HAUTE AUTORITÉ DE SANTÉ

**NUCLEAR MEDICINE**
**New medicinal product**
**May 2017**

**BRIEF SUMMARY OF THE TRANSPARENCY COMMITTEE OPINION**

# IODINATED HUMAN ALBUMIN ($^{125}$I) CIS BIO INTERNATIONAL (iodinated human albumin), radiopharmaceutical product for diagnostic use

**No clinical benefit demonstrated in the diagnostic strategy for polycythemia and anaemia with haemodilution.**

## Main points

- IODINATED HUMAN ALBUMIN ($^{125}$I) CIS BIO INTERNATIONAL is a medicinal product for diagnostic use that has Marketing Authorisation in the measurement of plasma volume and determination of the renewal rate of plasma albumin.
- Its use has been limited for many years in the measurement of plasma volume. In practice, in order to diagnose polycythemia or anaemia with haemodilution, a measurement of corpuscular volume is generally performed. Measurement of plasma volume is sometimes necessary, in addition to the measurement of corpuscular volume.
- This is the standard medicinal product for measurement of plasma volume.

## Therapeutic use

- The diagnosis of polycythemia is generally established by complete blood count. It is recognised that when the haematocrit is over 60% in men and over 56% in women, and in the absence of obvious special circumstances, the diagnosis of polycythemia is certain. in these cases, measurement of blood mass by an isotopic method is not indicated.
- If the increase of the haematocrit is moderate (haematocrit level between 52% and 60% in a man and 48% and 56% in a woman) polycythemia should be suspected. Measurement of blood mass is then necessary to confirm the diagnosis of polycythemia.
- Laboratory testing is generally sufficient to diagnose anaemia. However, documentation of the reduction of the blood mass is necessary in the case of suspected associated plasma inflation (major splenomegaly, hypergammaglobulinaemia).
- In all cases, the measurement of blood mass is based on the measurement of corpuscular volume by the technique of erythrocytes labelled with chromium-51, which is the standard examination for diagnosing of polycythemia or anaemia with haemodilution. However, in some situations, measurement of plasma volume is necessary, in addition to the measurement of corpuscular volume.
  The measurement of plasma albumin renewal rate is not used much in practice.
- **Role of the proprietary medicinal product in the therapeutic strategy**
  When the measurement of the plasma volume is necessary in addition to the measurement of corpuscular volume, the isotopic method by human serum albumin labelled with iodine-125 is the standard technique for measuring plasma volume.

## Clinical data

- No specific clinical studies have been conducted in the context of its Marketing Authorisation.
  Review of the literature confirms that this substance is considered one of the standard methods for the measurement of plasma volume. The available data come from studies with a low level of evidence.
- The safety profile does not show any safety signals. According to the SPC, cases of fever and allergic reactions have been reported after administration of iodinated human albumin.

## Special prescribing conditions

- Medicinal product reserved for hospital use.
- Radiopharmaceutical products must be used only by qualified professionals. They may only be issued to practitioners who have obtained special authorisation provided for by Article R 1333-24 of the French Public Health Code.

## Benefit of the medicinal product

- The actual benefit* of IODINATED HUMAN ALBUMIN ($^{125}$I) CIS BIO INTERNATIONAL is low.
- This medicinal product does not provide clinical added value** (CAV V) in the diagnostic strategy for polycythemia and anaemia with haemodilution.
- Recommends inclusion on the list of reimbursable products for hospital use.

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This document was created on the basis of the Transparency Committee Opinion of 17 May 2017 (CT-15909) and is available at **www.has-sante.fr**

* The actual clinical benefit (ACB) of a 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 ACB, which can be substantial, moderate, low or insufficient for reimbursement of the medicinal product 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 (equivalent to “no CAV”) means “no clinical added value”.