PRESCRIBING INFORMATION

# PrIMUNOVIR®

Inosine Pranobex

Tablets, 500mg

Subacute Sclerosing Panencephalitis Therapy

KoRa Healthcare
Swords, Co Dublin, Ireland

Date of Preparation:
19-Oct-2012

Submission Control No: 158337

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## INDICATIONS:

May be beneficial in retarding neurological deterioration and prolonging life in patients with slowly progressive subacute sclerosing panencephalitis (SSPE). Inosine pranobex is not indicated for any condition other than SSPE.

## CONTRAINDICATIONS:

None for SSPE patients.

## WARNINGS:

Because the purine (inosine) moiety of inosine pranobex is rapidly catabolized to uric acid, resulting in elevations of serum and uric acid, it should be used with care in patients with a history of gout, urolithiasis, nephrolithiasis, or renal dysfunction. Uricosuric agents may be administered to patients with severely elevated serum uric acid levels.

## PRECAUTIONS:

Pregnancy: Specific studies on the effects of inosine pranobex on animal reproduction have been performed and were negative. However, well-controlled trials concerning fetal risk and impairment of fertility in humans are not available. Therefore, care should be taken in the use of inosine pranobex by pregnant women and women of childbearing age, and the risks involved should be assessed.

## ADVERSE EFFECTS:

Imunovir tablets may cause unwanted side effects but these are infrequent and are usually of a mild and brief nature. The most consistent side effect is increased uric acid levels in the blood and urine, which return to pre-treatment levels after the dosing is finished. Infrequent side effects can include upset stomach, itching or rashes, headaches, dizziness, joint aches or feeling tired. Rare side effects can include diarrhea or constipation, increased urine volume, insomnia or feeling nervous or “on edge.”

## DOSAGE:

Adults and Children: The recommended dosage is 50 mg/kg/day, up to a maximum of 3 g/day, administered orally in 3 to 4 equally divided doses during waking hours.

## OVERDOSE:

Treatment: Toxic effects from an overdose of inosine pranobex have not been observed. Since the drug is rapidly metabolized, reduction in dosage or withdrawal from treatment with symptomatic general management of signs and symptoms would generally suffice should any untoward reaction occur. Similar management would apply to an accidental overdose.

## PHARMACOLOGY:

Mechanism(s) that might explain the results of the clinical studies employing inosine pranobex have not been completely elucidated. However, possible antiviral and immunomodulating properties of this drug may be involved.

Serum uric acid concentration rose with increasing inosine pranobex doses. Hyperuricemic levels (greater than 7.5 mg%) were seen at doses equal to or exceeding 3 g/day. At doses of 4 g/day, about 60% of the subjects had serum uric acid levels in excess of 7 mg%; 30% of the subjects exceeded 7.5 mg%. Urinary uric acid excretion was also elevated after inosine pranobex administration. The time for urine normalization was usually longer than that required for normalization of serum uric acid level. In 1 case, uricosuria was found to last more than 9 days, and another case was reported in which 3 weeks were required to restore uric acid excretion to normal level.

Inosine pranobex is composed of inosine and the p-acetamidobenzoic acid salt of N, N-dimethylamido-2-propanol. The principal metabolite (about 80%) of p-acetamidobenzoic acid is O-acylglucuronide and the principal metabolite of N, N-dimethylamine-2-propanol is N, N-dimethylamino- 2-propanol-N-oxide. Virtually 100% of the metabolites was recovered in urine within 8 through 24 hours postadministration period. Each of the components of inosine pranobex is rapidly metabolized, the inosine and p-acetamidobenzoic acid more extensively than N, N-dimethylamino-2-propanol.

## SUPPLIED:

Each white, oblong tablet, engraved D N on one side and with a breakline on the reverse contains inosine pranobex 500 mg. Nonmedicinal ingredients: magnesium stearate, mannitol, microcrystalline cellulose, povidone and wheat starch. Tartrazine free. Cartons of 100 tablets packed as 5 blister strips of 20 tablets. Store at room temperature.