Lidocaine/tetracaine plaster (Rapydan®) for the indication 'surface anaesthesia of the skin'
Pharmacotherapeutic report, summary

Recommendation by CVZ dated 24 June 2013, based on evaluation by the WAR (Scientific Advisory Committee)

Medicine. 70 mg of lidocaine and 70 mg of tetracaine plaster.
Registered Indication. "Surface anaesthesia of the skin in connection with needle puncture and in cases of superficial surgical procedures (such as excision of various skin lesions and punch biopsies) on normal intact skin in adults. Surface anaesthesia of the skin in connection with needle puncture on normal intact skin in children from 3 years of age".
Posology. *Adults:* 1 or at most 4 plasters simultaneously, maximum 4 plasters per 24 hours, application time = 30 minutes. *Children from 3 years of age:* 1 or at most 4 plasters simultaneously, maximum 4 plasters per 24 hours, application time = 30 minutes.
Mechanism of action. Local anaesthetic of the amithe type (lidocaine) and of the ester type (tetracaine). After application of the plaster, lidocaine and tetracaine are released into the epidermal and dermal parts of the skin. Thus a block is achieved of the sodium ion channels required for the initiation and conduction of nerve impulses, resulting in local anaesthesia. The degree of anaesthesia depends on the application time. The plaster contains a heat-releasing component that may reach a maximum temperature of 40°C.

Summary of the therapeutic value
Intended effects. The lidocaine/tetracaine plaster was more effective than placebo with regards to pain reduction prior to vascular access or superficial surgical procedures. In a head-to-head trial, pain reduction was comparable between the lidocaine/tetracaine plaster and the lidocaine/prilocaine cream if the application time recommended in the SPCs was used. This conclusion is also supported by the results of an indirect comparison. Furthermore, the results of an indirect comparison suggest that the efficacy of the lidocaine/tetracaine plaster is comparable with that of the lidocaine/prilocaine plaster if the application time recommended in the SPCs is used.
Unintended effects. In general, the adverse events of the lidocaine/tetracaine plaster, the lidocaine/prilocaine cream and the lidocaine/prilocaine plaster are considered mild to moderate in intensity. The most commonly reported adverse drug reactions are blanching of the skin, erythema and oedema.
Experience. Sufficient experience has been gained with the lidocaine/tetracaine plaster. Considerable experience has been gained with the lidocaine/prilocaine cream and the lidocaine/prilocaine plaster.
Applicability. There are no major differences between the lidocaine/tetracaine plaster, the lidocaine/prilocaine cream and the lidocaine/prilocaine plaster with respect to: contraindications, interactions with other medicinal products and special warnings/precautions of use.
Ease of use. There are no major differences between the lidocaine/tetracaine plaster, the lidocaine/prilocaine cream and the lidocaine/prilocaine plaster.

Final conclusion. For surface anaesthesia of the skin in connection with needle puncture in children from 3 years of age and adults, and in cases of superficial surgical procedures in adults, the therapeutic value of the lidocaine/tetracaine plaster is comparable with that of the lidocaine/prilocaine cream and the lidocaine/prilocaine plaster.

For further information, please contact: HSchelleman@cvz.nl; warcg@cvz.nl

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Furthermore, CVZ points out that only the summary of this report was translated. A proper understanding of all relevant considerations and facts would require familiarity with the Dutch version of this report, including all appendices.