PROFESSIONAL INFORMATION

Scheduling status : S3

Proprietary name and dosage form :

Oxybutynin 5 Oethmaan tablets

Composition :

Each Oxybutynin 5 Oethmaan tablet contains oxybutynin hydrochloride 5,0 mg

Excipients:

Crospovidone, lactose monohydrate, magnesium stearate, microcrystalline cellulose, FD&C Blue No 2 (CI # 73015).

Contains sugar (lactose monohydrate 118,90 mg).

Pharmacological classification :

A.5.4 Medicines affecting autonomic functions. Cholinolytics (Anticholinergics)

Pharmacological action :

Oxybutynin 5 Oethmaan tablets exert a direct antispasmodic effect on smooth muscle and inhibit the muscarinic action of acetylcholine on smooth muscle.

In patients with uninhibited neurogenic bladder and reflex neurogenic bladder, cystometric studies have demonstrated that oxybutynin chloride increases vesicle 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 an uninhibited neurogenic bladder.

Indications :

Oxybutynin 5 Oethmaan 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).

Oxybutynin 5 Oethmaan tablets are indicated for spastic neurogenic bladder (and not hypotonic neurogenic bladder – see contra – indications)

Oxybutynin 5 Oethmaan tablets are indicated for nocturnal enuresis.

Contra – indications :

Oxybutynin 5 Oethmaan 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, intestinal atony of the elderly or debilitated patient, megacolon, toxic megacolon complicating ulcerative colitis, severe colitis and myasthenia gravis. They are contra – indicated in patients with obstructive uropathy and in patients with unstable cardiovascular status in acute haemorrhage.

Oxybutynin 5 Oethmaan tablets are contra – indicated in hypotonic neurogenic bladder. The safety of oxybutynin hydrochloride administered to women who are or who may become pregnant has not been established. Therefore, Oxybutynin 5 Oethmaan tablets should not be given to pregnant women.

Oxybutynin 5 Oethmaan tablets are not recommended for use in children under 5 years of age.

Oxybutynin 5 Oethmaan tablets are contra – indicated in patients with prostatic enlargement and should be used with caution in elderly men.

The use of Oxybutynin 5 Oethmaan tablets is contra – indicated when the ambient temperature is high.

Oxybutynin 5 Oethmaan tablets are contra – indicated in patients with pyloric stenosis.

Hypersensitivity to oxybutynin hydrochloride.

Warnings :

Oxybutynin 5 Oethmaan 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 Oxybutynin 5 Oethmaan tablets is enhanced by its concomitant use with other agents with anticholinergic properties. These include the phenothiazines, butyrophenones, tricyclic antidepressants, amantadine, atropine, scopolamine and some of the antihistamines.

Dosage and directions for use :

Adults :

The usual dose is one 5mg tablet two to three times a day. The maximum recommended dose is one 5mg tablet four times per day.

Children over 5 years of age:

The usual dose is one 5mg tablet two times per day. The maximum recommended dose is one 5mg tablet three times per 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 :

Oxybutynin 5 Oethmaan tablets may cause: Dry mouth, difficulty swallowing, 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.

Oxybutynin 5 Oethmaan tablets should be used with caution in children, in the elderly and in all patients with autonomic neuropathy, hepatic or renal disease. Administration of Oxybutynin 5 Oethmaan 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.

Oxybutynin 5 Oethmaan tablets should be used with caution in conditions characterized 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 Oxybutynin 5 Oethmaan tablets.

Oxybutynin 5 Oethmaan tablets should be administered with caution in patients with hiatus hernia associated with reflux oesophagitis, since anticholinergic medicines may aggravate this condition.

Oxybutynin 5 Oethmaan tablets 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.

Oxybutynin 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 Oxybutynin 5 Oethmaan tablets would be inappropriate or and possibly harmful.

Known symptoms of overdosage and particulars of its treatment :

The symptoms of overdosage with Oxybutynin 5 Oethmaan tablets progress from an intensification of the usual side effect 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 :

Oxybutynin 5 Oethmaan tablet – light blue, circular, flat, bevelled edge tablet, embossed “OXB5” on one side, with a break line on the reverse side.

Presentation :

White, opaque polypropylene securitainers containing 100 tablets or white, opaque PVC/PVdC/Aluminium blisters containing 84 or 100 tablets.

Storage instructions :

Store below 25 °C, protected from light.

Do not remove the tablets from the container until required for use. Keep the blisters in the carton until required for use.

KEEP OUT OF REACH OF CHILDREN.

Registration number :

33/5.4/0359

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