

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

BACLOFEN ACTIVO, 10 mg tablets

Baclofen

Sugar free.

Read all of this leaflet carefully before you are take BACLOFEN ACTIVO:

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- BACLOFEN ACTIVO has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

1. What BACLOFEN ACTIVO is and what it is used for
2. What you need to know before you take BACLOFEN ACTIVO
3. How to take BACLOFEN ACTIVO
4. Possible side effects
5. How to store BACLOFEN ACTIVO
6. Contents of the pack and other information

1. What BACLOFEN ACTIVO is and what it is used for

BACLOFEN ACTIVO contains baclofen, which belong to a group of medicines called muscle relaxants.

BACLOFEN ACTIVO is used in adults and children to reduce and relieve the excessive tension (spasms) in your muscles occurring in various conditions such as multiple sclerosis, diseases or injuries of the spinal cord, and certain brain diseases.



2. What you need to know before you take BACLOFEN ACTIVO

Do not take BACLOFEN ACTIVO:

- If you are hypersensitive (allergic) to baclofen or any of the other ingredients of BACLOFEN ACTIVO (listed in [section 6](#) of this leaflet).
- If you suffer from porphyria (rare inherited blood disorder).

Warnings and precautions:

Tell your doctor before you take BACLOFEN ACTIVO if:

- You have certain mental illnesses accompanied by confusion or depression.
- You are suffering from Parkinson's disease.
- You are suffering from epilepsy (seizures).
- You have a history of pain in your stomach (ulcers) or intestines.
- You have breathing problems, a kidney or liver disease, or a disease of circulation in your brain.
- You have difficulty urinating.
- You are a diabetic.
- You have depression, if you have been using alcohol excessively, or if you had thoughts of killing yourself.
- You have a history of drug abuse or dependance.

Take special care if:

- You have thoughts of harming or killing yourself at any time while taking BACLOFEN ACTIVO, speak to your doctor straight away 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.
- You are elderly or have muscle spasms caused by a brain disease. You may experience more side effects therefore, your doctor will keep you under appropriate surveillance and may adapt the dose of BACLOFEN ACTIVO you take.



Other medicines and BACLOFEN ACTIVO:

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor if you are using:

- Medicines used to treat Parkinson's disease may intensify the adverse events associated with central nervous system as well as the symptoms of Parkinson's disease, e.g. levodopa or carbidopa.
- Medicines which slow down the nervous system, e.g. antihistamines such as promethazine, sedatives such as temazepam, opiates for pain relief such as morphine and anti-epileptic medicines, such as carbamazepine.
- Medicines to treat mood disorders such as lithium or tricyclic antidepressants such as amitriptyline.
- Medicines used to treat high blood pressure may result in a further decrease in blood pressure.
- Medicines for arthritis or pain may intensify the side effects of BACLOFEN ACTIVO by weakening kidney function.

BACLOFEN ACTIVO with food and drink:

Be careful when drinking alcohol, as it may intensify the sedative effect of BACLOFEN ACTIVO.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking BACLOFEN ACTIVO.

You should not take BACLOFEN ACTIVO during breastfeeding.



Driving and using machines:

Sedation, somnolence, drowsiness and fatigue may occur while you are taking BACLOFEN ACTIVO.

If this happens to you, do not drive a car, use a machine, or do other things that need your full attention.

3. How to take BACLOFEN ACTIVO

Do not share any medicines prescribed for you with any other person.

Always take BACLOFEN ACTIVO exactly as your doctor has told you. Check with your doctor if you are not sure.

Adults:

Adults usually start treatment with 5 mg taken 3 times daily initially. The dose is then gradually increased until the best results are obtained. This may be between 30 to 80 mg given in divided daily doses, usually 3 or 4 times a day.

If necessary, BACLOFEN ACTIVO tablets can be halved to make up the correct dose. Tablets can be halved by pressing the tablet with your fingers evenly on each side of the score mark until the pill splits in half. Each half tablet contains 5 mg baclofen.

Take BACLOFEN ACTIVO tablets orally (by mouth) during meals with a little liquid.

Children:

Children's dosing is based on their body weight. Your doctor will calculate the correct dose for your child.

Your doctor will tell you how long your treatment with BACLOFEN ACTIVO will last. If you have the impression that the effect of BACLOFEN ACTIVO is too strong or too weak, tell your doctor or pharmacist.



If you take more BACLOFEN ACTIVO than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take this leaflet and your remaining tablets with you so the doctor can see what you have taken.

The main symptoms of overdose are drowsiness, breathing difficulties, trouble of consciousness and being unconscious (coma). Other symptoms may include: feeling confused, hallucinations, agitation, convulsions (fits), blurred vision, unusual muscle slackness, sudden contraction of the muscles, poor or absent reflexes, high or low blood pressure, slow or fast heartbeat, low body temperature, nausea, vomiting, diarrhoea or salivating a lot.

If you forget to take BACLOFEN ACTIVO:

If you have forgotten to take your dose as scheduled, take it as soon as you remember. However, if it is almost time for your next dose, do not take a double dose to make up for a forgotten individual doses. Take the next dose as usual, when it is time to take it. If you have forgotten to take several doses, you should contact your doctor.

If you stop taking BACLOFEN ACTIVO:

Do not suddenly stop taking BACLOFEN ACTIVO without first checking with your doctor. He or she will tell you when and how you can stop taking BACLOFEN ACTIVO; stopping suddenly can make your condition worse.

If you stop your treatment suddenly, you may experience nervousness, feeling confused, hallucinations, abnormal thinking or behaviour, convulsions (fits), uncontrollable twitching, jerking or writhing movements, fast heartbeat, high body temperature. The excessive tension (spasms) in your muscles may also become worse.



4. Possible side effects

BACLOFEN ACTIVO can have side effects.

Not all side effects reported for BACLOFEN ACTIVO are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BACLOFEN ACTIVO, please consult your doctor, pharmacist or other health care provider for advice.

If any of the following happens, stop taking BACLOFEN ACTIVO and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to BACLOFEN ACTIVO. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Difficulty breathing.
- Shortness of breath at rest or with activity, swelling in the legs and tiredness (signs of decreased cardiac output).
- Trouble breathing during sleep (sleep apnoea syndrome).
- Difficulty passing urine, pain when passing urine or a sudden decrease in urine.
- Yellowing of the skin and eyes, dark urine, abdominal pain, tiredness which may be symptoms of liver problems.
- Symptoms after suddenly stopping taking the medicine (medicine withdrawal syndrome) as explained in the section 'If you stop taking BACLOFEN ACTIVO' above.

These are all serious side effects. You may need urgent medical attention.



Tell your doctor if you notice any of the following:

Side effects that may occur frequently:

- Excessively weak limbs or feeling tired and exhausted, aching muscles.
- Unsteadiness, trembling or other problems with muscle control.
- Headache, dizziness or light-headedness.
- Mood changes, confusion, hallucinations or nightmares.
- Dry mouth.
- Eye-focusing problems, resulting in blurred vision.
- Low blood pressure (fainting).
- Nausea, vomiting, retching, constipation and diarrhoea.
- Excessive sweating, rash.

Side effects that may occur less frequently:

- Numbness or tingling in hands or feet.
- Increased muscle spasm.
- Disturbed sense of taste.
- Stomach-ache.
- Sexual problems in men e.g. difficulty keeping an erection (impotence).
- Hypothermia (low body temperature).
- Ringing noise in the ear (tinnitus).

Side effect that may occur with unknown frequency:

- Raised, itchy rash (urticaria).
- Increase in blood sugar.
- Slow heart rate (bradycardia).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website. By reporting side effects, you can help provide more information on the safety of



BACLOFEN ACTIVO.

5. How to store BACLOFEN ACTIVO

- Store at or below 25 °C.
- Keep the blister strips in the outer carton until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What BACLOFEN ACTIVO contains:

The active ingredient is baclofen. Each BACLOFEN ACTIVO tablet contains 10 mg baclofen.

The other ingredients are: microcrystalline cellulose, pregelatinised maize, starch, maize starch, magnesium stearate.

What BACLOFEN ACTIVO looks like and contents of the pack:

White-coloured, round, flat, uncoated tablets having a breakline on one side and plain on the other side. Diameter is approximately 7 mm.

The tablet can be divided into equal halves.

Aluminium/PVC/PVDC blister strips containing 10 tablets each.

Pack size: 30 tablets.

Holder of certificate of registration:

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