1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

S3

PROPRIETARY NAME AND DOSAGE FORM

LENDITRO (tablet)

COMPOSITION

Each tablet of LENDITRO contains 5 mg of oxybutynin chloride.

Excipients:

Calcium stearate, lactitol monohydrate, microcrystalline cellulose

Contains sugar: Lactitol monohydrate 173 mg

CATEGORY AND CLASS

A 5.4 Medicines affecting autonomic functions. Cholinolytics (anticholinergics)

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

Oxybutynin chloride exert a direct antispasmodic effect on smooth muscle. Oxybutynin chloride inhibits the muscarinic action of acetylcholine on smooth muscle.

In patients with uninhibited neurogenic and reflex neurogenic bladder, cystometric studies have demonstrated that oxybutynin chloride increases vesical capacity, diminishes the frequency of uninhibited contractions of the detrusor muscle and delays the initial desire to

void. These effects are more consistently improved in patients with uninhibited neurogenic bladder.

INDICATIONS

LENDITRO is indicated for the relief of symptoms associated with voiding in patients with uninhibited neurogenic and reflex neurogenic bladder (i.e. urgency, frequency, urinary leakage, urge incontinence, dysuria).

LENDITRO is indicated for spastic neurogenic bladder (and not hypotonic neurogenic bladder - see CONTRAINDICATIONS).

LENDITRO is indicated for nocturnal enuresis.

CONTRAINDICATIONS

- LENDITRO is contraindicated in patients with closed angle glaucoma.
- LENDITRO is also contraindicated in patients with prostatic enlargement and should be used with caution in elderly men.
- LENDITRO is contraindicated in partial or complete obstruction of the gastro-intestinal tract, paralytic ileus, intestinal atony of the elderly or debilitated patient, megacolon, toxic megacolon complicating ulcerative colitis, severe colitis and myasthenia gravis.
- LENDITRO is also contraindicated in patients with obstructive uropathy and in patients with unstable cardiovascular status in acute haemorrhage.
- LENDITRO is contraindicated in hypotonic neurogenic bladder. It is also not recommended for children under 5 years of age.
- Safety during pregnancy and lactation has not been established.
- LENDITRO should not be used in the presence of fever or when the ambient temperature is high (see WARNINGS AND SPECIAL PRECAUTIONS).

- Hypersensitivity to LENDITRO.
- Patients with pyloric stenosis.

WARNINGS AND SPECIAL PRECAUTIONS

LENDITRO, when administered in the presence of high environmental temperature, can cause heat prostration (fever and heat stroke due to decreased sweating), especially in children.

It should be used cautiously in patients with fever.

LENDITRO should be used with caution in the elderly and in all patients with autonomic neuropathy, hepatic or renal disease. Administration of LENDITRO in large doses to patients with ulcerative colitis may suppress intestinal motility to the point of producing a paralytic ileus and precipitate or aggravate “toxic megacolon”, a serious complication of the disease.

LENDITRO should be used with caution in conditions characterised by tachycardia, such as thyrotoxicosis, cardiac insufficiency or failure and in cardiac surgery. The symptoms of hyperthyroidism, coronary heart disease, congestive heart failure, cardiac arrhythmias and hypertension may be aggravated following the administration of LENDITRO.

LENDITRO should be administered with caution to patients with hiatus hernia associated with reflux oesophagitis, since anticholinergic agents may aggravate this condition.

Diarrhoea may be an early symptom of incomplete intestinal obstruction, especially in patients with ileostomy or colostomy. In this instance treatment with LENDITRO would be inappropriate and possibly harmful.

Effects on ability to drive and use machines

LENDITRO may produce drowsiness or blurred vision. The patient should be cautioned regarding activities requiring mental alertness, such as operating a motor vehicle or other machinery or performing hazardous work while taking this medicine.

Excipients

Patients with the rare hereditary condition of lactitol intolerance should not take LENDITRO.

INTERACTIONS

The anticholinergic effects of LENDITRO may be enhanced by the concomitant administration of other medicines with anticholinergic properties. These include amantadine, some antihistamines, butyrophenones, phenothiazines, tricyclic antidepressants, atropine and scopolamine.

HUMAN REPRODUCTION

Safety during pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE

Adults:

The usual dose is one 5 mg tablet two to three times a day.

The maximum recommended dose is one 5 mg tablet four times a day.

Children over 5 years of age:

The usual dose is one 5 mg tablet two times a day.

The maximum recommended dose is one 5 mg tablet three times a day.

Pre-treatment examination should include cystometry and other appropriate diagnostic

procedures. Cystometry should be repeated at appropriate intervals to evaluate response to therapy.

The appropriate antimicrobial therapy should be instituted in the presence of infection.

SIDE EFFECTS

LENDITRO may cause dry mouth, difficulty to swallow and talk, thirst, decreased sweating, flushing and dryness of the skin, urinary hesitancy and retention, blurred vision, photophobia, transient bradycardia followed by tachycardia, palpitations, arrhythmias, dilatation of the pupil, cycloplegia, increased ocular tension, drowsiness, weakness, dizziness, insomnia, nausea, vomiting, constipation, retrosternal pain due to increased gastric reflux, bloated feeling, impotence, suppression of lactation, severe allergic reactions or drug idiosyncrasies including urticaria and other dermal manifestations.

LENDITRO may cause mental confusion, especially in the elderly.

Reduced bronchial secretions associated with the formation of mucus plugs may occur.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS

Symptoms

The symptoms of overdosage with LENDITRO tablets progress from an intensification of the usual side effect of central nervous system disturbances (restlessness, excitement and confusion) to psychotic behaviour, circulatory changes (flushing, fall in blood pressure, circulatory failure), respiratory failure, paralysis and coma. A rash may appear on the face and upper trunk.

Treatment

In event of an overdose, the stomach should be emptied and activated charcoal administered to reduce absorption. Treatment is symptomatic and supportive.

IDENTIFICATION

A round, white, biconvex tablet.

PRESENTATION

20 tablets are packed in a transparent polyvinyl chloride/polyvinylidine chloride blister, sealed with a hard tempered aluminum foil with bright side print backing. The blisters are packed in a cardboard carton together with a leaflet.

20 tablets packed into a white polypropylene white container with a white, linear low density polyethylene cap and a silica gel sachet and white round flat foam plug.

100 tablets packed into a white polypropylene container with a white, linear low density polyethylene cap and a silica gel sachet and a white round flat foam plug.
100 tablets packed into a white round high density polyethylene container with a white opaque polypropylene cap with continuous threading and a silica gel sachet and a white foam plug

Not all packs and pack sizes are necessarily marketed.

STORAGE INSTRUCTIONS

Store at or below 25 °C.

Keep container well closed.

Keep in original packaging until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

33/5.4/0411

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

PHARMACARE LIMITED

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