harm or and suicidal thoughts
- take any medicines for any other condition
- have any questions about why this medicine has been prescribed for you.

Your doctor may want to take special precautions if you have any of the above conditions. These precautions may include additional tests during or prior to taking CLOFEN.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

There is very little information on the use of this medicine in pregnancy or breastfeeding. Your doctor can discuss with you the risks and benefits involved.

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 just after delivery.

3. What if I am taking other medicines?

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

Some medicines may interfere with CLOFEN and affect how it works. These include:

- Any medicine that makes you sleepy such as medicines used to help you sleep or calm you, pain relievers, and medicines for cold or allergies
- medicines used to treat mood disorders, including tricyclic antidepressants, lithium and monoamine oxidase inhibitors (MAOIs)
- medicines used to treat diabetes
- medicines that lower blood pressure include those used to treat high blood pressure
- medicines used to treat Parkinson's disease, including selegiline and levodopa and carbidopa

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect CLOFEN.

4. How do I use CLOFEN?

How much to take

- Your doctor will tell you exactly how many tablets of CLOFEN to take.
- Do not exceed the recommended dose prescribed by your doctor.
- Treatment is usually started in hospital with small doses of CLOFEN. The dose is then gradually increased to an amount that works best for you. For example, CLOFEN may be started at a dose of 15 mg per day, then increased slowly to anywhere from 30 to 75 mg a day. Sometimes, doses up to 100 mg a day may be needed.
- If you are under the age of 16 or over 65, or you have kidney disease, your doctor may start you on a lower dose and increase it slowly to prevent unwanted side effects.
- Follow the instructions provided and use CLOFEN until your doctor tells you to stop.

When to take CLOFEN

- CLOFEN is usually taken in 3 divided doses throughout the day.

- Your doctor may tell you to take it more or less often, depending on your situation.

How to take CLOFEN

- Swallow the tablets whole during meals with a glass of water or other liquid.

If you forget to use CLOFEN

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 it as you would normally.

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

If you use too much CLOFEN

If you think that you have used too much CLOFEN, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

Symptoms of overdose include:

- Main symptoms such as drowsiness, breathing difficulties and being unconscious (coma).
- Other symptoms such as confusion, hallucinations, agitation, convulsions, blurred vision, unusual low muscle tone, sudden and involuntary muscle spasm, poor or absent reflexes, high or low blood pressure, slow, fast or irregular heartbeat, low body temperature, nausea, vomiting, diarrhoea, excessive salivation, trouble breathing during sleep (sleep apnoea), severe pain in your muscles with fever and dark urine (rhabdomyolysis) and ringing in the ears.
- If you have kidney disease and have accidentally taken more tablets than your doctor has prescribed, you may experience drowsiness, confusion or hallucinations.

5. What should I know while using CLOFEN?

Things you should do

Keep all doctor's appointments, so that your progress can be checked.

Call your doctor straight away if you:

- Become pregnant or think you might be pregnant
- Remind any doctor, dentist or pharmacist you visit that you are using CLOFEN.

Call your doctor straight away if you have symptoms such as increased sleepiness, new onset of drowsiness, confusion, or muscle jerks.

These may be signs of a condition known as encephalopathy and your doctor may decide to stop treatment with CLOFEN tablets.

To help prevent unwanted side effects from happening, your doctor may want to do some tests from time to time during the course of your treatment.

If your muscle spasms come back, tell your doctor.

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

Call your doctor straight away or go to a hospital if you have thoughts of harming or killing yourself.

Some people treated with CLOFEN have had thoughts of harming or suicide or have tried to kill themselves. 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.

Things you should not do

- **Do not stop using this medicine suddenly unless your doctor tells you to.**

Stopping this medicine suddenly may make your condition worse. You may experience the following: nervousness, feeling confused, hallucinations, abnormal thinking or behaviour, convulsions, uncontrollable twitching, jerking or writhing movements, fast heartbeat, high body temperature,

pain in muscles, fever, dark urine. The excessive stiffness (spasms) in your muscles may also get worse.

If CLOFEN must be stopped, your doctor will reduce the dose gradually over a period of 1 to 2 weeks so that these unwanted effects are avoided.

- Do not use this medicine to treat any other problems unless your doctor tells you to.
- Do not give this medicine to anyone else. Even if they have the same condition as you.

Driving or using machines

Be careful before you drive or use any machines or do other jobs that require you to be alert until you know how CLOFEN affects you.

CLOFEN may cause sleepiness and decreased alertness in some people, especially when you start taking it.

Drinking alcohol

Tell your doctor if you drink alcohol.

Be careful when drinking alcohol while taking CLOFEN.

Alcohol may make you feel more sleepy when taking CLOFEN.

Looking after your medicine

- Keep your tablets in the original container until it is time to take them

Follow the instructions on the label on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight below 25°C; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

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

When to discard your medicine

If your doctor tells you to stop taking CLOFEN, the expiry date on the medicine has passed or the packaging is torn, ask your pharmacist what to do with any tablets you have left over.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

Side effects happen mainly at the start of treatment with CLOFEN or if the dose is too high or increased too quickly. They can often be relieved by lowering the dose. Your doctor will adjust your dose if necessary.

If you are over 65 years of age, you should be especially careful while taking this medicine. Report any side effects promptly to your doctor.

As people grow older, they are more likely to get side effects from medicines.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Brain and nerves: <ul style="list-style-type: none">• daytime sleepiness or drowsiness• lack of energy, tiredness• dizziness or light-headedness	Speak to your doctor if you have any of these less serious side effects and they worry you. If these side effects become severe, please tell your doctor,

Less serious side effects	What to do
<ul style="list-style-type: none"> ● spinning sensation (vertigo) ● mental confusion ● headache ● difficulty sleeping or nightmares ● change in sense of taste ● blurred or double vision ● ringing in the ears <p>Airways:</p> <ul style="list-style-type: none"> ● stuffy or blocked nose ● dry mouth <p>Stomach problems:</p> <ul style="list-style-type: none"> ● nausea (feeling sick), retching or vomiting ● constipation, stomach cramps or diarrhoea ● loss of appetite <p>General problems:</p> <ul style="list-style-type: none"> ● numbness or tingling in hands and feet ● muscle weakness, spasms or pain ● problems with coordination and balance 	<p>pharmacist or healthcare provider.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> ● difficulty in speaking ● swelling of ankles due to fluid build-up ● frequent urination or bed wetting ● excessive sweating ● weight gain ● impotence or not able to ejaculate ● increased blood sugar ● feeling cold ● hair loss ● misuse, abuse and dependence 	

Serious side effects

Serious side effects	What to do
<p>Skin or muscle problems:</p> <ul style="list-style-type: none"> ● signs of allergy such as rash, itching or hives on the skin; swelling of the face, lips, tongue or other parts of the body; shortness of breath or wheezing 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> ● uncontrollable muscle spasms affecting the eyes, head, neck or body <p>Chest problems:</p> <ul style="list-style-type: none"> ● slow or difficult breathing ● irregular heartbeat (fast or slow) ● chest pain <p>Neurological problems:</p> <ul style="list-style-type: none"> ● fainting or seizures (fits) ● depression or other severe mood, behavioural or mental changes ● hallucinations (hearing or seeing things that are not there) ● thoughts of suicide ● anxiety, confusion, paranoia, and other mental problems following sudden discontinuation of the medicine (drug withdrawal syndrome) ● feeling more tired than normal, decreased 	

Serious side effects	What to do
<p>levels of awareness with uncontrolled muscle jerks.</p> <p>Other problems:</p> <ul style="list-style-type: none"> • being unable to urinate or pain when urinating, blood in the urine 	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What CLOFEN contains

Active ingredient (main ingredient)	baclofen
Other ingredients (inactive ingredients)	lactose monohydrate microcrystalline cellulose calcium hydrogen phosphate sodium starch glycollate colloidal anhydrous silica magnesium stearate
Potential allergens	sugars as lactose

Do not take this medicine if you are allergic to any of these ingredients.

What CLOFEN looks like

CLOFEN 10 is a flat bevelled edges white tablet with BN over 10 scored tablet (BN/10) on one side and G on the reverse (AUST R 42146).

CLOFEN 25 is a flat bevelled edges white tablet with BN over 25 scored tablet (BN/25) on one side and G on the reverse (AUST R 42147).

Who distributes CLOFEN

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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