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

BIZLO OD

1. Generic Name

Baclofen Extended Release Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each uncoated extended release tablet contains:

Baclofen I.P. …….20 mg

The excipients used are Microcrystalline Cellulose, Methocel K4M, Lactose, Polyvinyl Pyrrolidone, Isopropyl Alcohol, and Colloidal Silicon Dioxide & Magnesium Stearate.

3. DOSAGE FORM AND STRENGTH

Dosage Form: Uncoated Extended Release Tablet

Strength: 20 mg

4. CLINICAL PARTICULARS

4.1 Therapeutic Indication

For the symptomatic treatment of neuronal spasticity due to multiple sclerosis, spinal chord, pathology & injury.

4.2 Posology and Method of Administration

Dosage: As directed by the Physician.

Dosage

BIZLO OD is given orally in either tablet or liquid form. These two formulations are bioequivalent. The liquid may be particularly suitable for children or those adults who are unable to take tablets. Dosage titration can be more precisely managed with the liquid. The lowest dose compatible with an optimal response is recommended.

Before starting treatment with BIZLO OD it is prudent to realistically assess the overall extent of clinical improvement that the patient may be expected to achieve. Careful titration of dosage is essential (particularly in the elderly) until the patient is stabilised. If too high a dose is initiated or if the dosage is increased too rapidly side effects may occur. This is particularly relevant if the patient is ambulant in order to minimise muscle weakness in the unaffected limbs or where spasticity is necessary for support.

Once the maximum recommended dose has been reached, if the therapeutic effect is not apparent within 6 weeks a decision whether to continue with BIZLO OD should be taken.

Discontinuation of the treatment should always be gradual by successively reducing the dosage over a period of approximately 1 to 2 weeks, except in overdose-related emergencies, or where serious adverse effects have occurred.

Adults:

Treatment should be started with a dosage of 15 mg daily, preferably in divided doses. The following gradually increasing dosage regimen is suggested, but should be adjusted to suit individual patient requirements.

5 mg three times a day for three days

10 mg three times a day for three days

15 mg three times a day for three days

20 mg three times a day for three days

Satisfactory control of symptoms is usually obtained with doses of up to 60 mg daily, but a careful adjustment is often necessary to meet the requirements of each individual patient. The dose may be increased slowly if required, but a maximum daily dose of more than 100 mg is not advised unless the patient is in hospital under careful medical supervision. Small frequent dosage may prove better in some cases than larger spaced doses. Also some patients benefit from the use of BIZLO OD only at night to counteract painful flexor spasm. Similarly, a single dose given approximately 1 hour prior to performance of specific tasks such as washing, dressing, shaving, physiotherapy, will often improve mobility.

Special populations

Elderly patients (aged 65 years or above):

Elderly patients may be more susceptible to side effects, particularly in the early stages of introducing BIZLO OD. Small doses should therefore be used at the start of treatment, the dose being titrated gradually against the response, under careful supervision. There is no evidence that the eventual average maximum dose differs from that in younger patients.

Paediatric population (0 to < 18 years):

Treatment should usually be started with a very low dose (corresponding to approximately 0.3 mg/kg a day), in 2-4 divided doses, preferably in 4 divided doses. The dosage should be cautiously raised at about 1 week intervals, until it becomes sufficient for the child's individual requirements. The usual daily dosage for maintenance therapy ranges 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 dosage of 60 mg/day may be given.

BIZLO OD tablets are not suitable for use in children below 33 kg body weight.

Patients with impaired renal function:

In patients with impaired renal function or undergoing chronic haemodialysis, a particularly low dosage of BIZLO OD should be selected i.e. approx. 5 mg daily.

BIZLO OD should be administered to end stage renal failure patients only if the expected benefit outweighs the potential risk. These patients should be closely monitored for prompt diagnosis of early signs and/or symptoms of toxicity (e.g. somnolence, lethargy).

Patients with hepatic impairment:

No studies have been performed in patients with hepatic impairment receiving BIZLO OD therapy. The liver does not play a significant role in the metabolism of baclofen after oral administration of BIZLO OD. However, BIZLO OD has the potential of elevating liver enzymes. BIZLO OD should be prescribed with caution in patients with hepatic impairment

Patients with spastic states of cerebral origin:

Unwanted effects are more likely to occur in these patients. It is therefore recommended that a cautious dosage schedule be adopted and that patients be kept under appropriate surveillance.

Method of administration

BIZLO OD should be taken during meals with a little liquid.

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

Porphyria, history of alcoholism, hypertension, psychotic disorders, and schizophrenia, depressive or manic disorders, confusional states or Parkinson's disease may be exacerbated by treatment with baclofen. 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 OD may also exacerbate epileptic manifestations but can be employed provided appropriate supervision and adequate anticonvulsive therapy are maintained.

Others

BIZLO OD should be used with extreme care in patients already receiving antihypertensive therapy.

BIZLO OD 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 impairment 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 OD to drugs or medicinal products that can significantly affect renal function. Renal function should be closely monitored and BIZLO OD 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 OD 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.

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 OD, especially after long term medication.

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

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 OD 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 OD 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 OD 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 OD and levodopa/carbidopa.

Drugs causing Central Nervous System (CNS) depression

Increased sedation may occur when BIZLO OD 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 OD may be potentiated, resulting in pronounced muscular hypotonia.

Lithium

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

Antihypertensive

Since concomitant treatment with BIZLO OD and anti-hypertensive 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 OD 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 OD.

Breast-feeding

In mothers taking BIZLO OD 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 OD 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 OD 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 glucose increased

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

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

4.9 Overdose

Symptoms: Prominent features are signs of central nervous depression: somnolence, depressed level of consciousness, coma, and 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 OD.

A deterioration in the condition may occur if various substances or drugs acting on the central nervous system (e.g. alcohol, diazepam, and 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

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

5.2 Pharmacodynamics Properties

Pharmacotherapeutic group: Antispastic with spinal site attack, ATC code: M03B X01

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

The major benefits of BIZLO OD 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.

BIZLO OD also exerts an antinociceptive effect. General well-being 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 OD (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

Elderly patients (aged 65 years or above)

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 OD 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 ($T_{1/2}$) of 5.10 h have been reported.

Hepatic impairment

No pharmacokinetic data are available in patients with hepatic impairment after administration of BIZLO OD. 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 OD. 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

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

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.

BIZLO OD are white to off-white coloured, round, flat, one side scored, plain on other side and uncoated extended release tablets. The excipients used are Microcrystalline Cellulose, Methocel K4M, Lactose, Polyvinyl Pyrrolidone, Isopropyl Alcohol, and Colloidal Silicon Dioxide & Magnesium Stearate.

8. PHARMACEUTICAL PARTICULARS

8.1 Incompatibilities

Not Available

8.2 Shelf-life

Do not use later than date of expiry.

8.3 Packaging information

BIZLO OD is packed in blister strips of 10 tablets

8.4 Storage and Handing Instructions

Store protected from light & moisture, at a temperature not exceeding 30^0C.

Keep all medicines out of reach of children.

9. PATIENT COUNSELLING INFORMATION

BIZLO OD

(Baclofen)

Patient Information Leaflet

What you need to know about BIZLO OD Tablets

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

Please read this leaflet carefully before you start to take your medicine. It contains important information. Keep the leaflet in a safe place because you may want to read it again.

If you have any other questions, or if there is something you don't understand, please ask your doctor or Pharmacist.

This medicine has been prescribed for you. Never give it to someone else. It may not be the right medicine for them even if their symptoms seem to be the same as yours.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

9.1 What BIZLO OD Tablets are and what they are used for

BIZLO OD Tablets contain Baclofen 20 mg of active ingredient.

Baclofen is a muscle-relaxant drug. BIZLO OD Tablets are used to reduce and relieve the excessive tension In your muscles (spasms) occurring in various illnesses such as cerebral palsy, multiple sclerosis, Cerebrovascular accidents, spinal cord diseases and other nervous system disorders.

9.2 Things to consider before you start to take BIZLO OD Tablets

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

- You think you may be allergic to baclofen or to any of the other ingredients of the tablets, (these are listed at the end of the leaflet.)
- You have ever had a stomach ulcer.
- **You should also ask yourself these questions before taking BIZLO OD 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.)

If the answer to any of these questions is YES, tell your doctor or pharmacist because BIZLO OD 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 OD 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 OD during pregnancy, your unborn baby will also be exposed to BIZLO OD .After Birth your baby may develop withdrawal symptoms such as convulsions.

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

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 OD

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.
- Your doctor may want to give you a check-up from time to time while you are taking BIZLO OD
- Tablets.
- If you are going to have an operation of any kind, make sure that the doctor knows that you are taking BIZLO OD Tablets.

Children and adolescents:

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

9.3 How to take BIZLO OD Tablets

The doctor will tell you how many BIZLO OD 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 OD 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 OD 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 OD 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 OD Tablets, tell your doctor at once or contact your nearest hospital casualty department. Take your medicine with you.

If you stop taking BIZLO OD

You should not stop taking BIZLO OD Tablets suddenly. If the doctor decides to stop your treatment with BIZLO OD 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 OD 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 (see '3. How to take BIZLO OD Tablets').

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.

9.5 How to store BIZLO OD Tablets

Store protected from light & moisture, at a temperature not exceeding 30^0C.

9.6 Contents of the pack and other information

Bizlo OD contains Baclofen 20 mg as active ingredient.

The excipients used are Microcrystalline Cellulose, Methocel K4M, Lactose, Polyvinyl Pyrrolidone, Isopropyl Alcohol, Colloidal Silicon Dioxide & Magnesium Stearate.

BIZLO OD is packed in blister strips of 10 tablets

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

Not Applicable

MARKETED BY

TORRENT PHARMACEUTICALS LTD.

IN/ BIZLO OD 20mg /Dec 19/01/PI