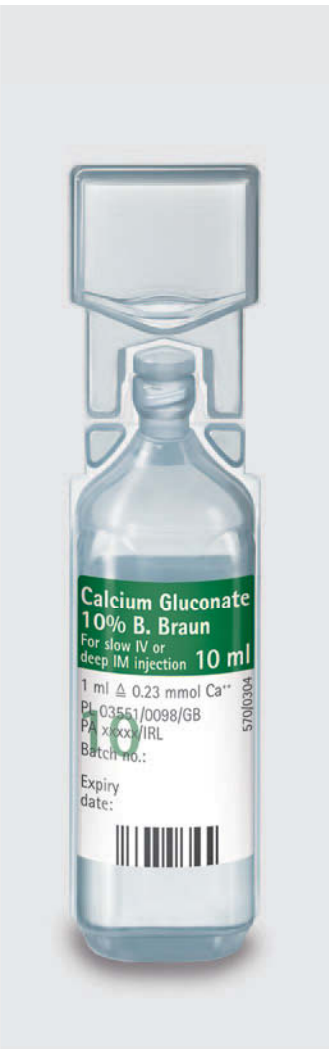
Calcium Gluconate 10 % B. Braun

Maximize safety – minimize risks – optimize patient care



Fluid Administration

B BRAUN
SHARING EXPERTISE

Calcium Gluconate 10 % B. Braun

Maximize safety

Your patients deserve the maximum in safety

Intensive care patients - especially infants and those with impaired renal function - are at high risk of the toxicity caused by aluminium accumulating in bone, plasma, liver and the central nervous system.

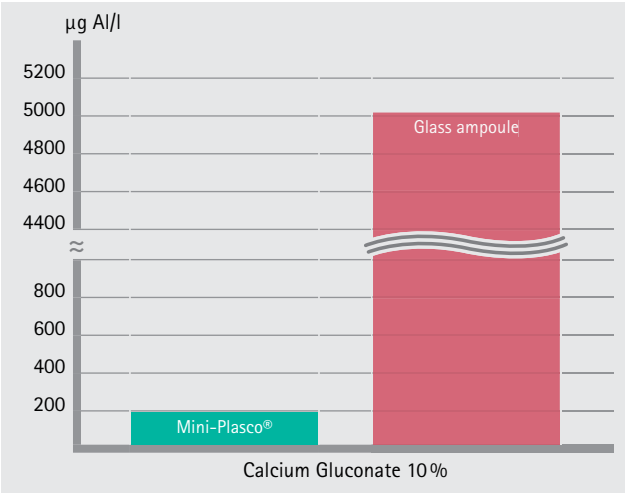
Therefore, critical care specialists recommend minimizing aluminium exposure in all patients receiving total parenteral nutrition (TPN) and electrolyte solutions. Patient safety should remain the first and foremost consideration when choosing the solution that is optimally suited for the indication.

In some IV solutions, such as Calcium Gluconate, however, high aluminium loading originates from the container rather than from the solution itself. That is why B. Braun has committed research into developing a container type that does not elevate the aluminium content of its Calcium Gluconate 10 % B. Braun.

See also MHRA Public Assessment Report September 2010.[1]

No needle is required for applying aseptic technique

Minimize risks



Aluminium contamination of Calcium Gluconate 10 %[2]

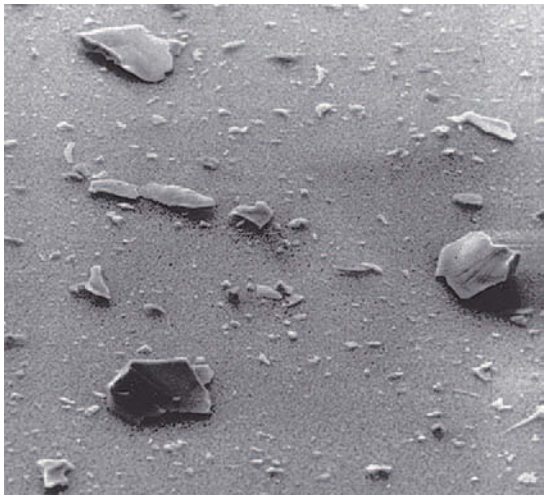
Mini-Plasco®

Calcium Gluconate 10 % is now supplied in Mini-Plasco® connect, B. Braun's well-proven, small-volume polyethylene ampoule.
Use Mini-Plasco® connect and reduce the risk of aluminium loading to a minimum.

Alongside these outstanding safety benefits, Mini-Plasco® connect features secure and convenient handling, thereby optimizing the care of your patients even further.

Safety benefits:

- Minimized aluminium contamination reduces the risk of aluminium toxicity
- No more needles that can cause needlestick injuries
- Minute glass particles no longer contaminate the solution
- Smooth ampoule opening prevents scratches from sharp edges



Microscopic magnification of a glass ampoule solution.

With glass ampoules, the user risks tiny glass particles contaminating the solution and sharp edges causing injury.

Calcium Gluconate 10 % B. Braun

Calcium Gluconate 10% B.Braun – Solution for Injection

Composition
10 ml Calcium Gluconate 10 % B. Braun solution for injection contain:

Active incredients:	
Calcium Gluconate for Injection	940 mg
Excipients:	
Calcium saccharate, Water for injections	
Calcium concentrations:	0.23 mmol/ml
Theoretical osmolarity	660 mosm/l
pH	5.5-7.5

Indications
Treatment of acute symptomatic hypocalcaemia

Contraindications
Calcium Gluconate 10% B. Braun must not be administered in the following conditions:
- Hypersensitivity to calcium gluconate and to the excepient
- Hypercalcaemia (e.g. in patients with hyperparathyroidism, hypervitaminosis D, decalcifying malignancies, renal insufficiency, immobilisation osteoporosis, sarcoidiosis, milkalkali syndrome)
- Hypercalciuria
- Intoxication with cardiac glycosides
- Therapy with cardiac glycosides

The only exception may be that IV 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.

Special warning and precautions for use

Special warnings
In the exceptional case of i.v. administration of calcium gluconate to patients receiving cardiac glycosides, adequate cardiac monitoring is mandatory and emergency treatment of cardiac complications such as serious arrhythmias must be available.

Calcium salts should only be used with caution and after careful establishment of the indication in patients with nephrocalcinosis, heart diseases, sarcoidosis (Boeck's disease), in patients receiving epinephrine, or in the elderly.

Renal impairment may be associated with hypercalcaemia and secondary hyperparathyroidism. Therefore, to patients with renal impairment, parenteral calcium should be administered only after careful assessment of the indication and the calciumphosphate balance should be monitored.

Precautions for use
Solutions containing calcium should be administered slowly to minimise peripheral vasodilation and cardiac depression.

Intravenous injections should be accompanied by heart rate or ECG control because bradycardia with vasodilatation or arrhythmia can occur when calcium is administered too quickly.

In children, Calcium Gluconate 10% B. Braun should not be injected i.m. but only slowly i.v.

Patients receiving calcium salts should be monitored carefully to ensure maintenance of correct calcium balance without tissue deposition.

Plasma levels and urinary excretion of calcium should be monitored when high-dose parenteral calcium is administered.

Calcium is insoluble in adipose tissue and may therefore cause infiltration and subsequent abscess formation, tissue induration and necrosis.

After perivascular or superficial i.m. injection local irritation, possibly followed by skin ablation or tissue necrosis, may occur. Extravasation must be avoided; the injection site should be monitored carefully.

High Vitamin D intake should be avoided.

Pregnancy and lactation
Calcium passes across the placental barrier and its concentration in fetal blood is higher than in maternal blood.

Calcium gluconate injections should be used during pregnancy only if considered to be essential by the physician. The administered dose should be carefully calculated, and the serum calcium level regularly evaluated in order to avoid hypercalcaemia, which may be deleterious for the foetus.

Calcium is excreted in breast milk This should be borne in mind when administering calcium to women who are breast-feeding their infants.

Undesirable effects
Cardiovascular and other systemic undesirable effects are likely to occur as symptoms of acute hypercalcaemia resulting from i.v. overdose or too rapid i.v. injection. Their occurrence and frequency is directly related to the administration rate and the administered dose. Under the conditions of proper administration, they are rare (< 1:1000).

Cardiac and vascular disorders
Hypotension, bradycardia, cardiac arrhythmia, vasodilatation, vasomotor collapse (possibly fatal), flushing, mainly after too rapid injection.

Gastro-intestinal disorders
Nausea, vomiting

General disorders
Heat sensations, sweating

Administration site conditions
Common (< 1:10, ≥ 1:100)
Intramuscular injection may be accompanied by pain sensations or erythema.

Adverse reactions only occurring with improper administration technique
If intramuscular injection is not performed sufficiently deep i.m., infiltration into the adipose tissue may occur with subsequent abscess formation, tissue induration, and necrosis.
Soft tissue calcification, 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.

Status
Only available on prescription

Marketing Autorisation Holder
B. Braun Melsungen AG
34212 Melsungen
Germany

Version 07.2005

[1] Medicines and Healthcare products Regulatory Agency (MHRA), MHRA Public Assessment Report - Calcium gluconate injection 10 % in 10 ml glass containers: risk of aluminium exposure, September 2010

[2] Frey OR, Maier L. Polyethylene vials of calcium gluconate reduce aluminium contamination of TPN. Ann Pharmacother. 2000 Jun; 34(6): 811-2.