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Betreff: Tiaprid – hältige Arzneispezialitäten – Änderungen der Fach- und Gebrauchsinformationen aufgrund des HBD – PSUR Worksharing Projektes

Sehr geehrte Damen und Herren,

basierend auf der Evaluierung des PSURs im EU-HBD-worksharing Projekt (Verfahrensnummer: FR/H/PSUR/0023/002) kommt es zu der Empfehlung, folgende Ergänzungen in die **Fach- und Gebrauchsinformation** aller Tiaprid – hältigen Arzneispezialitäten zur aufzunehmen.

Sollten diese bereits aufgenommen worden sein, betrachten Sie dieses Schreiben als gegenstandslos.

• **Amendments to the Product Information**

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

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

The section 4.8 of the SmPC should be updated with the following adverse events: hepatic enzymes increased, loss of consciousness/syncope, convulsion, confusion, hallucination, pneumonia aspiration, blood creatine phosphokinase increased, rhabdomyolysis, rash including rash erythematous, rash maculo-papular and urticaria, hyponatremia, syndrome of inappropriate antidiuretic hormone secretion (SIADH), fall, constipation, intestinal obstruction, ileus.

SmPC wording

Section 4.8

Gastrointestinal disorders:

Not known: Constipation, intestinal obstruction, ileus.

Hepatobiliary disorders

Not known: Hepatic enzymes increased



Nervous system disorders

Not known: Loss of consciousness/syncope, Convulsion

Psychiatric disorders

Not known: Confusion, Hallucination

Respiratory, thoracic and mediastinal disorders

Not known: Pneumonia aspiration

Musculoskeletal and connective tissue disorders

Not known: Blood creatine phosphokinase increased, Rhabdomyolysis

Skin and subcutaneous tissue disorders

Not known: Rash including rash erythematous, rash maculo-papular and urticaria

Metabolism and nutrition disorders

Not known: Hyponatremia, Syndrome of inappropriate antidiuretic hormone secretion (SIADH)

Injury, poisoning and procedural complications

Not known: Fall

PL wording

These adverse effects should be added in section "4. Possible side effects" of the PL

Unknown frequency: constipation, intestinal obstruction, increases in liver enzymes, loss of consciousness, convulsion, confusion, hallucinations, pneumonia aspiration caused by food particles or vomit entering into the lungs, increases in levels of creatine phosphokinase in the blood, muscle weakness and/or muscle pain, rash, sodium decrease in the blood (hyponatremia), an illness called 'syndrome of inappropriate anti-diuretic hormone secretion' (SIADH), fall

Oben angeführte Textabschnitte stellen eine Mindestanforderung dar, zusätzliche nationale Hinweise in diesen Abschnitten sind zu belassen.