

# <sup>51</sup>Cr edetate

## 1. Indications

<sup>51</sup>Cr edetate (EDTA) is indicated for the determination of glomerular filtration rate in the assessment of renal function.

## 2. Preparation

Approved product, see summary of product characteristics (SmPC).

## 3. Quality control

Approved product, see summary of product characteristics (SmPC).

## 4. Interactions

No interaction studies have been performed.

## 5. Adverse reactions

No adverse reactions have been reported

This medicinal product contains benzyl alcohol. Benzyl alcohol may cause toxic reactions and anaphylactoid reactions in infants and children up to 3 years old.

## 6. Biodistribution & pharmacokinetics

Following intravenous administration, the <sup>51</sup>Cr edetate complex is excreted almost exclusively by the kidneys via the glomerular membrane (less than 1% faecal excretion in 24 h reported for an anuric patient). Less than 0,5% plasma protein binding occurs. In patients with normal or near-normal glomerular filtration rate the recovery of unchanged chelate in the urine during the first 24 h after administration is close to 100% of the injected activity, cumulative faecal clearance accounting for less than 0,1%. There is no significant tubular secretion or re-absorption of <sup>51</sup>Cr edetate. However, a small amount of tubular re-absorption, some whole body retention or complex dissociation have each been postulated to explain the known but small underestimation of inulin clearance by <sup>51</sup>Cr edetate.

After intravenous administration, the <sup>51</sup>Cr edetate equilibrates within the intra- and extravascular spaces, a process taking between 30 and 90 min. Beyond this period a constant percentage of the <sup>51</sup>Cr edetate present in the extracellular fluid is excreted by the kidneys per unit time. Total body retention is described by a double exponential function.

The mean value of the glomerular filtration rate in the normal adult is approximately 130 ml/min in men and 120 ml/min in women (normalized for body surface area of 1,73 m<sup>2</sup>).

## 7. Stability

The shelf-life of the product is not more than 90 days after the date of release. The reference date of the product is 60 days before expiry. Store below 25°C. Do not freeze.