SCHEDULING STATUS: S3

PROPRIETARY NAME (AND DOSAGE FORM):

MYLAN OXYBUTYNIN 5 (Tablets)

COMPOSITION:

Each tablet contains oxybutynin chloride 5 mg.

Contains sugar.

PHARMACOLOGICAL CLASSIFICATION:

A5.4 – Medicines affecting autonomic functions. Cholinolytics (Anticholinergics).

PHARMACOLOGICAL ACTION:

MYLAN OXYBUTYNIN 5 tablets exert a direct antispasmodic effect on smooth muscle and inhibit 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 vagal capacity, diminished 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:

MYLAN OXYBUTYNIN 5 tablets are 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.

- Spastic neurogenic bladder (and not hypotonic neurogenic bladder – see contra-indications).
- Nocturnal enuresis.

CONTRA-INDICATIONS:

Hypersensitivity to oxybutynin chloride.

MYLAN OXYBUTYNIN 5 tablets are contra-indicated in patients with closed angle glaucoma. They are also contra-indicated in partial or complete obstruction of the gastrointestinal tract, paralytic ileus or pyloric stenosis, intestinal atony of the elderly or debilitated patient, megacolon, toxic megacolon complicating ulcerative colitis and myasthenia gravis.

It is contra-indicated in patients with obstructive uropathy and in patients with unstable cardiovascular status in acute haemorrhage.

MYLAN OXYBUTYNIN 5 tablets are contra-indicated in hypotonic neurogenic bladder.

The safety of oxybutynin chloride administered to women who are or who may become pregnant has not been established. Therefore, **MYLAN OXYBUTYNIN 5** tablets should not be given to pregnant women.

MYLAN OXYBUTYNIN 5 tablets are not recommended for children under 5 years of age.

MYLAN OXYBUTYNIN 5 tablets are contra-indicated in patients with prostatic enlargement and should be used with caution in elderly men.

WARNINGS:

MYLAN OXYBUTYNIN 5 tablets, 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 with caution in-patients with fever.

The anticholinergic effect of **MYLAN OXYBUTYNIN 5** is enhanced by concomitant use with other agents with anticholinergic properties. These include phenothiazines,

butyrophenones, tricyclic antidepressants, amantadine, atropine, scopolamine and some of the antihistamines.

DOSAGE AND DIRECTIONS FOR USE:

Adults: The usual dose is 5 mg two to three times a day. The maximum recommended dose is 5 mg four times a day.

Children over 5 years of age: The usual dose is 5 mg two times a day. The maximum recommended dose is 5 mg three times a day. Pretreatment 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 AND SPECIAL PRECAUTIONS:

MYLAN OXYBUTYNIN 5 tablets may cause: dry mouth, difficulty to swallow, thirst, decreasing sweating, flushing and dryness of the skin, urinary hesitancy and retention, blurred vision, photophobia, tachycardia, palpitations, dilation of the pupil, cycloplegia, increased ocular tension, drowsiness, weakness, dizziness, insomnia, nausea, vomiting, constipation, retrosternal pain due to gastric reflux, bloated feeling, impotence, suppression of lactation, severe allergic reactions or drug idiosyncrasies including urticaria and other dermal manifestations.

MYLAN OXYBUTYNIN 5 tablets should be used with caution in children, in the elderly and in all patients with autonomic neuropathy, hepatic or renal disease.

Administration of **MYLAN OXYBUTYNIN 5** tablets 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.

MYLAN OXYBUTYNIN 5 tablets 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 administration of **MYLAN OXYBUTYNIN 5** tablets.

MYLAN OXYBUTYNIN 5 tablets should be used with caution in patients with hiatal hernia associated with reflux oesophagitis, since anticholinergic drugs may aggravate this condition.

MYLAN OXYBUTYNIN 5 tablets may produce drowsiness and 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 drug.

MYLAN OXYBUTYNIN 5 may cause mental confusion, especially in the elderly. Reduced bronchial secretion associated with the formation of mucous plugs may occur. Diarrhoea may be an early symptom of incomplete intestinal obstruction, especially in patients with ileostomy or colostomy. In this instance, treatment with **MYLAN OXYBUTYNIN 5** tablets would be inappropriate and possibly harmful.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

The symptoms of overdosage with **MYLAN OXYBUTYNIN 5** tablets progress from an intensification of the usual side effects of CNS 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 is supportive and symptomatic.

IDENTIFICATION:

Blue, round biconvex tablet.

PRESENTATION:

Opaque white securitainers of 20, 100 and 500 tablets.

STORAGE INSTRUCTIONS:

Keep well closed and store in a dry place below 25 °C.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

32/5.4/0740

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

Viatris South Africa (Pty) Ltd

4 Brewery Street

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