

MANDATORY DRUG INFORMATION

1 NAME AND ADDRESS OF MARKETING AUTHORIZATION HOLDER

B.Braun Melsungen AG
34209 Melsungen, Germany

2. NAME OF THE MEDICINAL PRODUCT

Sodium Bicarbonate 8.4% w/v concentrate for solution for infusion

3. QUALITATIVE AND QUANTITATIVE COMPOSITION

Sodium Bicarbonate 8.4% w/v concentrate for solution for infusion

1000 ml of solution contain

Sodium bicarbonate	84.0 g
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Electrolyte concentrations:

Na+	1000 mmol/l
HCO ₃	1000 mmol/l

4. THERAPEUTIC INDICATIONS

- Correction of metabolic acidosis
- Urine alkalinisation:
 - in the case of intoxication with weak organic acids, e. g. barbiturates or acetylsalicylic acid
 - in order to improve the solubility of drug substances that are poorly soluble in neutral or acid medium, e. g. methotrexate, sulphonamides
 - in the case of haemolysis

5. CONTRAINDICATIONS

- Hypersensitivity to the active substance or to any of the excipients
- Respiratory or metabolic alkalosis
- Hypoventilation
- Hyponatraemia
- Hypokalaemia
- Excessive chloride loss

6. UNDESIRABLE EFFECTS

Listing of undesirable effects

The frequency of undesirable effects listed below is defined using the following convention:

Very common (≥1/10)

Common (≥1/100 to <1/10)

Uncommon (≥1/1,000 to <1/100)

Rare (≥1/10,000 to <1/1,000)

Very rare (< 1/10,000)

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

Metabolism and nutrition disorders

Not known: Hyponatraemia, serum hyperosmolarity

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7. NOTE

Prescription only.

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.

8. DATE OF LATEST UPDATE

04/2012