For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only

BIZLO

1. **Generic Name**

   Baclofen Tablets IP

2. Qualitative and quantitative composition

Each uncoated tablet contains:

Baclofen I.P. ……..10 mg

The excipients used are Starch, Microcrystalline Cellulose, Magnesium Stearate, Talcum, and Sodium Starch Glycolate and Colloidal silicon dioxide.

3. Dosage form and strength

Dosage form: Uncoated Tablets

Strength: Baclofen - 10 mg

4. Clinical particulars

4.1 Therapeutic indication

Baclofen is indicated for the relief of spasticity of voluntary muscle resulting from such disorders as: multiple sclerosis, other spinal lesions, e.g. tumours of the spinal cord, syringomyelia, motor neurone disease, transverse myelitis, traumatic partial section of the cord.

4.2 Posology and method of administration

Posology

Dose: As directed by the Physician.

Method of administration

Baclofen 10 mg uncoated tablets should be administered orally.

4.3 Contraindications

- Hypersensitivity to baclofen or to any of the excipients
- Peptic ulceration

4.4 Special warnings and precautions for use

Psychiatric and nervous system disorders

Psychotic disorders, schizophrenia, depressive or manic disorders, confusional states or Parkinson's disease may be exacerbated by treatment with BIZLO. Patients suffering from these conditions should therefore be treated cautiously and kept under close surveillance.

Suicide and suicide-related events have been reported in patients treated with baclofen. In most cases, the patients had additional risk factors associated with an increased risk of suicide including alcohol use disorder, depression and/or a history of previous suicide attempts. Close supervision of patients with additional risk factors for suicide should

accompany drug therapy. Patients (and caregivers of patients) should be alerted about the need to monitor for clinical worsening, suicidal behaviour or thoughts or unusual changes in behaviour and to seek medical advice immediately if these symptoms present.

Cases of misuse, abuse and dependence have been reported with baclofen. Caution should be exercised in patients with a history of substance abuse and the patient should be monitored for symptoms of baclofen misuse, abuse or dependence e.g. dose escalation, drug-seeking behaviour, development of tolerance.

Epilepsy

BIZLO may also exacerbate epileptic manifestations but can be employed provided appropriate supervision and adequate anticonvulsive therapy are maintained.

Others

BIZLO should be used with extreme care in patients already receiving antihypertensive therapy, BIZLO should be used with caution in patients suffering from cerebrovascular accidents or from respiratory or hepatic impairment.

Since unwanted effects are more likely to occur, a cautious dosage schedule should be adopted in elderly and patients with spasticity of cerebral origin.

Renal impairment

Baclofen should be used with caution in patients with renal impairement and should be administered to end stage renal failure patients only if the expected benefit outweighs the potential risk. Neurological signs and symptoms of overdose including clinical manifestations of toxic encephalopathy (e.g. confusion, disorientation, somnolence and depressed level of consciousness) have been observed in patients with renal impairment taking oral baclofen at doses of more than 5mg per day. Patients with impaired renal function should be closely monitored for prompt diagnosis of early symptoms of toxicity.

Particular caution is required when combining BIZLO to drugs or medicinal products that can significantly affect renal function. Renal function should be closely monitored and BIZLO daily dosage adjusted accordingly to prevent baclofen toxicity.

Cases of baclofen toxicity have been reported in patients with acute renal failure.

Besides discontinuing treatment, unscheduled haemodialysis might be considered as a treatment alternative in patients with severe baclofen toxicity. Haemodialysis effectively removes baclofen from the body, alleviates clinical symptoms of overdose and shortens the recovery time in these patients.

Urinary disorders

Under treatment with BIZLO neurogenic disturbances affecting emptying of the bladder may show an improvement. In patients with pre-existing sphincter hypertonia, acute retention of urine may occur; the drug should be used with caution in such cases.

Laboratory tests

In rare instances elevated aspartate aminotransferase, blood alkaline phosphatase and blood glucose levels in serum have been recorded. Appropriate laboratory tests should be performed in patients with liver diseases or diabetes mellitus in order to ensure that no drug induced changes in these underlying diseases have occurred.

Excipients

BIZLO tablets contain wheat starch. Wheat starch may contain gluten, but only in trace

amounts. Taking BIZLO tablets is therefore considered safe for people with coeliac disease.

Abrupt withdrawal:

Treatment should always, (unless serious adverse effects occur), be gradually discontinued by successively reducing the dosage over a period of about 1-2 weeks. Anxiety and confusional state, delirium, hallucination, psychotic disorder, mania or paranoia, convulsion (status epilepticus), dyskinesia, tachycardia, hyperthermia, rhabdomyolysis and temporary aggravation of spasticity have been reported with abrupt withdrawal of BIZLO, especially after long term medication.

Drug withdrawal reactions including postnatal convulsions in neonates have been reported after intrauterine exposure to oral BIZLO.

Treatment should always, (unless serious adverse effects occur), therefore be gradually discontinued by successively reducing the dosage over a period of about 1-2 weeks.

Paediatric patients

There is very limited clinical data on the use of BIZLO in children under the age of one year. Use in this patient population should be based on the physician's consideration of individual benefit and risk of therapy.

Posture and balance

BIZLO should be used with caution when spasticity is needed to sustain upright posture and balance in locomotion.

4.5 Drugs interactions

Levodopa/dopa decarboxylase (DDC) inhibitor (Carbidopa)

In patients with Parkinson's disease receiving treatment with BIZLO and levodopa (alone or in combination with DDC inhibitor, carbidopa), there have been reports of mental confusion, hallucinations, nausea and agitation. Worsening of the symptoms of Parkinsonism has also been reported. Hence, caution should be exercised during concommitant administration of BIZLO and levodopa/carbidopa.

Drugs causing Central Nervous System (CNS) depression

Increased sedation may occur when BIZLO is taken concomitantly with other drugs causing CNS depression including other muscle relaxants (such as tizanidine), with synthetic opiates or with alcohol.

The risk of respiratory depression is also increased. In addition, hypotension has been reported with concomitant use of morphine and intrathecal baclofen. Careful monitoring of respiratory and cardiovascular functions is essential especially in patients with cardiopulmonary disease and respiratory muscle weakness.

Antidepressants

During concomitant treatment with tricyclic antidepressants, the effect of BIZLO may be potentiated, resulting in pronounced muscular hypotonia.

Lithium

Concomitant use of oral BIZLO and lithium resulted in aggravated hyperkinetic symptoms. Thus, caution should be exercised when BIZLO is used concomitantly with lithium.

Antihypertensives

Since concomitant treatment with BIZLO and anti-hypertensives is likely to increase the fall in blood pressure, the dosage of antihypertensive medication should be adjusted accordingly.

Agents reducing renal function

Drugs or medicinal products that can significantly affect renal function may reduce baclofen excretion leading to toxic effects.

4.6 Use in special populations (such as pregnant women, lactating women, paediatric patients, geriatric patients etc.)

Pregnancy

During pregnancy, especially in the first 3 months, BIZLO should only be employed if its use is of vital necessity. The benefits of the treatment for the mother must be carefully weighed against the possible risks for the child. Baclofen crosses the placental barrier.

Foetal/neonatal adverse reactions

Drug withdrawal reactions including postnatal convulsions in neonates have been reported after intra-uterine exposure to oral BIZLO.

Breast-feeding

In mothers taking BIZLO at therapeutic doses, the active substance passes into the breast milk, but in quantities so small that no undesirable effects in the infant are to be expected.

4.7 Effects on ability to drive and use machines

BIZLO may be associated with adverse effects such as dizziness, sedation, somnolence and visual impairment which may impair the patient's reaction. Patients experiencing these adverse reactions should be advised to refrain from driving or using machines.

4.8 Undesirable effects

Adverse effects occur mainly at the start of treatment (e.g. sedation, somnolence and nausea), if the dosage is raised too rapidly, if large doses are employed, or in elderly patients. They are often transitory and can be attenuated or eliminated by reducing the dosage; they are seldom severe enough to necessitate withdrawal of the medication.

Should nausea persist following a reduction in dosage, it is recommended that BIZLO be ingested with food or a milk beverage.

In patients with a history of psychiatric illness or with cerebrovascular disorders (e.g. stroke) as well as in elderly patients, adverse reactions may assume a more serious form.

Lowering of the convulsion threshold and convulsions may occur, particularly in epileptic patients.

Certain patients have shown increased spasticity as a paradoxical reaction to the medication.

An undesirable degree of muscular hypotonia - making it more difficult for patients to walk or fend for themselves - may occur and can usually be relieved by re-adjusting the dosage (i.e. by reducing the doses given during the day and possibly increasing the evening dose).

Adverse reactions (Table 1) are ranked under heading of frequency, the most frequent

first, using the following convention: very common (≥ 1/10); common (≥ 1/100, < 1/10); uncommon (≥ 1/1,000, < 1/100); rare (≥ 1/10,000, < 1/1,000) very rare (< 1/10,000) and Not known (cannot be estimated from the available data).

Table 1: Tabulated summary of adverse drug reactions

Nervous system disorders	
Very common:	Sedation, somnolence
Common:	Respiratory depression, confusional state, dizziness, hallucination, depression, fatigue, insomnia, euphoric mood, muscular weakness, ataxia, tremor, nightmare, myalgia, headache, nystagmus, dry mouth
Rare:	Paraesthesia, dysarthria, dysgeusia
Unknown:	Sleep Apnoea syndrome*
Eye disorders	
Common:	Visual impairment, accommodation disorder
Cardiac disorders	
Common:	Cardiac output decreased
Not known:	Bradycardia
Vascular disorders	
Common:	Hypotension
Gastrointestinal disorders	
Very common:	Nausea
Common:	Gastrointestinal disorder, constipation, diarrhoea, retching, vomiting
Rare:	Abdominal pain
Hepatobiliary disorders	
Rare:	Hepatic function abnormal
Skin and subcutaneous tissue disorders	
Common:	Rash, hyperhidrosis
Not known	Urticaria
Renal and urinary disorders	
Common:	Pollakiuria, enuresis, dysuria
Rare:	Urinary retention
Reproductive system and breast disorders	
Rare:	Erectile dysfunction
General disorders and administration site conditions	
Very rare	Hypothermia
Not known	Drug withdrawal syndrome*
Investigations	
Not known:	Blood gluocse increased

*Drug withdrawal syndrome including postnatal convulsions in neonates has also been reported after intra-uterine exposure to oral BIZLO.

* Cases of central sleep apnoea syndrome have been observed with baclofen at high doses (≥ 100 mg) in patients who are alcohol dependent.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

Healthcare professionals are asked to report any suspected adverse reactions via Yellow Card Scheme (www.mhra.gov.uk/yellowcard).

4.9 Overdose

Symptoms: Prominent features are signs of central nervous depression: somnolence, depressed level of consciousness, coma, respiratory depression. Also liable to occur are: confusion, hallucination, agitation, convulsion, abnormal electroencephalogram (burst suppression pattern and triphasic waves), accommodation disorder, impaired pupillary reflex, generalised muscular hypotonia, myoclonus, hyporeflexia or areflexia, peripheral vasodilatation, hypotension or hypertension, bradycardia, tachycardia or cardiac arrhythmia, hypothermia, nausea, vomiting, diarrhoea, salivary hypersecretion, increased hepatic enzymes and rhabdomyolysis. Patients with renal impairment can develop signs of overdose even on low doses of oral BIZLO.

A deterioration in the condition may occur if various substances or drugs acting on the central nervous system (e.g. alcohol, diazepam, tricyclic antidepressants) have been taken at the same time.

Treatment: No specific antidote is known.

Supportive measures and symptomatic treatment should be given for complications such as hypotension, hypertension, convulsions, gastrointestinal disorders and respiratory or cardiovascular depression.

Since the drug is excreted chiefly via the kidneys, generous quantities of fluid should be given, possibly together with a diuretic. Haemodialysis (sometimes unscheduled) may be useful in severe poisoning associated with renal failure.

5. Pharmacological properties

5.1 Mechanism of Action

Baclofen depresses monosynaptic and polysynaptic reflex transmission, probably by stimulating the GABA -receptors, this stimulation in turn inhibiting the release of the excitatory amino acids glutamate and aspartate. Neuromuscular transmission is unaffected by Baclofen.

5.2 Pharmacodynamic properties

Pharmacotherapeutic group: Antispastic with spinal site attack,

ATC code: M03B X01

Baclofen is an antispastic agent acting at the spinal level. A gamma-aminobutyric acid (GABA) derivative, Baclofen is chemically unrelated to other antispastic agents.

The major benefits of Baclofen stem from its ability to reduce painful flexor spasms and spontaneous clonus thereby facilitating the mobility of the patient, increasing his independence and helping rehabilitation.

Baclofen also exerts an antinociceptive effect. General wellbeing is often improved and sedation is less often a problem than with centrally acting drugs.

Baclofen stimulates gastric acid secretion.

5.3 Pharmacokinetic properties

Absorption: BIZLO (baclofen) is rapidly and completely absorbed from the gastro-intestinal tract. No significant difference between the liquid and tablet formulations is observed in respect of T_{max}, C_{max} and bioavailability. Following oral administration of single doses (10-30mg) peak plasma concentrations are recorded after 0.5 to 1.5 hours and areas under the serum concentration curves are proportional to the dose.

Distribution: The volume of distribution of baclofen is 0.7 l/kg, The protein binding rate is approximately 30% and is constant in the concentration range of 10 nanogram/mL to 300 microgram/mL. In cerebrospinal fluid active substance concentrations are approximately 8.5 times lower than in the plasma.

Biotransformation: Baclofen is metabolised to only a minor extent. Deamination yields the main metabolite, β-(p-chlorophenyl)-4-hydroxybutyric acid, which is pharmacologically inactive.

Elimination/excretion: The plasma elimination half-life of baclofen averages 3 to 4 hours.

Baclofen is eliminated largely in unchanged form. Within 72 hours, approximately 75% of the dose is excreted via the kidneys with about 5% of this amount as metabolites.

Special populations

The pharmacokinetics of baclofen in elderly patients are virtually the same as in patients below 65 years of age. Following a single oral dose, elderly patients have slower elimination but a similar systemic exposure of baclofen compared to adults below 65 years of age. Extrapolation of these results to multi-dose treatment suggests no significant pharmacokinetic difference between patients below 65 years of age and elderly patients.

Paediatric patients

Following oral administration of 2.5 mg BIZLO tablet in children (aged 2 to12 years), Cmax of 62.8±28.7 nanogram/mL, and Tmax in the range of 0.95-2 h have been reported. Mean plasma clearance (Cl) of 315.9 mL/h/kg; volume of distribution (Vd) of 2.58 L/kg; and half-life ($T_{½}$) of 5.10 h have been reported.

Hepatic impairment

No pharmacokinetic data are available in patients with hepatic impairment after administration of BIZLO. However, as the liver does not play a significant role in the disposition of baclofen, it is unlikely that baclofen pharmacokinetics would be altered to a clinically significant level in patients with hepatic impairment.

Renal impairment

No controlled clinical pharmacokinetic study is available in patients with renal impairment after administration of BIZLO. Baclofen is predominantly eliminated unchanged in urine. Sparse plasma concentration data collected only in female patients under chronic hemodialysis or compensated renal failure indicate significantly decreased clearance and increased half-life of baclofen in these patients. Dosage adjustment of baclofen based on its systemic levels should be considered in renal impairment patients, and prompt hemodialysis is an effective means of reversing excess baclofen in systemic circulation.

6. Nonclinical properties

6.1 Animal Toxicology or Pharmacology

In a reported study baclofen increases the incidence of omphaloceles (ventral hernias) in the foetuses of rats given approximately 13 times the maximum oral dose (on a mg/kg basis) recommended for human use. This was not seen in mice or rabbits.

In reported study an apparently dose related increase in the incidence of ovarian cysts, and a less marked increase in enlarged and/or haemorrhagic adrenals have been observed in female rats treated for 2 years. The clinical relevance of these findings is not known.

Experimental evidence to date suggests that baclofen does not possess either carcinogenic or mutagenic properties.

7. Description

Baclofen is (RS)-4-amino-3-(4-chlorophenyl) butyric acid having molecular formula as $C_{10}H_{12}ClNO_2$ and molecular weight of 213.7. It is a white or almost white powder which is soluble in slightly soluble in water; very slightly soluble in ethanol (95%); practically insoluble in acetone.

Baclofen Tablets are white to off-white, round, flat, scored on one side, plain on other side & uncoated tablets. The excipients used are Starch, Microcrystalline Cellulose, Magnesium Stearate, Talcum, Sodium Starch Glycolate and Colloidal silicon dioxide.

8. Pharmaceutical particulars

8.1 Incompatibilities

None known

8.2 Shelf-life

Do not use later than date of expiry.

8.3 Packaging information

BIZLO is available in blister strip of 10 Tablets.

8.4 Storage and handing instructions

Protect from light and moisture, at a temperature not exceeding 30°C.

Keep all medicines out of reach of children.

9. Patient counselling information

BIZLO

Baclofen 10 mg

Your doctor has decided that you or your child needs this medicine to help treat your condition.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet?

9.1 What BIZLO is and what it is used for

BIZLO Tablets contain 10 mg of the active ingredient baclofen.

Baclofen is a muscle-relaxant drug. It is indicated for the relief of spasticity of voluntary muscle resulting from such disorders as: multiple sclerosis, other spinal lesions, e.g. tumours of the spinal cord, syringomyelia, motor neurone disease, transverse myelitis, traumatic partial section of the cord.

9.2 What you need to know before you take BIZLO

Some people MUST NOT take BIZLO Tablets. Talk to your doctor if:

- You think you may be allergic to baclofen or to any of the other ingredients of the tablets,
- You have ever had a stomach ulcer.

You should also ask yourself these questions before taking BIZLO Tablets:

- Have you had a stroke?
- Do you have epilepsy?
- Do you suffer from any mental illness?
- Are you being treated for high blood pressure?
- Do you have Parkinson's disease?
- Do you suffer from any liver, kidney or lung disease?
- Do you have diabetes?
- Do you have difficulties in urinating?
- Are you pregnant or breast-feeding?
- Do you have an intolerance to wheat flour? (The tablets contain small amounts of wheat starch. They are suitable for people with coeliac disease, however if you have a wheat allergy (different from coeliac disease), you should not take this medicine.)
- Do you have a history of drug abuse or dependance

If the answer to any of these questions is YES, tell your doctor or pharmacist because BIZLO Tablets might not be the right medicine for you.

Are you taking other medicines?

Some medicines can interfere with your treatment. Tell your doctor or pharmacist if you are taking any of the following:

- Other medicines to relax muscles e.g. tizanidine
- Medicines to treat mood disorders such as lithium or tricyclic antidepressants such as amitriptyline
- Medicines for high blood pressure e.g. diltiazem
- Other drugs which also affect the kidney, e.g. ibuprofen
- Medicines for Parkinson's disease e.g. levodopa or carbidopa
- Medicines which slow down the nervous system, e.g. anti-histamines such as promethazine, sedatives such as temazepam, opiates for pain relief such as morphine and anti-convulsants (antiepileptic medicines such as carbamazepine).

Always tell your doctor or pharmacist about all the medicines you are taking. *This means medicines you have bought yourself as well as medicines on prescription from your doctor.*

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

You should not use BIZLO during pregnancy unless your doctor advises you to do so. Tell your doctor if you are pregnant, or planning to become pregnant.

If you have to take BIZLO during pregnancy, your unborn baby will also be exposed to BIZLO. After birth your baby may develop withdrawal symptoms such as convulsions (symptoms of withdrawal are described in the section "**If you stop taking BIZLO**").

Only a very small amount of BIZLO passes into breast milk. Your doctor will discuss with you whether you should breast-feed whilst taking BIZLO.

Will there be any problems with driving or using machinery?

Some people may feel drowsy and/or dizzy or have problems with their eyes while they are taking BIZLO Tablets. If this happens, you should not drive or do anything that requires you to be alert (such as operate tools or machinery) until these effects have worn off.

Other special warnings

- Be careful when drinking alcohol - it may affect you more than usual
- Some people being treated with baclofen have had thoughts of harming or killing themselves or have tried to kill themselves. Most of these people also had depression, had been using alcohol excessively or were prone to having thoughts of killing themselves. If you have thoughts of harming or killing yourself at any time, speak to your doctor straightaway 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.
- Your doctor may want to give you a check-up from time to time while you are taking BIZLO Tablets.
- If you are going to have an operation of any kind, make sure that the doctor knows that you are taking BIZLO Tablets.

Children and adolescents:

BIZLO Tablets are not suitable for use in children under 33 kg body weight.

9.3 How to take BIZLO

The doctor will tell you how many BIZLO Tablets to take and when to take them. Always follow his/her instructions carefully. The dose will be on the pharmacist's label. Check the label carefully. If you are not sure, ask your doctor or pharmacist.

The doctor will tell you the best time to take the medicine. Some people take it only at night or before doing a task such as washing, dressing, shaving, etc.

The final dose of BIZLO depends on how each person responds to the drug. You will be started on a low dose, and this will be increased gradually over a few days, under the supervision of the doctor, until you are having the dose which is right for you. If the starting dose is too high, or if the dose is increased too quickly, you may experience side effects, particularly if you are elderly, have kidney problems or have had a stroke.

If you feel sick after taking BIZLO Tablets, you may find it helps to take them with food or a milk drink.

Adults

- The usual dose is 20 mg (2 tablets) three times a day.
- The maximum daily dose is 100 mg (10 tablets) except if you are in hospital when a higher dose may be used.

Children (0 to < 18 years)

Children's treatment is adjusted to their body weight. Children's treatment usually starts with a very low dose (approximately 0.3 mg/kg/day), in 2-4 divided doses (preferably in 4 doses). The dosage is then gradually increased until it becomes sufficient for the child's individual requirements, this may be between 0.75 and 2 mg/kg body weight. The total daily dose should not exceed a maximum of 40 mg/day in children below 8 years of age. In children over 8 years of age a maximum daily dose of 60 mg/day may be given. BIZLO Tablets are not suitable for use in children below 33 kg body weight.

Patients with kidney problems

You will probably be given a much lower dose. The doctor will decide what the dose should be.

What if you forget to take a dose?

If you forget to take a dose, take the next dose at the usual time. DO NOT take a double dose.

What if you take too much?

If you accidentally take too many BIZLO Tablets, tell your doctor at once or contact your nearest hospital casualty department. Take your medicine with you.

If you stop taking BIZLO

You should not stop taking BIZLO Tablets suddenly. If the doctor decides to stop your treatment with BIZLO Tablets, the dose will be reduced gradually 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, feeling persecuted or convulsions (fits).

9.4 Possible side effects

BIZLO Tablets are suitable for most people, but, like all medicines, they can sometimes cause side effects.

The side effects listed below have been reported:

More than 1 in 10 people have experienced:

Tiredness, sleepiness, nausea (feeling sick).

Up to 1 in 10 people have experienced:

- Excessively weak limbs or feeling tired and exhausted, aching muscles
- Headache, dizziness or light-headedness
- Breathing difficulties
- Sleeplessness
- Mood changes, confusion, hallucinations or nightmares
- Dry mouth
- Problems with their eyes
- Unsteadiness, trembling or other problems with muscle control
- Low blood pressure (fainting)
- Stomach problems including retching, vomiting, constipation and diarrhoea
- Excessive sweating, rash
- Increased need to pass urine or pain on passing urine.

Up to 1 in 1,000 people have experienced:

- Numbness or tingling in hands or feet
- Increased muscle spasm
- Disturbed sense of taste
- Slurred or slow speech
- Stomach ache
- Liver problems
- Difficulty in passing urine
- Sexual problems in men, e.g. impotence
- Convulsions (particularly in epileptics).

Very rarely (less than 1 in 10,000) people have experienced:

- Hypothermia (low body temperature).

Other side-effects (how often they happen is not known)

- Raised, itchy rash (urticaria – also known as nettle rash or hives).
- Slow heartbeat.
- Increase in blood sugar.

- Trouble breathing during sleep (sleep apnoea syndrome)
- Symptoms caused by stopping treatment suddenly.

If any of the symptoms become troublesome, or if you notice anything else not mentioned here, please go and see your doctor. He/she may want to adjust the dose or give you a different medicine.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via any point of contact of Torrent Pharma available at:
http://www.torrentpharma.com/Index.php/site/info/adverse_event_reporting.

By reporting side effects, you can help provide more information on the safety of this medicine

9.5 How to store BIZLO

Protect from light and moisture, at a temperature not exceeding 30°C.

9.6 Contents of the pack and other information

What **BIZLO** contains

The active substances in BIZLO is Baclofen.

The excipients used are Starch, Microcrystalline Cellulose, Magnesium Stearate, Talcum, Sodium Starch Glycolate and Collidal silicon dioxide.

10. Details of manufacturer

Manufactured in India by:
Pure & Cure Healthcare Pvt. Ltd.
(A subsidiary of Akums Drugs & Pharmaceuticals Ltd.)
Plot No. 26A-30, Sector -8A, I.I.E., SIDCUL, Haridwar- 249403, Uttarakhand.

11. Details of permission or licence number with date

Mfg Lic No. 31/UA/2013 issued on 10.10.2014.

12. Date of revision

Jun/2020

MARKETED BY

TORRENT PHARMACEUTICALS LTD.

IN/BIZLO 10 mg/JUN-20/02/PI