HAUTE AUTORITÉ DE SANTÉ

RHEUMATOLOGY
Update
July 2016

BRIEF SUMMARY OF THE TRANSPARENCY COMMITTEE OPINION

COLTRAMYL and thiocolchicoside generics, muscle relaxant

Insufficient actual benefit in the management of painful muscle contractures associated with acute low back pain

Main points

- COLTRAMYL has Marketing Authorisation in the adjuvant treatment for painful contractures in acute lumbar pain.
- Its efficacy is at best modest.
- A risk of aneuploidy, known to be a potential risk factor for cancer and for teratogenicity, embryotoxicity, spontaneous abortion and impaired male fertility, has been associated with its use.
- Considering that alternatives exist for which this risk has not been demonstrated, the clinical interest of thiocolchicoside is henceforth insufficient to justify its reimbursement.

Therapeutic use

In the management of acute lumbar pain (less than 3 months' duration), analgesics and non-steroidal antiinflammatories (NSAIDs) intended to relieve pain are indicated. Paracetamol is the first-line analgesic. If paracetamol should prove insufficient, an NSAID may be prescribed as a second-line treatment, either alone or in combination with an analgesic. In chronic forms, non-pharmacological treatments have an essential role Recourse to NSAIDs should be confined to painful flare-ups that fail to respond to paracetamol or to other analgesic measures.

Role of the medicinal product in the therapeutic strategy

Taking into account its at best modest efficacy and mediocre tolerability, COLTRAMYL and its generics no longer have a place in the management of painful muscle contractures associated with acute low back pain.

Clinical data

- The efficacy of thiocolchicoside (TCC) is at best modest and is based on very old data.
- Recently safety concerns, particularly with regard to a potential risk of genotoxicity, have been raised. New data obtained from preclinical studies have shown that one of the metabolites of TCC could induce aneuploidy (variation in the number of chromosomes and loss of heterozygosity) at concentrations close to those observed in human subjects at the maximum recommended therapeutic oral dose (8 mg twice daily).
- It should be used according to the new recommendations relating to its indication, dosage, treatment duration and respecting its contraindications (women who are pregnant or breastfeeding and children). As a precaution, its long-term use should be avoided.
- Other potential risks have recently been identified by pharmacovigilance, in particular the risk of anaphylactic shock, convulsions and liver damage.

Benefit of the medicinal product

- The actual benefit* is insufficient to justify inclusion on the list of medicines reimbursed by National Health Insurance.
- Unfavorable opinion forinclusion on the list of reimbursable products for supply by pharmacists and for hospital use.

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This document was created on the basis of the Transparency Committee Opinion of 20 July 2016 (CT-13761-CT 14460) and is available at **www.has-sante.fr**

* The actual benefit (AB) of a proprietary medicinal product describes its benefit primarily in terms of its clinical efficacy and the seriousness of the condition being treated. The HAS Transparency Committee assesses the AB, which can be substantial, moderate, low or insufficient for reimbursement for hospital use.

** The clinical added value (CAV) describes the improvement in treatment provided by a medicinal product compared with existing treatments. The HAS Transparency Committee assesses the degree of CAV on a scale from I (major) to IV (minor). A level V CAV means “no clinical added value”.