Practice sting Sinaspril paracetamol syrup and babies
This Practice Sting is particularly interesting for prescribers, pharmacists and chemists

When some self-care products are used by certain patient groups, medication monitoring by the pharmacist is crucial, as can be seen from the following notification.

Notification
A 6-week-old baby with a high fever has been referred to a paediatrician by the general practitioner. The paediatrician advises the mother to buy a bottle of Sinaspril paracetamol syrup from the chemist's shop and to give 2.5 ml 4 to 6 times a day. After buying the bottle of Sinaspril syrup, the mother notices that the syrup is meant for children from 3 months to 12 years old. She calls a friend who is a pharmacist and asks her if this syrup is safe for the baby. Her friend notices that the dose of paracetamol is too high. She also notices that the amount of propylene glycol that the baby ingests through the syrup is much too high for a 6-week-old baby who weighs 4.3 kg. She advises administering paracetamol 60 mg suppositories four times a day instead of the syrup.

Analysis
Dosage recommendations
In the Dutch NHG-Standard for Children with fever, paracetamol is the first choice for fever. The use of paracetamol is registered for children from 3 months. Dosages for younger children are also included in the Dutch Children's Formulary. The dosage of oral presentations for children from 1 month to 18 years is 10 to 15 mg/kg four times a day as needed. The dosage of rectal presentations is 10 to 20 mg/kg 3 to 4 times daily, if necessary. For both oral and rectal presentations, the maximum daily dose is 60 mg/kg.
The advice to the baby's mother was to give her child 2.5 ml of syrup, which contains 24 mg paracetamol per ml, 4 to 6 times a day. This amounts to a maximum of 360 mg of paracetamol per day. Based on body weight, the baby should only receive a maximum of 258 mg per day. A too high dose of paracetamol can lead to serious liver damage.

Excipients
Propylene Glycol
There are three oral liquid acetaminophen products on the market. These products contain 24 mg paracetamol per ml. The amount of propylene glycol per ml is different in these products. Sinaspril paracetamol syrup contains 70 mg propylene glycol per ml, paracetamol Sanias oral solution contains 5.44 mg propylene glycol per ml and Daro paracetamol syrup contains 0.49 mg propylene glycol per ml. Propylene glycol can lead to serious side effects when used for a long time and/or when using a high dose. In neonates and children, it can lead to, among other things, depression of the central nervous system. For this reason, the European Medicines Agency (EMA) has set safety limits for propylene glycol. These are:
• children up to 1 month: 1 mg/kg per day
• children from 1 month to 4 years: 50 mg/kg per day
• adults and children from 5 years: 500 mg/kg per day

These (conservative) limits have been set by the EMA on the basis of available literature. Exceeding these limits may be unavoidable in individual cases. However, this always requires careful assessment of alternatives and consideration of risks and benefits.

The baby from this notification weighs 4.3 kg and is 6 weeks old. The baby can safely ingest 215 mg of propylene glycol per day. With the amount of Sinaspril paracetamol syrup recommended by the paediatrician, the baby would have received 700 to 1050 mg of propylene glycol. Even if the paediatrician had not exceeded the maximum daily dose of paracetamol (60 mg/kg), the amount of propylene glycol would have been much too high. The baby would then have received 753 mg of propylene glycol per day. If the paediatrician had advised Daro paracetamol syrup or paracetamol Sanias oral solution, the safety limit for propylene glycol would not have been exceeded. A dose of Sinaspril paracetamol syrup once a day in children from 1 month to 4 years is safe according to the Dutch Children's Formulary.

Ethanol
In addition to propylene glycol, Sinaspril paracetamol syrup contains 40 mg ethanol per ml. The baby therefore receives 100 mg ethanol per dose of 2.5 ml. This is 23 mg/kg body weight. According to the Dutch Children's Formulary, doses of 15-75 mg/kg may cause drowsiness in young children. The Dutch Children's Formulary prefers prescribing a medicine without ethanol. Daro paracetamol syrup and paracetamol Sanias oral solution do not contain ethanol. It should be noted that the paracetamol Sanias oral solution contains benzyl alcohol which makes this oral solution not suitable for children under 1 month and should not be administered for more than one week to children under 3 years of age.

Self-care product
Sinaspril paracetamol syrup can be bought as a self-care product at the chemist's store and the pharmacy. The syrup is suitable for children from 3 months. In children under 5 years of age, according to the package leaflet, the physician or pharmacist should be contacted before administration. This is because of the amount of propylene glycol and alcohol that Sinaspril paracetamol syrup contains.

Recommendations
For prescribers
- Prescribe paracetamol for young children on prescription.
- Be aware that paracetamol drinks and syrups may contain excipients that may be harmful to a young child. For young children, choose a product that contains no or very few (undesirable) excipients.

For pharmacists
- For prescriptions for liquid forms of paracetamol for young children, check the amount of excipients that the child receives in addition to the dosage. These include propylene glycol, ethanol and benzyl alcohol. Also take into account the presence of these excipients in other medicines that a young child is taking.
- Also carry out these checks for self-care questions for medicines containing paracetamol for young children. For young children, advise a product that contains no or very few (undesirable) excipients.

For chemists
- Ask for the age of the user if someone wants to buy a bottle of Sinaspril paracetamol syrup. Refer – if the user is under 5 years old – the customer to his or her physician or pharmacist.