

## Part VI: Summary of the risk management plan by product

### VI.1 Elements for summary tables in the EPAR

#### VI.1.1 *Summary table of Safety concerns*

Summary of safety concerns	
Important identified risks	<ul style="list-style-type: none"><li>• Hepatobiliary disorders</li><li>• Abnormal liver function</li><li>• Drug interaction with anticoagulants</li><li>• Drug interaction with enzyme inducers</li></ul>
Important potential risks	Not applicable
Important missing information	None

#### VI.1.2 *Table of on-going and planned additional PhV studies/activities in the Pharmacovigilance Plan*

Not applicable

#### VI.1.3 *Summary of Post authorisation efficacy development plan*

Not applicable

#### VI.1.4 *Summary table of risk minimisation measures*

Not applicable

### VI.2 Elements for a Public Summary

#### VI.2.1 *Overview of disease epidemiology*

Fever is a normal part of childhood illness, affecting around 70% of preschool children yearly. It can be miserable for the child, cause anxiety for parents, and be expensive for health services. Up to 40% of preschool children see a health professional for a febrile illness each year. Although fever is considered by many to be an advantageous evolutionary byproduct of the host response to infection, and as such should not be treated, the use of antipyretics is widespread.

The reasons for treating fever are contested and not necessarily evidence based but include minimising discomfort, controlling the fever, and preventing febrile convulsions.

**VI.2.2 Summary of treatment benefits**

Paracetamol doses of 10 to 15 mg/kg per dose given every 4 to 6 hours orally are generally regarded as safe and effective. Typically, the onset of an antipyretic effect is within 30 to 60 minutes; approximately 80% of children will experience a decreased temperature within that time (Sullivan JE et al, 2011).

**VI.2.3 Unknowns relating to treatment benefits**

Not applicable

**VI.2.4 Summary of safety concerns**

**Important identified risks**

<b>Risk</b>	<b>What is known</b>	<b>Preventability</b>
Hepatobiliary disorders	In case of an overdose a doctor must immediately be contacted even if the patient appears to be well as there is a risk of delayed serious and irreversible liver damage.	The symptoms of overdose usually occur during the first 24 hours and they include nausea, vomiting, loss of appetite, pallor and abdominal pain.
Abnormal liver function	Paracetamol should be used with caution in patients with liver problems.	There is a risk of poisoning, particularly in patients with liver disease, in cases of chronic alcoholism, in patients with chronic malnutrition and in patients receiving enzyme inducers.
Drug interaction with anticoagulants	Patients should be aware that anticoagulants (e.g. warfarin) may interact with paracetamol	It is important to inform the doctor before giving paracetamol to your child, if your child is taking anticoagulants (e.g. warfarin) at the same time.

Drug interaction with enzyme inducers	Medicines like metoclopramide, cholestyramine or antiepileptic may interact with paracetamol	It is important to inform the doctor before giving paracetamol to your child, if your child is taking metoclopramide, cholestyramine or antiepileptic drugs at the same time.
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**Important potential risks**

Risk	What is known (Including reason why it is considered a potential risk)
N/A	N/A

**Important missing information**

Risk	What is known
None	/

**VI.2.5 Summary of additional risk minimisation measures by safety concern**

Not applicable

**VI.2.6 Planned post authorisation development plan**

Not applicable

**VI.2.7 Summary of changes to the Risk Management Plan over time**

Not applicable