



PRESERVATIVES

Are they safe?

31 May 2010

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Key Principles - Excipients

Most experts agree that formulations for the paediatric population may need to be different to those for adults:

- Formulations should be as simple as possible
- Number of excipients should be reduced to a minimum
- No unnecessary additives
- Excipient levels should be reduced to a minimum



Key Principles - Preservatives

According to *Guideline on Excipients in the Dossier for Application for Marketing Authorisation of a Medicinal Product* (Doc. Ref. **EMA/CHMP/QWP/396951/2006**):

“Antimicrobial preservatives are normally added to prevent microbial proliferation arising under in use conditions. The properties are due to certain chemical groups which are usually harmful to living cells and might therefore be associated to certain risks when used in man.”



Key Principles - Preservatives

“Inclusion of antimicrobial preservatives or antioxidants in a finished product needs special justification.

The use of these substances should be avoided in general, especially when considering the suitability of related formulations to the paediatric population.”



Problem?

We have the Guideline ...

so what is the problem?

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