

## **Levobupivacaine/Chirocaine**

### **Amendments to the Product Information**

There are changes to the product information recommended

During the assessment of the information in the PSUR the following issue was considered:

Chondrolysis

It has been agreed that the following amendments to the Product Information are required:

SmPC wording

Section 4.4

‘There have been post-marketing reports of chondrolysis in patients receiving post-operative intra-articular continuous infusion of local anaesthetics. The majority of reported cases of chondrolysis have involved the shoulder joint. Due to multiple contributing factors and inconsistency in the scientific literature regarding mechanism of action, causality has not been established. Intra-articular continuous infusion is not an approved indication for levobupivacaine.’

Leaflet wording (if available)

N/A