TRB CHEMEDICA UK

Response by TRB Chemedica (UK) Ltd

Regarding the inclusion on SmPC of Hypo- or Hypertension as an undesirable effect following injection with OSTENIL®, OSTENIL® Mini, or OSTENIL® Plus.

Vasovagal reactions:

It is well elucidated medical knowledge that vasovagal (blood pressure and heart rate) reactions can occur when people experience painful or unpleasant stimuli, e.g. after watching or experiencing medical procedures such as injections. It is also basic knowledge that those conceivable adverse reactions to an injection are not related to the kind of substance applied, but to the procedure itself. The vasovagal - triggered reactions can include, for instance; reduction in heart rate and blood pressure, as well as light-headedness, dizziness, palpitations, weakness, blurred vision, nausea and epigastric distress, feeling warm or cold, facial pallor, excessive sweating, and syncope (fainting).

Hypertension:

While some published clinical data exists to demonstrate that intra-articular injections of steroid have been shown to produce a transient elevation of systolic BP (returning to baseline value approx. 3 days following injection), there are no published data to demonstrate that the same effect is associated with Sodium Hyaluronate intra-articular injection. However, due to certain EU certification requirements, every potential or reported undesirable effect of any injectate is now required to be listed on the Summary of Product Characteristics (SmPC) sheet and the pack inserts. In the case of OSTENIL®, OSTENIL® Mini, or OSTENIL® Plus, the number of reported systemic reactions is extremely rare, and none were reported as a serious adverse event.

In the absence of any definitive data pertaining to systemic / vasovagal reaction as a consequence or direct corollary of intra-articular infiltration of OSTENIL®, OSTENIL® Mini, or OSTENIL® Plus, the only correlation that might reasonably be drawn therefore, is that the IA injection itself MAY produce transient elevation/reduction of BP.

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