REPUBLIC OF ESTONIA
AGENCY OF MEDICINES

Kavandatavad muutused abiainete märkimisel pakendile ja infolehte

Laivi Saaremäel
Ravimiamet/ juhtivspetsialist

26.05.2017

Kehtiv juhend

EUROPEAN COMMISSION
ENTERPRISE DIRECTORATE-GENERAL

Single market : management & legislation for consumer goods
Pharmaceuticals : regulatory framework and market authorisations

Brussels,
ENTR/F2/BL D(2003)

Revision 1

NOTICE TO APPLICANTS

VOLUME 3B

Guidelines

Medicinal products for human use

Safety, environment and information

Excipients in the label and package leaflet of medicinal products for human use

July 2003

Excipients Drafting Group (ExcpDG)

Ajutine abiainete töögrupp loodi 2011a.

Põhiprobleemid:

- Ei kajasta hoiatusi abiainete kasutamise kohta lastel ega rasedatel
- Vajadus lisada abiaineid, millel on ilmnenud soovimatud kõrvaltoimed
- Ei kajasta kõiki olulisi manustamisviise

Ülesanded:

- vaadata üle juhendis senised abiainete hoiatused
- lisada nimekirja uusi abiaineid ning täiendavaid hoiatusi

CHMP ajutine töögrupp

Alates 2016 a

Multidistsiplinaarse töögrupi liikmed

- PRAC (ravimite riskihindamise komitee)
- PDCO (lasteravimite komitee)
- SWP (ohutuse töörühm)
- QWP (kvaliteedi töörühm)
- EMA (Euroopa Ravimiamet)

Telekonverentsid 10 korda aastas

1 plenaaristung aastas

Senine töö

Juhend „Use of phthalates as excipients in human medicinal products“ (2014 a.)

- kehtib uutele taotlustele alates juunist 2015
- müügiloaga ravimitele juunist 2018

  - ✓ DEP (dietüülftalaat) maksimaalne lubatud kokkupuude 4mg/kg/ööpäevas
  - ✓ DBP (dibutüülftalaat) maksimaalne lubatud kokkupuude 0.01mg/kg/ööpäevas

Reflection paper on the use of methyl- and propylparaben as excipients in human medicinal products for oral use (2015 a.)

- Konservantide kasutamine alati põhjendatud ning lisatud minimaalses kontsentratsioonis
- metüülparabeeni sisaldus kuni 0.2% pole ohtlik olenemata vanusegrupist
- propüülparabeen soovituslik ööpäevane kokkupuude maksimaalselt 2mg/kg

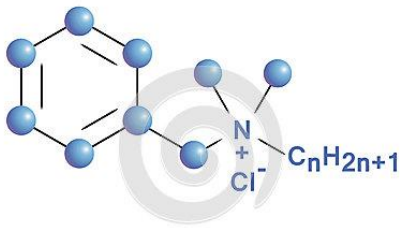
22.05.2017 lõppes juhendi täiendatud põhiteksti avalik konsultatsioon

Avalikustatud Q&A

- Aspartame
- Benzalkonium chloride
- Benzoic acid and benzoates
- Benzyl alcohol
- Boric acid
- Cyclodextrins
- Ethanol
- Fragrance allergens
- Fructose and sorbitol
- Phosphates
- Propylene glycol and esters
- Sodium
- Sodium laurilsulfate
- Wheat starch (containing gluten)

Benzalkonium chloride

- Questions and Answers on Benzalkonium chloride in the context of the revision of the guideline on 'Excipients in the label and package leaflet of medicinal products for human use' (2014)
- Background review for benzalkonium chloride used as an excipient



Benzalkonium chloride

Name	Route of Administration	Threshold	Information for the Package Leaflet	Comments
Benzalkonium chloride	All routes of administration	Zero	This medicine contains x mg benzalkonium chloride in each <volume/dosage unit>, which is equivalent to x mg/<weight or volume>.	
	Ocular	Zero	Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. You should remove contact lenses before using this medicine and put them back 15 minutes afterwards. Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disorders of the cornea (the clear layer at the front of the eye). If you feel abnormal eye sensation, stinging or pain in the eye after using this medicine, talk to your doctor.	From the limited data available, there is no difference in the adverse event profile in children compared to adults. Generally, however, eyes in children show a stronger reaction for a given stimulus than the adult eye. Irritation may have an effect on treatment adherence in children. Benzalkonium chloride has been reported to cause eye irritation, symptoms of dry eyes and may affect the tear film and corneal surface. Should be used with caution in dry eye patients and in patients where the cornea may be compromised. Patients should be monitored in case of prolonged use.
	Nasal	Zero	Benzalkonium chloride may cause irritation or swelling inside the nose, especially if used for a long time.	Long-term use may cause oedema of the nasal mucosa.
	Inhalation	Zero	Benzalkonium chloride may cause wheezing and breathing difficulties (bronchospasm), especially if you have asthma.	
	Cutaneous	Zero	Benzalkonium chloride may irritate the skin. You should not apply this medicine to the breasts if you are breast-feeding because the baby may take it in with your milk.	Use during pregnancy and lactation is not expected to be associated with harmful effects as cutaneous absorption of benzalkonium chloride is minimal. Not for application to mucosa.
	Oromucosal, rectal and vaginal	Zero	Benzalkonium chloride may cause local irritation.	

Edaspidine töö

- Azo-dyes
- Dextrans
- Lactose
- Maltodextrin
- Maltose
- Macrogols
- Polysorbate
- Proline
- Sucrose
- Xylitol, Maltitol

Kuna hakkavad kehtima?

- QRD töögrupp tegeleb uute hoiatuste tõlkimisega
- Uued sõnastused hakkavad kehtima peale ametlike tõlgete kokkuleppimist ja avalikustamist EMA ning EC kodulehel

REPUBLIC OF ESTONIA
AGENCY OF MEDICINES

Aitäh!

Laivi Saaremäel
laivi.saaremael@ravimiamet.ee