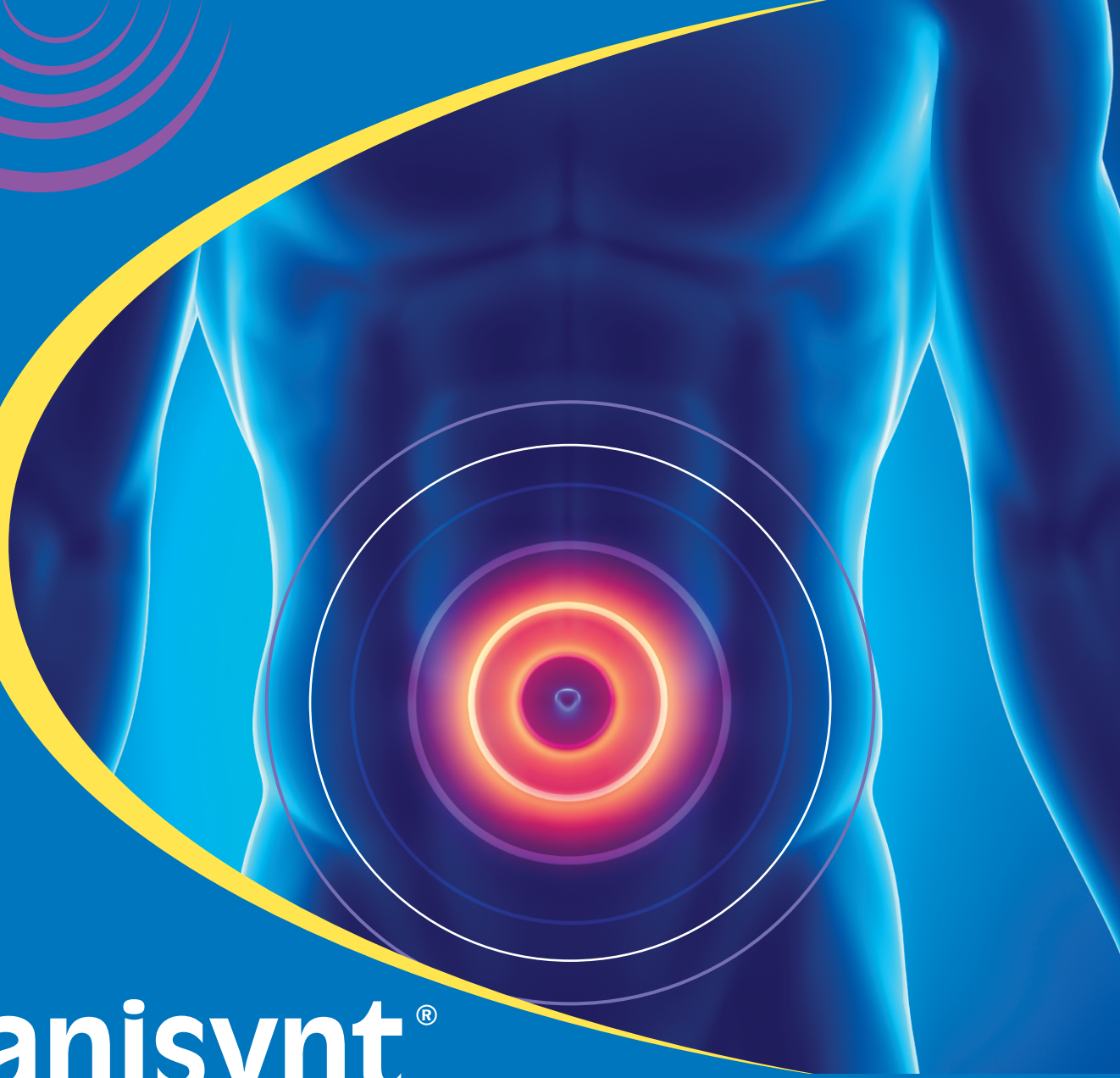
Highly effective relief



Ranisynt®

Ranitidine

RANISYNT® 50mg/2ml solution for injection/infusion

CODAL-SYNTO

Summary of SPC for Ranisynt®

Trade Name of the Medicinal Product:	Ranisynt®
Qualitative and Quantitative Composition:	Each ampoule contains 2 ml of a solution containing ranitidine 50mg as Ranitidine hydrochloride.
Therapeutic Indications:	Treatment of duodenal ulcer, benign gastric ulcer, post operative ulcer, oesophageal reflux disease and Zollinger-Ellison syndrome. In patients where the reduction of gastric secretion and acid output is desirable with the following conditions: Prophylaxis of gastro-intestinal haemorrhage from stress ulceration in seriously ill patients; Prophylaxis of recurrent haemorrhage in patients with bleeding peptic ulcers; Prior to general anaesthesia in patients at risk from acid aspiration (Mendelson's syndrome), i.e obstetric patients in labour.
Posology and Method of Administration:	For parenteral administration only. It may be administered as a slow, over at least two minutes, intravenous injection up to a maximum of 50mg, after dilution to 20ml per 50mg dose, which can be repeated every six to eight hours. It may also be administered as an intermittent intravenous infusion over two hours at a rate of 25mg per hour. This can be repeated at six to eight hour intervals. It may be administered as an intramuscular injection of 50mg every six to eight hours. In patients with severe renal impairment, the dose should be reduced to 25mg as plasma levels of the drug are elevated. *Children:* not recommended.
Contra-indications:	Hypersensitivity to ranitidine hydrochloride or to any component of the preparation.
Special Warnings and Precautions for Use:	If gastric ulcer is suspected, the possibility of malignancy must be excluded before initiating therapy; Severe renal impairment; Bradycardia in association with rapid administration of ranitidine injection; The recommended rates of administration must not be exceeded; Use should be avoided in patients with a history of porphyria; In patients such as the elderly, persons with chronic lung disease, diabetes or the immunocompromised, there may be an increased risk of developing community acquired pneumonia.
Interactions with Other Medicinal Products and Other Forms of Interaction:	Altered prothrombin time with coumarin anticoagulants (e.g. warfarin); High doses of ranitidine may reduce the excretion of procainamide and N-acetylprocainamide resulting in increased plasma level of these drugs; The bioavailability of certain drugs may be affected. This can result in either an increase in absorption (e.g. triazolam, midazolam, glipizide) or a decrease in absorption (e.g. ketoconazole, atazanavir, delaviridine, gefitnib).
Pregnancy and Lactation:	Ranitidine, should only be administered during pregnancy and lactation if use is considered essential.
Undesirable Effects:	Leukopenia, thrombocytopenia, agranulocytosis or pancytopenia, sometimes with marrow hypoplasia or marrow aplasia; Hypersensitivity reactions (urticaria, angioneurotic oedema, fever, bronchospasm, hypotension and chest pain), anaphylactic shock; Depression, reversible mental confusion and hallucinations; Headache, dizziness, reversible involuntary movement disorders; Reversible blurred vision; Bradycardia and A-V Block, vasculitis; Diarrhoea, acute pancreatitis; Transient and reversible changes in liver function tests, hepatitis with or without jaundice; Skin Rash, erythema multiforme, alopecia; Musculoskeletal symptoms such as arthralgia and myalgia; Acute interstitial nephritis; Reversible impotence; Breast conditions in men (such as gynaecomastia and galactorrhoea).
	MAH: Codal Synto Ltd.