

**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 rigidity and/or spasms in the
muscles in various conditions such as multiple
sclerosis, spinal cord diseases or injuries and
certain diseases in the brain.

As a result of muscle relaxation which leads
to a reduction in pain, **Baclosal** improves the
ability to move, makes it easier to perform the
daily activities and physical therapy.

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
"Pregnancy and breastfeeding" section).
- 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.

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 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).

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 "If you stop taking the medicine"
section).

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. These people
also usually had depression, excessively
used alcohol or had a tendency for 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 he is 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**.

Use in children and adolescents

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

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 usual dosage is generally:

Your doctor will instruct you on the optimal
time to take **Baclosal**. Some patients need
to take the medicine only at night or before
performing tasks such as washing, dressing,
shaving, etc.

The final dosage of **Baclosal** depends on
the individual 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. If the
starting dosage is too high, or if the dosage
is increased too quickly, you may suffer from
side effects, particularly if you are elderly,
have kidney problems or have had a stroke
in the past.

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.

Instructions for use

Do not chew! Swallow the medicine with a little
water. Take the medicine with a meal.

If necessary, the tablet can be halved for
immediate use. There is no information
regarding tablet crushing or chewing.

If you forget to take the medicine

If you forgot to take this medicine at the
scheduled time, do not take a double dose.
Take the next dose at the usual time and
consult 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.

Adhere to the treatment regimen as
recommended by the doctor.

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, 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 a feeling of
tiredness.
- muscle pain.
- headache, dizziness or lightheadedness.
- breathing difficulties.
- inability to sleep.
- mood swings, confusion, hallucinations or
nightmares.
- dry mouth.
- eye problems.
- unsteadiness, trembling or additional effects
associated with lack of muscle control.
- low blood pressure (fainting).
- digestive system disturbances: stomach
problems, including retching; vomiting;
constipation; diarrhea.
- increased sweating, rash.
- passing more urine than usual or pain upon
urination.

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

- tingling or numbness in 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 rash on the skin, accompanied by
itching (urticaria – also known as nettle-rash
or hives).
- slow heart rate.
- increase in blood sugar level.
- breathing difficulties during sleep (sleep
apnea syndrome).
- withdrawal symptoms resulting from abrupt
discontinuation of use of the medicine (see
"If you stop taking the medicine" section).

**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.

If your doctor has told you to stop taking
Baclosal tablets, give your remaining tablets
to the pharmacist to be discarded. Keep the
tablets only if your doctor tells you to do
so. Do not throw away the tablets into the
wastewater or wastebin. This is to preserve
the environment.

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** has 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 21429, Tel Aviv, 6121301.

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

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

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