Prescribing Information; Sibnayal® (potassium citrate/ potassium hydrogen carbonate). Please refer to the Summary of Product Characteristics (SmPC) for full details of Prescribing Information. **Name of the medicinal product:** Sibnayal 8 mEq prolonged release granules, Sibnayal 24 mEq prolonged release granules. **Composition**: one sachet of Sibnayal 8 mEq prolonged release granules contains 282 mg of potassium citrate and 527 mg of potassium hydrogen carbonate. One sachet of Sibnayal 24 mEq prolonged release granules contains 847 mg of potassium citrate and 1 582 mg of potassium hydrogen carbonate. **Therapeutic indications**: Sibnayal is indicated for the treatment of distal renal tubular acidosis dRTA in adults, adolescents and children aged one year and older **Posology and method of administration:** Dosing is based on age and weight. When initiating alkalising therapy, the target starting daily dose for each age group should be used and incrementally titrated to obtain the optimal dose that provides adequate metabolic acidosis control based on plasma bicarbonate levels. The total daily dose is administered twice daily, typically twelve hours apart In case of vomiting within two hours after intake, the patient should take another dose. The use of this medicine requires medical supervision. **Contraindications:** Hypersensitivity to the active substances or to any of the excipients, renal impairment with glomerular filtration rate (GFR) ≤44 mL/min/ 1.73 m², hyperkalaemia. **Special warnings and precautions for use**: *Hyperkalaemia and cardiotoxicity:* Sibnayal should be used with caution in patients who have conditions predisposing them to hyperkalaemia, such as renal impairment, or crush syndrome, as a further rise in plasma potassium may lead to cardiac arrest. Close monitoring of plasma potassium in patients at risk is required at starting dose and after new dose increase or in case of worsening of pre-existing disease. Then frequency is according to physician's criteria, but at least twice a year. Sibnayal should be used with caution in case of combination with other products increasing plasma potassium or predisposing to cardiac dysrhythmia. *Gastrointestinal disorders:* Sibnayal should be used with caution in patients having gastrointestinal disorders as they could affect efficacy and safety, such as malabsorption, delayed gastric emptying, diarrhoea, nausea, vomiting. In such cases the blood bicarbonate levels should be regularly monitored and dose adjusted to maintain within normal ranges. The matrix of the granules can be found in the stools, which does not affect the efficacy or safety of Sibnayal. *Renal insufficiency:* Sibnayal should only be used in individuals with GFR >44 mL/min/ 1.73 m². For individuals with GFR between 45 and 59 mL/min/ 1.73 m² Sibnayal should only be used if the potential benefits are considered to outweigh the potential risks. For these patients doses should be adjusted by regular monitoring of plasma bicarbonate and potassium. Special care should be taken in elderly people in whom renal function can be decreased. *Potassium contents*: Sibnayal 8 mEq contains 308 mg of potassium per sachet. This is to be taken into consideration if the patient has a reduced kidney function or if the patient is on a controlled potassium diet. Sibnayal 24 mEq contains 924 mg of potassium per sachet This is to be taken into consideration if the patient has a reduced kidney function or if the patient is on a controlled potassium diet. **Interaction with other medicinal products and other forms of interaction:** No interaction studies have been performed. **Fertility, pregnancy and lactation**: There are no data from the use of Sibnayal in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development. Sibnayal should only be used during pregnancy if the expected benefits outweigh the potential risks. Although during pregnancy and more so during labour, there is more risk associated to a potentially severe acidosis and hypokalaemia in dRTA patients than to alkali treatment, in women with problem pregnancies there might be an increased risk to develop hyperkalaemia when potassium intake is high. Potassium is excreted in human milk, but at therapeutic doses of Sibnayal no effects on the breastfed newborns/infants are anticipated. Sibnayal can be used during breast feeding. Potassium citrate and potassium hydrogen carbonate are not known to affect fertility. **Effects on ability to drive and use machines:** Sibnayal has no or negligible influence on the ability to drive and use machines. **Undesirable effects:** *Very common:* abdominal pain. *Common:* upper abdominal pain, diarrhoea, dyspepsia, gastrointestinal disorder, gastrointestinal pain, nausea and vomiting. For more information on uncommon or rare adverse reactions, see the Summary of Product Characteristics. **Overdose:** Reports of a laxative effect after excessive oral doses of individual alkalising salts have occurred. An acute massive intake of potassium can cause hyperkalaemia resulting in nausea, vomiting, and diarrhoea and in severe cases paraesthesia, muscular weakness, mental confusion, electrocardiographic abnormalities (large and symmetric T waves), arrhythmia, atrioventricular block and heart failure. Hyperkalaemia is a particular concern in patients with underlying renal insufficiency. In case of severe hyperkalaemia, patients should be monitored (mostly plasma potassium level and ECG) and the appropriate symptomatic and supportive therapy instituted in specialised care units, where emergency treatments leading to rapid elimination of potassium such as ion exchange resin, combination of insulin dextrose or β2 mimetics (salbutamol) or haemodialysis will be implemented. **Special precautions for storage and disposal:** do not store above 25ºC. After opening the sachet, discard any unused content. **Legal classification:** Prescription Only Medicine **NHS indicative price:** 24mEq prolonged-release granules, 60 sachets £360.00 PL GB 46766/0003. 8mEq prolonged-release granules, 60 sachets £120.00. PL GB 46766/0002. **Marketing Authorisation Holder:** Advicenne, 262 rue du Faubourg Saint Honoré, 75008 Paris, France **Date of last revision**: April 2025. PP/SIB/2025/001 April 2025

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Advicenne@vigipharm.fr. Information about this product, including adverse reactions, precautions, contraindications and method of administration can be found in the full SmPC. For a copy of the SmPC or further information please contact Advicenne@vigipharm.fr