

**PATIENT PACKAGE INSERT
IN ACCORDANCE WITH THE
PHARMACISTS' REGULATIONS
(PREPARATIONS) – 1986**

The medicine is dispensed with
a doctor's prescription only

BACLOSAL 10, 25 Tablets

Composition:

Each tablet of **Baclosal 10** contains:
Baclofen 10 mg

Each tablet of **Baclosal 25** contains:
Baclofen 25 mg

Inactive ingredients: see section 6 "Further information".

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Therapeutic group: Muscle relaxant with spinal activity.

Therapeutic activity: Relaxation of muscles and/or spasms caused by different factors.

Baclosal is used to reduce and relieve excessive stiffness and/or spasms in the muscles due to various diseases and conditions.

Muscle relaxation by **Baclosal** improves the ability to move and makes it easier to perform daily activities.

If you have questions about the way **Baclosal** works, or why this medicine was prescribed for you, refer to the doctor.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- you are sensitive (allergic) to baclofen or to any of the additional ingredients contained in the medicine (see section 6 "Further information").
- you are suffering, or have suffered in the past, from a stomach ulcer.

Special warnings regarding use of the medicine

Before treatment with Baclosal, tell the doctor if:

- you had a stroke.
- you suffer from epilepsy.

- you suffer from any mental disorder.
- you have Parkinson's disease.
- you are being treated for hypertension.
- you suffer from kidney, liver, or lung disease.
- you have diabetes.
- you have difficulties in urinating.
- you are pregnant or breastfeeding (see section 2 "Pregnancy and breastfeeding").
- you have a history of addiction or dependency on a medicine.

If one or more of these conditions apply to you, inform the doctor or pharmacist before taking **Baclosal**, since **Baclosal** may not be appropriate for you.

Use in children and adolescents

Baclosal is not intended for children weighing less than 33 kg.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. In particular, inform the doctor or pharmacist if you are taking:

- other medicines to relax muscles, e.g., tizanidine.
- medicines used to treat mood disorders, e.g., lithium or tricyclic antidepressants, such as amitriptyline.
- medicines that lower blood pressure including medicines used to treat hypertension e.g., diltiazem.
- other medicines which also affect the kidneys, e.g., ibuprofen.
- medicines to treat Parkinson's disease, e.g., levodopa or carbidopa.
- medicines that slow down the nervous system, e.g., antihistamines, such as promethazine, sedatives, such as temazepam, opiate pain relievers, such as morphine, and anticonvulsants (medicines for epilepsy, such as carbamazepine).

Using the medicine and food

Take **Baclosal** with a meal and a little liquid. **Pregnancy and breastfeeding**
Consult with the doctor or pharmacist before taking any medicine.

Do not use **Baclosal** during pregnancy, unless the doctor advises you to do so. Inform the doctor if you are pregnant, or planning a pregnancy. If you need to take **Baclosal** during pregnancy, the unborn baby will also be exposed to **Baclosal**. After the delivery, your baby may have withdrawal symptoms such as convulsions (withdrawal symptoms are described in the section "If you stop taking the medicine").

Only a small amount of **Baclosal** passes into breast milk. Your doctor will discuss with you whether you can breastfeed during treatment

with **Baclosal**.

Driving and operating machinery

Some patients may feel sleepy and/or dizzy or have vision disturbances when taking **Baclosal**. If this happens to you, do not drive a car, or do anything else that requires you to be alert (such as operating a machine or machinery) until these effects pass.

Children should be cautioned against riding a bicycle or playing near the road, and the like.

Special warnings

- Be careful when drinking alcoholic beverages – they may affect you more than usual.
- Some patients taking baclofen have had thoughts of harming or killing themselves or have tried to kill themselves. Most of these people also had depression, used alcohol excessively or were prone to suicidal thoughts. If you have thoughts of harming or killing yourself at any time, talk to the doctor immediately or proceed to a hospital. In addition, ask a relative or close friend to tell you if they are concerned about any change in your behavior and ask them to read this leaflet.
- The doctor may want to perform periodic tests while you are taking **Baclosal**.
- If you are due to undergo any surgery, inform the doctor that you are taking **Baclosal**.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions.

Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

The dosage and treatment regimen will be determined by the doctor only.

The doctor will tell you exactly how many **Baclosal** tablets to take. The doctor may increase or decrease the dosage of the medicine, according to your response to the treatment.

The dosage of **Baclosal** depends on the response of the patient to the medicine. Start with a low dosage and increase the dosage gradually over a few days, under medical supervision, until you reach the dosage which is right for you. The doctor will tell you when you should take the medicine.

Method of administration

Take the medicine with a meal and swallow the medicine with a little liquid, such as a milky beverage.

If you feel sick after taking **Baclosal**, you may find it helpful to take them with a meal or a milky beverage. If necessary, the tablet can be halved for immediate use. There is no information regarding tablet crushing or chewing.

Taking **Baclosal** at the same time every day will help you remember when to take the tablet. Use this medicine at set time intervals, as determined by the attending doctor.

Adults

- The usual dosage is 20 mg (2 tablets of **Baclosal 10**) three times a day.
- The maximum daily dosage is 100 mg a day, except for hospitalized patients, where a higher dosage may be prescribed.

Children

The dosage in children is calculated according to body weight.

Patients with kidney diseases

Patients with kidney diseases will usually receive a significantly lower dosage of the medicine, per the doctor's decision.

Do not exceed the recommended dose.

If you forget to take the medicine

If you forgot to take this medicine at the designated time, do not take a double dose. Take the next dose at the usual time and consult the doctor. Adhere to the treatment regimen as recommended by the doctor.

If you accidentally took a higher dosage inform the doctor immediately.

If you took an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you. Symptoms of an overdose are: tinnitus.

If you stop taking the medicine

Do not suddenly stop taking **Baclosal**. Before stopping, talk to your doctor or pharmacist. If the doctor decides to stop treatment with **Baclosal**, the dose will be gradually reduced to prevent withdrawal symptoms, such as muscle spasms and increased muscle rigidity, high muscle tone, fast heart rate, fever, confusion, hallucinations, changes in mood and emotion, mental disorders, feelings of persecution or convulsions.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them. If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of **Baclosal** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

The side effects listed below have been reported:

Very common side effects (effects that appear in more than 1 user in 10):

- tiredness.
- sleepiness.
- nausea.

Common side effects (effects that appear in up to 1 user in 10):

- increased weakness in limbs or feeling tired and exhausted, muscle pain.
- headache, dizziness or lightheadedness.
- breathing difficulties.
- inability to sleep.
- mood swings, confusion, hallucinations or nightmares.
- dry mouth.
- eye problems.
- unsteadiness, trembling or other problems with muscle control.
- low blood pressure (fainting).
- gastrointestinal disorders: stomach problems, including retching; vomiting; constipation; diarrhea.
- increased sweating, rash.
- urinating more than usual or pain upon urinating.

Rare side effects (effects that appear in up to 1 user in 1,000):

- tingling or numbness of the hands and/or feet.
- increased muscle spasms.
- disturbances in sense of taste.
- impaired or slow speech.
- abdominal pain.
- liver problems.
- difficulty in passing urine.
- sexual problems in men, e.g., impotence.
- convulsions (particularly in epileptic patients).

Very rare side effects (effects that appear in less than 1 user in 10,000):

- hypothermia (low body temperature).
- Additional side effects (at unknown frequency):**
- raised itchy rash on the skin (urticaria – also known as nettle-rash or hives).
 - slow heart rate.
 - increase in blood sugar level.
 - breathing difficulties during sleep (sleep apnea syndrome).
 - swelling in the ankle joint, feet or lower legs.
 - swelling in the face.
 - allergic reaction (hypersensitivity).
 - hair loss.
 - difficulties in sexual function.
 - withdrawal symptoms resulting from abrupt discontinuation of the medicine (see section 3 "If you stop taking the medicine").

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il>

Additionally, you can report to "Unipharm Ltd."

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.

Storage conditions: Store at a temperature below 25°C and in a place protected from light.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:
Microcrystalline cellulose; Maize starch; Povidone; Magnesium stearate.

What the medicine looks like and the contents of the package:

Baclosal is packaged in trays (blister) which are inserted into a carton package. Each package of **Baclosal** contains 50, 60, 100 or 1,000 tablets.

Not all package sizes may be marketed.

Baclosal 10 are white, round, convex tablets with a break line on one side.

Baclosal 25 are white, round, flat tablets with a crossed break line on one side.

Registration holder and address: Unipharm Ltd., P.O. Box 16545, Tel Aviv, 6116401.

Manufacturer and address: Unipharm Ltd., "Mevo Carmel" Industrial Park.

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Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Baclosal 10: 046 07 23779 02

Baclosal 25: 045 34 23780 04