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Betreff: *Oxybutynin*– hältige Arzneispezialitäten – Änderungen der Fach- und Gebrauchsinformationen aufgrund des HBD – PSUR Worksharing Projektes

Sehr geehrte Damen und Herren,

basierend auf der Evaluierung des PSURs im EU-HBD-worksharing Projekt (Verfahrensnummer: BE/H/PSUR/0014/001 und BE/H/PSUR/0014/002) kommt es zu der Empfehlung, folgende Ergänzungen in die **Fach- und Gebrauchsinformation** aller *Oxybutynin*– hältigen Arzneispezialitäten aufzunehmen.

Sollten diese bereits aufgenommen worden sein, betrachten Sie dieses Schreiben als gegenstandslos.

Fachinformation

4.3 Contraindications

- Hypersensitivity to oxybutynin or any component
- Patients with bladder outflow obstruction where urinary retention may be precipitated
- Gastro-intestinal obstructive disorders, intestinal atony or paralytic ileus
- Toxic megacolon
- Severe ulcerative colitis
- Myasthenia gravis
- Narrow-angle glaucoma or shallow anterior chamber

4.4 Special warnings and precautions for use

- Oxybutynin should be used with caution in the frail elderly and children who may be more sensitive to the effects of the product and in patients with autonomic neuropathy (such as those with Parkinson's disease), severe gastro-intestinal motility disorders, hepatic or renal impairment.
- Anticholinergics should be used with caution in elderly patients due to the risk of cognitive impairment.
- Gastrointestinal disorders: Anticholinergic medicinal products may decrease gastrointestinal motility and should be used with caution in patients with gastrointestinal obstructive disorders, intestinal atony and ulcerative colitis.
- Oxybutynin may aggravate tachycardia (and thus hyperthyroidism, congestive heart failure, cardiac arrhythmia, coronary heart disease, hypertension), cognitive disorders and symptoms of prostatic hypertrophy.
- Anticholinergic CNS effects (e.g. hallucinations, agitation, confusion, somnolence) have been reported; monitoring recommended especially in first few months after initiating therapy or increasing the dose; consider discontinuing therapy or reducing the dose if anticholinergic CNS effects develop.
- Since oxybutynin can cause narrow-angle glaucoma, patients should be advised to contact a physician immediately if they are aware of a sudden loss of visual acuity or ocular pain.
- Oxybutynin may reduce salivary secretions which could result in dental caries, parodontosis or oral candidiasis.
- Anticholinergic medicinal products should be used with caution in patients who have hiatus hernia/gastro-oesophageal reflux and/or who are concurrently taking medicinal products (such as bisphosphonates) that can cause or exacerbate oesophagitis.
- When oxybutynin is used in high environmental temperatures, this can cause heat prostration due to decreased sweating.
- The use of oxybutynin in children under 5 years of age is not recommended; it has not been established whether oxybutynin can be safely used in this age group.

4.5 Interaction with other medicinal products and other forms of interaction

Care should be taken if other anticholinergic agents are used together with oxybutynin, as a potentiation of anticholinergic effects may occur.

The anticholinergic activity of oxybutynin is increased by concurrent use of other anticholinergics or medicinal products with anticholinergic activity, such as amantadine and other anticholinergic antiparkinsonian medicinal products (e.g. biperiden, levodopa), antihistamines, antipsychotics (e.g. phenothiazines, butyrophenones, clozapine), quinidine, digitalis, tricyclic antidepressants, atropine and related compounds like atropinic antispasmodics and dipyrindamole.

By reducing gastric motility, oxybutynin may affect the absorption of other drugs. Oxybutynin is metabolised by cytochrome P 450 isoenzyme CYP 3A4. Concomitant administration with a CYP3A4 inhibitor can inhibit oxybutynin metabolism and increase oxybutynin exposure. Oxybutynin may antagonize prokinetic therapies.

Concomitant use with cholinesterase inhibitors may result in reduced cholinesterase inhibitor efficacy.

Patients should be informed that alcohol may enhance the drowsiness caused by anticholinergic agents such as oxybutynin (see section 4.7).

4.6 Pregnancy and lactation

- Pregnancy: there are no adequate data from the use of oxybutynin in pregnant women. Animal studies are insufficient with respect to effects on pregnancy, embryonal/foetal development, parturition or postnatal development (see section 5.3). The potential risk for humans is unknown. Oxybutynin should not be used during pregnancy unless clearly necessary.

- Lactation: when oxybutynin is used during lactation, a small amount is excreted in mother's milk.

Use of oxybutynin during breast feeding is therefore not recommended.

4.7 Effects on ability to drive and use machines

Oxybutynin may cause drowsiness or blurred vision. Patients should be cautioned regarding activities requiring mental alertness such as driving, operating machinery or performing hazardous work while taking this drug.

4.8 Undesirable effects

Classification of expected frequencies:

Very common ($\geq 1/10$); common ($\geq 1/100$ to $< 1/10$); uncommon ($\geq 1/1,000$ to $< 1/100$); rare ($\geq 1/10,000$ to $< 1/1,000$); very rare ($< 1/10,000$), not known (cannot be estimated from the available data).

- Infections and infestations

Not known: urinary tract infection

- Gastro-intestinal disorders

Very common: constipation, nausea, dry mouth Common: diarrhoea, vomiting

Uncommon: abdominal discomfort, anorexia, decreased appetite, dysphagia

Not known: gastroesophageal reflux disease, pseudo-obstruction in patients at risk (elderly or patients with constipation and treated with other medicinal products that decrease intestinal motility)

- Psychiatric disorders

Common: confusional state

Not known: agitation, anxiety, hallucinations, nightmares, paranoia, cognitive disorders in elderly, symptoms of depression, dependence (in patients with history of drug or substance abuse)



- Nervous system disorders
Very common: dizziness, headache, somnolence
Not known: cognitive disorders, convulsions
- Cardiac disorders
Not known: tachycardia, arrhythmia
- Injury, poisoning and procedural complications
Not known: heat stroke
- Eye disorders
Common: dry eyes

Gebrauchsinformation

Diese ist gemäß der Fachinformation anzupassen.

Sollte eine Häufigkeit bekannt sein oder errechnet werden können, so ist diese bitte anzugeben.

Oben angeführte Textabschnitte stellen eine Mindestanforderung dar, zusätzliche nationale Hinweise in diesen Abschnitten sind zu belassen.