HAUTE AUTORITÉ DE SANTÉ

RHEUMATOLOGY
Update
November 2017

BRIEF SUMMARY OF THE TRANSPARENCY COMMITTEE OPINION

HYDROCORTANCYL (prednisolone), glucocorticoid

Low actual benefit and no clinical benefit demonstrated in the treatment of radiculalgia by epidural injection.

Main points

- HYDROCORTANCYL has Marketing Authorisation in the treatment of radiculalgia by epidural injection.
- The efficacy data, which provide a low level of evidence, suggest at best a low level of efficacy against pain in the short term.
- No data relating to a possible reduction in recourse to the use of systemic analgesics, recourse to surgery, or to the duration of incapacity have been identified.
- Reinforcement of the precautions for use and contraindications of HYDROCORTANCYL aim to limit the risk of serious neurological complications during epidural injections.

Pre-existing indications*

HYDROCORTANCYL has Marketing Authorisation in other rheumatological conditions depending on the injection site, and in dermatological, neoplastic, ophthalmological and ENT conditions.

Therapeutic use

- The objectives for management of radiculalgia are treatment of pain, screening of patients requiring an urgent surgical procedure and prevention of recurrences. The first line treatment of radiculalgia comprises rest, NSAIDs for a short period and analgesics.
  Corticosteroid injections may target the epidural space (interspinous, interlaminar and sacral hiatus approach), the intervertebral foramen (foraminal approach) or the posterior articular cavity (posterior articular approach - it is not an epidural approach).
  The administration of corticosteroids by epidural injection for the treatment of intractable lumbar radiculalgia and cervicobrachial neuralgia, the usual causes of which are herniated discs and spondyloarthropathy, should only be considered after first line treatment has failed.
  Non-medicinal alternatives include spinal traction, back braces or corsets. Surgery is a last resort treatment.

- **Role of the medicinal product in the therapeutic strategy**
  HYDROCORTANCYL is a last resort drug therapy before surgery in certain forms of radiculalgia that have been present for several months and which are resistant to well-conducted medical treatments including rest, analgesics and NSAIDs.
  HYDROCORTANCYL is contraindicated for use in epidural injection:
  - in the cervical spine using a CT-guided or non-CT-guided foraminal approach or by posterior approach
  - in the lumbar spine using a CT-guided or non-CT-guided foraminal approach.

  Injection of HYDROCORTANCYL into a spine that has undergone surgery is a risk factor for serious neurological adverse effects, in particular medullary infarction. In a patient who has undergone spinal surgery, before considering an epidural injection via posterior approach or posterior articular approach, the physician should assess the risks and benefits as part of a multidisciplinary review meeting.
  The decision must be shared with the patient. In order to reduce neurological risks, the injection should be done at a distance from the area that underwent surgery or using sacral hiatus approach.

* This summary does not cover these indications.

Clinical data

- Some studies have demonstrated a significant short-term reduction in pain (1 to 60 days).
- The risk of serious ischaemic neurological complications (medullary infarction type) during epidural injections (especially foraminal) is well identified and the contributing factors are partly known. These may include arterial spasm related to the needle, direct trauma or an embolism related to aggregation of particulate corticosteroid solutions for injection. The latter hypothesis is widely favoured. All of the lumbar foramina are likely to host a spinal artery that also has a medullary destination. The SmPC of HYDROCORTANCYL contraindicates its use in epidural injection in the cervical spine using a CT-guided or non-CT-guided foraminal approach as well as in epidural injection in the lumbar spine using a CT-guided or non-CT-guided foraminal approach. In a subject who has undergone surgery, the epidural scar tissue has significant vascularisation which results in neoangiogenesis. These vessels may be connected to a radiculomedullary artery. The risk of arterial emboli thus appears higher. The decision to implement treatment with HYDROCORTANCYL in a spine that has undergone surgery must be made as part of a multidisciplinary review meeting due to the risks of serious neurological adverse effects.

Benefit of the medicinal product

- The actual benefit* of HYDROCORTANCYL is low in the treatment of radiculalgia by epidural injection.
- HYDROCORTANCYL does not provide clinical added value** (CAV V) in the management of radiculalgia by epidural injection.
- Recommends inclusion 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 09 November 2017 (CT-16248) 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”.