South Africa

13/03/2023

Front

English Language - PI

6578

Oxybutynin 5 Oethmaan

SCHEDULING STATUS: S3

PROPRIETARY NAME AND DOSAGE FORM:
Oxybutynin 5 Oethmaan tablets

COMPOSITION:
Each Oxybutynin 5 Oethmaan tablet contains oxybutynin hydrochloride 5,0 mg
Contains sugar (lactose monohydrate 118,90 mg).
Excipients: Crospovidone, microcrystalline cellulose, magnesium stearate, Indigo carmine aluminium lake.

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 hydrochloride 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 5 mg tablet two to three times a day. The maximum recommended dose is one 5 mg tablet four times per day.
Children over 5 years of age:
The usual dose is one 5 mg tablet two times per day. The maximum recommended dose is one 5 mg 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 84 or 100 tablets or PVC/PVDC/Aluminium blisters containing 84 or 100 tablets per carton.

STORAGE INSTRUCTIONS:
Store below 25 °C, protected from light.
Do not remove the tablets from the container until required for use.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:
33/5.4/0359

NAME AND BUSINESS ADDRESS OF APPLICANT:
Oethmaan Biosims (Pty) Ltd.
1st Floor
Sherwood House
Greenacres Office Park
Cnr Victory & Rustenburg Roads
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DATE OF PUBLICATION OF THIS PACKAGE INSERT:
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Size: 140x240 mm

Rusan Specification Checklist For Artwork		CMYK / PANTONE
Product: Oxybutynin 5 Oethmaan	**Date:** 13/03/2023	■ Black
Component: Leaflet	**Country:** South Africa	
SAP / Item Code: 20006578/LLT742	**Commodity Code:** Ensa/lf/oxy	
Dimension: 140x240 mm	**Folding:** V-1 , H-3	
Specification.: 60 gsm Maplitho Paper		**Supersedes Commodity Code**
Reason for change: New Development		
Artwork Path: P:\01 Product Artwork\Oxybutynin 5 - South Africa - KDL		

Back

African Language - PI

Oxybutynin 5 Oethmaan

SKEDULERINGSTATUS: S3

EIENDOMSNAAM EN DOSEERVORM:
Oxybutynin 5 Oethmaan Tablette

SAMESTELLING:
Elke Oxybutynin 5 Oethmaan tablet bevat Oksibutinienhidrochloried 5 mg
Bevat suiker (laktosemonohidraat 118,90 mg).
Hulpstowwe: Krospovidoon, mikrokristallyne sellulose, magnesium-stearaat, Indigo-karmyn-aluminiummeer.

FARMAKOLOGIESE KLASSIFIKASIE:
A5.4 Middels met uitwerking op outonome funksies. Cholinolitika (anticholinergiese middels)

FARMAKOLOGIESE WERKING:
Oxybutynin 5 Oethmaan oefen 'n direkte antispasmodiese uitwerking uit op die gladde spier en inhibeer die muskariniese werking van asetielcholien op gladde spier.
By pasiënte met ongeïnhibeerde neurogene blaas en refleks neurogene blaas, het blaasmetingstudies getoon dat oksibutinienhidrochloried blaaskapasiteit verhoog, die gereeldheid van ongestremde kontraksies van die detrusorspier verminder en die aanvanklike begeerte om te ledig, vertraag. Hierdie uitwerking word meer konsekwent verbeter by pasiënte met ongeïnhibeerde neurogene blaas.

INDIKASIES:
Oxybutynin 5 Oethmaan word aangedui vir die verligting van simptome geassossieer met lediging by pasiënte met ongestremde neurogene en refleks neurogene blaas, d.w.s. drang, gereeldheid, urienlekkasie, beheerverliesdrang, disurie.
Oxybutynin 5 Oethmaan word aangedui vir spastiese neurogene blaas (en nie hipotoniese neurogene nie blaas- sien newe-effekte).
Oxybutynin 5 Oethmaan is aangedui vir nagtelike urienbeheerverlies.

KONTRA-INDIKASIES:
Oxybutynin 5 Oethmaan word teen aangedui by pasiënte met toehoekgloukoom. Dit word ook teenaangedui by gedeeltelike of algehele obstruksie van die maagdermkanaal, dermverlamming, dermverslapping van bejaarde of verswakte pasiënte, megakolon, toksiese megakolon, wat ulseretiewe kolitis vererger, hewige dikdermontsteking en miastenia gravis. Dit is teenaangedui by pasiënte met obstruktiewe urienbaanaandoening en by pasiënte met onstabiele hartvaat status by akute bloeding. Oxybutynin 5 Oethmaan is teenaangedui by hipotoniese neurogene blaas. Die veiligheid van oksibutinienhidrochloried toegedien aan vroue wat swanger is, of kan word, is nog nie vasgestel nie.
Daarom behoort Oxybutynin 5 Oethmaan nie aan swanger vroue gegee te word nie. Oxybutynin 5 Oethmaan word nie aanbeveel vir kinders onder 5 jaar nie.
Oxybutynin 5 Oethmaan is teenaangedui by pasiënte met prostaat vergroting en moet met versigtigheid gebruik work by bejaarde mans.
Oxybutynin 5 Oethmaan, moet nie toegedien word nie as die omringende temperatuur hoog is.
Oxybutynin 5 Oethmaan word teenaangedui by pasiënte wat aan piloriese stenose ly. Hipersensitiviteit vir oksibutinienhidrochloried.

WAARSKUWINGS:
Oxybutynin 5 Oethmaan, wanneer toegedien in die teenwoordigheid van hoë omgewingstemperatuur, kan hitte uitputting veroorsaak (koors en hittesteek weens verminderde sweet) veral by kinders. Dit moet vesigtig gebruik word by pasiënte met koors. Die anticholinergiese uitwerking van Oxybutynin 5 Oethmaan word versterk deur gelyktydige gebruik saam met ander middels met anticholinergiese eienskappe.
Dit sluit in die fenotiasiene, butirofenone, trisikliese antidepressante, amantadien, atropien, skopalamien en sommige antihistamiene.

DOSIS EN GEBRUIKSAANWYSI NGS:
Volwassenes :
Die gebruiklike dosis is een 5 mg tablet twee tot drie keer per dag. Die maksimale aanbevole dosis is een 5 mg tablet vier keer per dag.

Kinders ouer as 5 jaar :
Die gewone dosis is een 5 mg tablet twee keer per dag. Die maksimum aanbevole dosis is een 5 mg tablet drie keer per dag.

Voorbehandeling ondersoek moet blaasmeting en ander toepaslike diagnostiese prosedures insluit. Blaasmeting moet met toepaslike intervalle herhaal word om reaksie op behandeling te bepaal. Die toepaslike antimikrobiese behandeling moet in die teenwoordigheid van infeksie ingestel word.

NEWE - EFFEKTE EN SPESIALE VOORSORGMATREËLS:
Oxybutynin 5 Oethmaan kan veroorsaak: Droë mond, moeilikheid om te sluk, dors, verminderde sweet, gloede en droë vel, urienaarseling en -terughouding, belemmerde sig, fotofobie, tagikardie, verbygaande hartvertraging gevolg deur tagikardie, hartkloppings, aritmie, dilatasie van die pupil, oogaanpassingverlies, verhoogde oogdruk, lomerigheid, swakheid, duiseligheid, slaaploosheid, naarheid, braking, hardlywigheid, retrosternale pyn, a.g.v. verhoogde maagrefluks, opgeblase gevoel, impotensie, onderdrukking van laktasie, ernstige allergiese reaksie of geneesmiddel idiosinkrasiee insluitende urtikarie en ander velverskynsels.

Oxybutynin 5 Oethmaan behoort met sorg by kinders, by bejaardes en by alle pasiënte met outonome senusiekte, lewer- of niersiekte gebruik te word. Toediening van Oxybutynin 5 Oethmaan in groot dosisse aan pasiënte met ulseratiewe kolitis kan dermbeweeglikheid onderdruk tot die punt waar dermverlamming te weeg gebring kan word en "toksiese megakolon", 'n ernstige komplikasie van die siekte omtketen of vererger word.

Oxybutynin 5 Oethmaan behoort met sorg by toestande gekenmerk deur tagikardie, soos tirotoksikose, hartontoereikendheid of -versaking en by hart chirugie, gebruik word. Die simptome van hipertireose, koronere hartsiekte, kongestiewe hartversaking, hart aritmie en hipertensie kan na toediening van Oxybutynin 5 Oethmaan vererger. Oxybutynin 5 Oethmaan moet met sorg aan pasiënte met hiatale breuk geassosieer met refluks esofagitis toegedien word aangesien cholinerge middels hierdie toestand kan vererger.

Oxybutynin 5 Oethmaan kan lomerigheid en belemmerde sig teweegbring. Die pasiënte moet vermaan word aangaande aktiwiteite wat geesteswakkerheid vereis, soos die beheer van 'n motorvoortuig of ander masjienarie, of die uitvoer van gevaarlike werk terwyl die middel geneem word. Oksibutinien tablette kan geestesverwarring veral by bejaardes veroorsaak.

Verminderede brongiale sekresies geassosieer met die vorming van slymproppe kan voorkom.

Diaree kan die vroeë simptoom van onvolledige dermobstruksie wees, veral by pasiënte met kronkeldermverbinding of dikdermbemonding. In hierdie geval sal behandeling met Oxybutynin 5 Oethmaan ontoepaslik en moontlik skadelik wees.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:
Die simptome van oordosering met Oxybutynin 5 Oethmaan vorder van 'n verergering van die gewone newe - effekte van SSS - versteurings (rusteloosheid, opgewondenheid en verwarring) tot psigotiese gedrag, bloedsomloop veranderinge (gloede, val in bloeddruk, bloedsomloop versaking), asemhalingsversaking, verlamming en koma. 'n Uitslag kan op die gesig en bolyf verskyn.
Behandeling is simptomaties en ondersteunend.

IDENTIFIKASIE:
Oxybutynin 5 Oethmaan: ligblou, ronde, plat tablet afgeskuinste rande, geemboseer met "OXB5" op een kant en 'n breeklyn op die rugkant.

AAN BIEDING:
Wit, ondeurskynende polipropilien houers wat elk 84 of 100 tablette bevat of stulpakke van PVC/PVDC/aluminium met 84 of 100 tablette per karton bevat.

BERGINGSAANWYSINGS:
Bere benede 25 °C. Beskerm teen lig.
Moenie die tablette uit die houers verwyder voordat dit vir gebruik nodig is nie.
HOU BUITE DIE DEREIK VAN KINDERS

REGISTRASIE NOMMER:
33/5.4/0359

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DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET:
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