

STELAX

baclofen

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about STELAX.

It does not contain all of 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 STELAX against the benefits they expect it will have for you.

Talk to your doctor or pharmacist if you have any concerns about taking this medicine.

Keep this leaflet with your medicine. You may need to read it again.

What STELAX is used for

STELAX is used to treat muscle spasms that occur in various illnesses such as multiple sclerosis and diseases and injuries of the spinal cord.

STELAX belongs to a group of medicines called muscle relaxants. These medicines reduce excess tension in your muscles that cause spasms and pain.

Reducing these spasms may help to increase your mobility and make everyday activities easier to manage.

Your doctor may have prescribed this medicine for another reason. Ask your doctor if you have any questions about why it has been prescribed for you.

It is available only with a doctor's prescription.

Before you take it

When you must not take it

Do not take STELAX if you are allergic to medicines containing 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.

Do not take it if the expiry date (Exp.) printed on the pack has passed.

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

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.

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

If you have to take STELAX during pregnancy your baby may have convulsions and other symptoms related to sudden discontinuation of the medicine just after delivery.

Your doctor will discuss the risks

and benefits of taking STELAX during pregnancy.

Tell your doctor if you are breastfeeding or wish to breastfeed.

Your doctor will discuss the risks and benefits of taking STELAX when breastfeeding.

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

- a mental illness
- Parkinson's disease
- epilepsy or fits
- stomach ulcers
- stiffness and restriction of movement in a group of muscles
- stroke or other blood vessel disease
- heart disease
- liver disease
- kidney disease
- lung or breathing problems
- diabetes
- alcoholism
- high blood pressure
- porphyria, a rare blood disorder.

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

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 STELAX, or may affect how well it works. These include:

- medicines used to treat diabetes
- medicines used to treat high blood pressure

- medicines used to treat depression such as tricyclic antidepressants and monoamine oxidase inhibitors
- lithium, a medicine used to treat mental illness
- levodopa and carbidopa, medicines used to treat Parkinson's disease
- any medicine that can make you sleepy, such as medicines to help you sleep or calm you down, pain relievers and medicines for colds and allergies.

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 this medicine.

How to take it

How much to take

Treatment with STELAX is usually started in hospital with a small dose which is gradually increased to a dose that has the best result for you.

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

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 more gradually to prevent unwanted side effects.

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

How to take it

Take your medicine during or immediately after food with a little glass of water.

This will lessen the chance of a stomach upset.

STELAX is usually taken in at least 3 divided doses throughout the day. But your doctor may tell you to take it more or less often, 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, ask your doctor or pharmacist.

How long to take it for

To properly control your condition, STELAX must be taken every day.

Keep taking your medicine for as long as your doctor recommends.

If you take too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much STELAX. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much, you may feel dizzy, weak or confused, have blurred vision, vomiting, diarrhoea, breathing problems, faint or have fits, breathing difficulties, drowsiness, consciousness disorders and being unconscious (coma).

Other symptoms may include: hallucinations, agitation, convulsions, unusual muscle slackness, sudden contraction of the muscles, poor or absent reflexes, high or low blood pressure, slow, fast or irregular heartbeat, low body temperature, nausea, vomiting, diarrhoea or excessive salivation, trouble breathing during sleep (sleep apnoea), pain in muscles, fever and dark urine (rhabdomyolysis).

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)

While you are taking it

Things you must do

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

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

If your muscle spasms come back, tell your doctor.

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

If you become pregnant while taking it, tell your doctor.

Visit your doctor regularly so they can check on your progress.

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.

Things you must not do

Do not stop taking it suddenly, or lower the dose, without checking with your doctor.

Stopping STELAX suddenly may cause severe spasms and other unwanted symptoms, such as

nervousness, feeling confused, hallucinations, abnormal thinking or behaviour, convulsions, uncontrollable twitching, jerking or writhing movements, fast heartbeat, high body temperature, pain in muscles, fever and dark urine. The excessive stiffness (spasms) in your muscles may also get worse.

Your doctor may want you to gradually reduce the amount of medicine you are taking before stopping completely.

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

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

Things to be careful of

Be careful driving or operating machinery or doing jobs that require you to be alert while you are taking STELAX until you know how it affects you.

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

Be careful when drinking alcohol while taking this medicine.

Combining it with alcohol can make you more drowsy and less alert.

Side effects

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

Like all other medicines, it may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Side effects happen mainly at the start of treatment or if the dose is too high or is increased too rapidly.

They can often be relieved by lowering the dose.

If you are over 65 years of age, you may have an increased chance of getting side effects.

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

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
- lack of energy, feeling exhausted
- dizziness, lightheadedness
- spinning sensation (vertigo)
- mental confusion
- headache
- difficulty sleeping, nightmares
- feeling sick (nausea), vomiting or retching
- constipation, stomach cramps, diarrhoea
- loss of appetite
- stuffy or blocked nose
- dry mouth
- change in taste
- numbness or tingling in the hands or feet
- muscle weakness, spasms or pain
- problems with co-ordination or balance
- swelling of ankles due to fluid build-up
- increased blood sugar
- low body temperature
- blurred or double vision
- ringing in the ears
- frequent urination or bed wetting
- excessive sweating
- weight gain

- impotence or inability to ejaculate

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- slow or difficult breathing
- 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.
- fast or irregular heartbeat
- chest pain
- uncontrolled muscle spasms affecting the eyes, head, neck or body
- symptoms following sudden discontinuation of the medicine (drug withdrawal syndrome). Refer to “Things you must not do” above
- fainting or fits
- depression or other severe mood changes or mental changes
- hallucinations
- inability to urinate, pain when urinating, blood in the urine.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.

After using it

Storage

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

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

Do not store STELAX 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. Stelax will keep well if it is cool and dry.

Disposal

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

This leaflet was revised in February 2018.

Product description

What it looks like

STELAX comes in 2 strengths of tablets:

- STELAX 10 - round off-white tablet marked BL | 10 on one side, “>” on the reverse.
- STELAX 25 - round off-white tablet marked BL | 25 on one side, “>” on the reverse .

Each pack contains 100 tablets.

Ingredients

The active ingredient in STELAX is baclofen.

- each STELAX 10 tablet contains 10 mg of baclofen
- each STELAX 25 tablet contains 25 mg of baclofen.

The tablets also contain:

- microcrystalline cellulose
- maize starch
- povidone
- colloidal anhydrous silica
- magnesium stearate.

The tablets are gluten free.

Sponsor

Arrow Pharma Pty Ltd
15 – 17 Chapel Street
Cremorne VIC 3121

Australian registration numbers:

STELAX 10 - Aust R 92251

STELAX 25 - Aust R 92252