CODAL-SYNTO

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Syntovir®

Aciclovir

PENEMER® 500mg vials • **PENEMER®** 1g vials

Summary of SPC for Syntovir®

Trade Name of the Medicinal Product:	Syntovir®
Qualitative and Quantitative Composition:	Aciclovir 200mg, 400mg, 800 mg.
Therapeutic indications and Posology and Method of Administration:	Adults: **Treatment of herpes simplex infections:** 200mg, 5 times a day, at approximately four hour intervals, omitting the night time dose. Treatment is usually for 5 days, in the case of severe initial infections this may need to be extended. In patients with impaired gut absorption or severely immunocompromised patients the dose may be doubled to 400mg. **Suppression of herpes simplex infections in immune-compromised patients:** 200mg, 4 times a day at approximately six-hour intervals. Dose of 400mg, 2 times a day at approximately twelve hour intervals is convenient for many patients. In some 200mg, 3 times a day at eight hour intervals, or 200mg, 2 times a day at twelve hour intervals, may be effective. Cases of breakthrough infection on total doses of 800mg a day may occur in some patients. **Prophylaxis of herpes simplex infection in immune-compromised patients:** 200mg, 4 times a day at approximately six-hour intervals. In patients with impaired gut absorption, or severely immune-compromised, dose may be doubled to 400mg. **Treatment of varicella and herpes zoster infections:** 800mg, 5 times a day at approximately four hour intervals, omitting the night time dose. Treatment should last 7 days. In patients with impaired gut absorption, or severely immunocompromised, use of intravenous administration should be considered. Children: **Treatment and prophylaxis of herpes simplex infection in immunocompromised patients:** Children two years of age or older, as adult dosages. Children under two years of age: half the adult dose. **Treatment of varicella infections:** Treatment should last five days. Age 6 years and over: 800mg, 4 times a day. Age 2 - 5 years: 400mg, 4 times a day. Age under 2 years: 200mg, 4 times daily. Dosing may be calculated more accurately as 20mg/kg bodyweight 4 times a day. Total daily dosage must not exceed 800mg.
Contra-indications:	Hypersensitivity to aciclovir or valaciclovir or to any other component of the product.
Special Warnings and Precautions for Use:	Severely immunocompromised patients; Hydration status; Renal impairement; Concomitant use with other nephrotoxic agents; Elderly; Pregnancy and Lactation.
Interactions with other Medicaments and other forms of Interaction:	No clinically significant interactions have been identified.
Undesirable Effects:	Skin rash, photosensitivity, urticaria, pruritis, abdominal pain, diarrhea, nausea, vomiting, headaches, confusion, dizziness, hallucinations, somnolence, convulsions, coma, accelerated diffuse hair loss, mild transient increases in bilirubin and liver related enzymes, small rise in creatinine and blood urea, decreases in haematological indices-anaemia, leucopenia, thrombocytopenia, acute renal failure, hepatitis, jaundice, hypersensitivity reactions: dyspnoea, angioedema and anaphylaxis, fatigue.
	MAH: Codal Synto Ltd.