



**ASSESSMENT OF THE PAEDIATRIC NEEDS
MIGRAINE**

DISCLAIMER

The Paediatric Working Party (PEG) is working to identify the needs in the different therapeutic areas where there should be research and development of medicinal products for children, either old (i.e. off patent) or new ones (including those under development). Products on the list are not in any order of priority.

The lists should not be viewed as a prescription tool nor as recommendations for treatment. Accuracy of data including in particular authorised doses cannot be guaranteed.

Information on existing marketing authorisations is very limited and therefore information under “authorised” includes the indication in broad term (only related to chemotherapy), the lower age group authorised in at least one Member State, the authorised dose(s) (if authorised for use in patients less than 18 years of age) and formulation(s) in at least in one Member State.

Please refer to the EMEA/PEG procedure for identifying the paediatric needs for further information.

Comments from third parties are expected especially to complete and or update the list as necessary.

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| END OF CONSULTATION (DEADLINE FOR COMMENTS) | 31 December 2006 |

Comments should be provided using this [template](#) to PEG Secretariat: peg@emea.europa.eu
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| Analgesics | |
| PARACETAMOL | |
| <i>Authorised indication</i> | Pain |
| <i>Authorised age group</i> | - |
| <i>Authorised dose</i> | - |
| <i>Authorised formulation</i> | Tablets, suppositories, oro dispersable tablets, oral solution; infusion, not authorised for this indication |
| Needs | Dose finding study for migraine and safety of this dose in migraine Efficacy in paediatric migraine shown in academic trial. |
| NSAIDs: | |
| IBUPROFEN | |
| <i>Authorised indication</i> | Indication related to NSAIDS |
| <i>Authorised age group</i> | - |
| <i>Authorised dose</i> | - |
| <i>Authorised formulation</i> | Tablets, suppositories, oral solution; not authorized for this indication |
| Needs | Dose finding study for migraine and safety of this dose in migraine Efficacy in paediatric migraine shown in academic trials |
| DICLOFENAC | |
| <i>Authorised indication</i> | Indication related to NSAIDS |
| <i>Authorised age group</i> | - |
| <i>Authorised dose</i> | - |
| <i>Authorised formulation</i> | Tablets, dispersable tablets, suppositories, injection; not authorised for this indication |
| Needs | Dose finding study for migraine, efficacy and safety of this dose in migraine |
| Antiemetics + Analgesics | |
| PARACETAMOL / METOCLOPRAMIDE | |
| <i>Authorised indication</i> | Treatment of acute migraine attack |
| <i>Authorised age group</i> | > 12 years |
| <i>Authorised dose</i> | 12-18 years: 1 tablet (500mg/5mg), at onset of attack, then 1 every 4 hours when necessary to max of 3 in 24 h |
| <i>Authorised formulation</i> | Scored tablets (500mg/5mg), sachets |
| Needs | Dose finding study for migraine Efficacy and safety for migraine in children 6-12 years |
| Selective 5HT1 agonists: Limited and conflicting data on efficacy exist on the age group 12-17 for some 5HT1 agonists, partly due to methodological limitations (high placebo response, choice of end point). Long term safety data is needed for all 5HT1 agonists. | |
| SUMATRIPTAN | |
| <i>Authorised indication</i> | Treatment of migraine attacks with or without aura |
| <i>Authorised age group</i> | > 12 years |
| <i>Authorised dose</i> | One spray (10 mg) into one nostril |
| <i>Authorised formulation</i> | 50/100 mg tablets, 10/20 mg nasal spray (the only formulation authorised in children), parenteral solution, 25 mg suppositories |
| Needs | Data on PK, efficacy and safety in children 6-12 years |
| NARATRIPTAN | |
| <i>Authorised indication</i> | Treatment of the headache phase of migraine attacks, with or without aura |
| <i>Authorised age group</i> | Not authorised in children < 17 years |
| <i>Authorised dose</i> | - |
| <i>Authorised formulation</i> | Tablets |

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| Needs | Data on PK, efficacy and safety in children 6-17 years. Age and disease appropriate formulation |
| ZOLMITRIPTAN | |
| <i>Authorised indication</i> | Treatment of the headache phase of migraine attacks, with or without aura |
| <i>Authorised age group</i> | Not authorised in children |
| <i>Authorised dose</i> | - |
| <i>Authorised formulation</i> | Orally dispersible and film-coated tablets, nasal spray (Germany) |
| Needs | Data on PK, efficacy and safety in children 6-18 years. |
| ALMOTRIPTAN | |
| <i>Authorised indication</i> | Treatment of the headache phase of migraine attacks, with or without aura |
| <i>Authorised age group</i> | Not authorised in children |
| <i>Authorised dose</i> | - |
| <i>Authorised formulation</i> | Film-coated tablets |
| Needs | Data on PK, efficacy and safety in children 6-18 years. Age and disease appropriate formulation |
| ELETRIPTAN | |
| <i>Authorised indication</i> | Treatment of the headache phase of migraine attacks, with or without aura |
| <i>Authorised age group</i> | Not authorised in children |
| <i>Authorised dose</i> | - |
| <i>Authorised formulation</i> | Film-coated tablets |
| Needs | Data on PK, efficacy and safety in children 6-18 years. Age and disease appropriate formulation |
| RIZATRIPTAN | |
| <i>Authorised indication</i> | Treatment of the headache phase of migraine attacks, with or without aura |
| <i>Authorised age group</i> | Not authorised in children < 17 years |
| <i>Authorised dose</i> | - |
| <i>Authorised formulation</i> | Tablets, orally dispersible tablets |
| Needs | Data on PK, efficacy and safety in children 6-17years. |
| FROVATRIPTAN | |
| <i>Authorised indication</i> | Treatment of the headache phase of migraine attacks, with or without aura. |
| <i>Authorised age group</i> | Not authorised in children |
| <i>Authorised dose</i> | - |
| <i>Authorised formulation</i> | Tablets |
| Needs | Data on PK, efficacy and safety in children 6-18 years. Age and disease appropriate formulation. |
| Beta blockers | |
| PROPRANOLOL | |
| <i>Authorised indication</i> | Prophylactic treatment for migraine |
| <i>Authorised age group</i> | > 7 years (Finland) |
| <i>Authorised dose</i> | >35 kg: 20-40 mg x 3, <35 kg: 20 mg x 3 (Finland) |
| <i>Authorised formulation</i> | Tablets, capsules, oral solution, retard capsules (80 mg lowest strength) |
| Needs | Age and disease appropriate formulation. Relevant formulations to be made available in all Member States. Long term safety. |
| METOPROLOL | |
| <i>Authorised indication</i> | Prophylactic treatment for migraine |
| <i>Authorised age group</i> | Not authorised in children |
| <i>Authorised dose</i> | 100-200 mg/d |
| <i>Authorised formulation</i> | Tablets, retard tablets (25 mg lowest strength), solution for i.v. injection |
| Needs | PK, efficacy, safety > 6 years. Age and disease appropriate formulation. Long term safety. |
| Other | |
| TOPIRAMATE | |
| <i>Authorised indication</i> | Prophylactic treatment of migraine |

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| <i>Authorised age group</i> | Not authorised in children |
| <i>Authorised dose</i> | - |
| <i>Authorised formulation</i> | Tablets, Capsules (can be opened and sprinkled) |
| Needs | PK, efficacy, safety in children > 6 years. Long term safety. Depending on the dose, age appropriate formulation needed |
| UNMET MEDICAL NEEDS | |
| <i>Proposed indications:</i> | Prophylactic treatment of migraine > 6 y, as alternative treatments to propranolol. |

PRODUCTS CONSIDERED BY PEG TO BE DEVOID OF THERAPEUTIC INTEREST IN CHILDREN

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| PARACETAMOL / CODEIN / BUCLIZINE |
| ACETYLSALICYLATE METOCLOPRAMIDE |
| ERGOTAMINE |
| DIHYDROERGOTAMINE |
| METHYSERGIDE |
| PIZOTIFEN |
| OXOTERONE |
| FLUNARIZINE Efficacy has been shown, however, safety issues and unfavorable PK (very long half life) suggest no further needs. |
| INDORAMINE |