

## **NAME OF THE MEDICINAL PRODUCT**

Calcium Gluconate 10 % B. Braun solution for injection

## **COMPOSITION**

1 ml contains 94 mg calcium gluconate as active ingredient, equivalent to 0.21 mmol calcium.  
10 ml contain 940 mg calcium gluconate as active ingredient, equivalent to 2.10 mmol calcium.

Excipients:

The product also contains an amount of the excipient calcium D-saccharate tetrahydrate equivalent to 0.02 mmol calcium per ml (or 0.15 mmol calcium per 10 ml), water for injections.

Total calcium content: 0.23 mmol per ml (2.25 mmol per 10 ml).

## **THERAPEUTIC INDICATIONS**

Treatment of acute symptomatic hypocalcaemia.

## **CONTRAINDICATIONS**

Hypersensitivity to the active substance or to any of the excipients.

Hypercalcaemia (e.g. in patients with hyperparathyroidism, hypervitaminosis D, decalcifying malignancies, renal insufficiency, immobilisation osteoporosis, sarcoidosis, milk-alkali syndrome); hypercalciuria; intoxication with cardiac glycosides; therapy with cardiac glycosides.

The only exception may be that intravenous calcium administration is imperative for treatment of severe hypocalcaemia symptoms putting the patient at immediate vital risk, if safer therapeutic alternatives are not available and calcium administration via the oral route is not possible.

Concomitant use of ceftriaxone and intravenous calcium-containing products is contraindicated in premature neonates and neonates ( $\leq 28$  days of age). Ceftriaxone should not be used in premature neonates and neonates ( $\leq 28$  days of age) if they are receiving (or are expected to receive) calcium-containing intravenous products.

## **UNDESIRABLE EFFECTS**

Cardiovascular and other systemic undesirable effects are likely to occur as symptoms of acute hypercalcaemia resulting from intravenous overdose or too rapid intravenous injection. Their occurrence and frequency is directly related to the administration rate and the administered dose.

Undesirable effects are listed according to their frequencies as follows:

Not known: (cannot be estimated from the available data)

***Cardiac disorders***

Not known: Bradycardia, cardiac arrhythmia

***Vascular disorders***

Not known: Hypotension, vasodilatation, circulatory collapse (possibly fatal), flushing, mainly after too rapid injection

***Gastrointestinal disorders***

Not known: Nausea, vomiting

***General disorders and administration site conditions***

Not known: Heat sensations, sweating

Not known: Intramuscular injection may be accompanied by pain sensations or erythema.

***Ceftriaxone-calcium salt precipitation***

Rarely, severe, and in some cases, fatal, adverse reactions have been reported in pre-term and full-term neonates (aged <28 days) who had been treated with intravenous ceftriaxone and calcium. Precipitations of ceftriaxone-calcium salt have been observed in lung and kidneys post-mortem. The high risk of precipitation in neonates is a result of their low blood volume and the longer half-life of ceftriaxone compared with adults.

***Adverse reactions only occurring with improper administration technique:***

If intramuscular injection is not performed sufficiently deep intramuscularly, infiltration into the adipose tissue may occur with subsequent abscess formation, tissue induration, and necrosis.

Calcinosis cutis, possibly followed by skin ablation and necrosis, due to extravasation, has been reported.

Reddening of skin, burning sensation or pain during intravenous injection may indicate accidental perivascular injection, which may lead to tissue necrosis.

**WARNINGS**

Keep out of the sight and reach of children. The solution should only be used if it is clear, colourless to light brown aqueous solution, practically free from particles and the container is undamaged.

**NOTE**

Not all products are registered and approved for sale in all countries or regions. Indications of use may also vary by country and region. Please contact your country representative for product availability and information.

**B. Braun Melsungen AG, 34212 Melsungen, Germany, 10/2015**