

## **VI.2 Elements for a public summary**

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

#### **Loco-regional anaesthesia**

Anaesthesia means 'loss of sensation'. Medications that cause anaesthesia are called anaesthetics. A local anaesthetic is often used during minor procedures where a small area of the body is numbed and patient remains fully conscious. Regional anaesthetic is a local anaesthetic given to a defined region of your body, usually served by a large nerve bundle (such as arm), giving numbness or pain relief for deeper operations where more extensive numbness is needed.

In UK (70%) of paediatric anaesthetists practiced paediatric anaesthesia as more than 50% of their workload. 96% use caudal anaesthesia and 72% use caudal, epidural (shots given in and around the spine) and peripheral nerve block. 91% have no lower age limit for using caudal anaesthesia. 58% used adjuvants with local anaesthetics in caudal block, the most common being fentanyl, clonidine, diamorphine and ketamine. Each dentist in Canada injects approximately 1,800 cartridges of local anesthetic yearly, and it has been estimated that more than 300 million cartridges are administered by dentists in the United States every year.

### **VI.2.2 Summary of treatment benefits**

Mepivacaine solution for injection is used to numb (anaesthetise) a limited part of the body particularly during surgery (except obstetrical).

There were two studies conducted for Mepivacaine.

In one study, 4% articaine or 3% mepivacaine were evaluated and compared for the reaction to pain during injection and duration of numbness in 25 boys and 25 girls (age: 7-13 years). Both 4% articaine and 3% mepivacaine showed the same effectiveness, and children displayed the same behavior during injection.

In another study, 2% lidocaine and 2% mepivacaine with 1:100,000 epinephrine were compared for relief in pain due to tooth removal in a group of 35 patients (of both sex, age: 13-27 years). This study showed that lidocaine and mepivacaine have similar time of numbing effect, they were adequate for surgical procedures that last one hour, and there was no difference between the two solutions in relation to the severity of pain.

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

There is insufficient clinical data with regard to the administration of mepivacaine in children aged below 1 year.

**VI.2.4 Summary of safety****concerns Important identified****risks**

<b>Risk</b>	<b>What is known</b>	<b>Preventability</b>
<p>Serious side effects due to overdose or rapid accidental intravenous injection [Toxic reactions (cardiovascular or neurological) due to overdose or rapid intravenous injections]</p>	<p>Overdose or rapid accidental intravenous injection can cause toxic reactions. The sign and symptoms of overdose are vertigo, dizziness, numbness of lips and the area around the mouth, numbness of the tongue, hearing problems and vision problems.</p> <p>The most serious side effects due to overdose of mepivacaine are speech disorders, muscle jerking, shivers, convulsions (fits) and loss of consciousness.</p>	<p>Yes</p> <p>In such situation, specific treatment is given to patient by doctor who is experienced in managing this type of situation.</p> <p>To reduce the risk of serious side effects, doctor must discontinue the administration of drug to patients as soon as these signs appear. This means that if one of these symptoms occurs or patients think they have received too much drug, they should immediately inform to their doctor.</p> <p>Neurological toxicity events are treated by short-acting barbiturate injection or benzodiazepine, oxygenation and assisted ventilation.</p>
<p>Allergic reactions</p>	<p>Allergic reactions to mepivacaine are rare possible side effects which may affects less than 1 in</p>	<p>Yes</p> <p>Doctor should not prescribe this medicine if patient has</p>

<b>Risk</b>	<b>What is known</b>	<b>Preventability</b>
	1,000 patients.	allergy to local anaesthetics or this type of medicine (amide local anaesthetics).

### **Important potential risks**

<b>Risk</b>	<b>What is known</b>
Potential to harm to foetus in utero (Foetotoxicity)	Animal studies have shown that mepivacaine can harm the foetus. This medicine must not generally be used during pregnancy except if told otherwise by your doctor.

### **Missing information**

<b>Risk</b>	<b>What is known</b>
Use in children aged below 1 year	Mepivacaine is not recommended in children under the age of 1 due to the lack of clinical data.

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

All medicines have a Summary of Product Characteristics (SPC) which provides physicians, pharmacists and other health care professionals with details on how to use the medicine, the risks and recommendations for minimizing them. An abbreviated version of this in lay language is provided in the form of the package leaflet (PL). The measures in these documents are known as routine risk minimisation measures.

This medicine has no additional risk minimization measures.

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

No studies planned.

### **VI.2.7 Summary of changes to the risk management plan over time**

Not applicable