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Type of Document:

TECHNICAL DATA SHEET

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94380-ALLOPURINOL

1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION

1.1 Identification of the substance or preparation

Name: Allopurinol

Bulk code: 94380

1.2 Synonyms

Allopurinol, Allopurinolum, Allopurinolis, 1,5-Dihydro-4H-pyrazolo[3,4-d]pyrimidin-4-one.

2. DESCRIPTION

Appearance: Powder.

Colour: White or almost white.

3. COMPOSITION/INFORMATION ON COMPONENTS

Formula: $C_5N_4H_4O$

CAS: 315-30-0

Molecular weight: 136.1 g/mol

4. PHYSICO-CHEMICAL DATA.

See detailed specifications on analysis certificate.

Solubility: Slightly soluble in water and alcohol. It dissolves in dilute solutions of alkali hydroxides.

5. PROPERTIES/USES


ACTIVE PHARMACEUTICAL INGREDIENT

Allopurinol is an anti-gout agent, a structural isomer of hypoxanthine, which acts by competitively inhibiting xanthine oxidase, thereby preventing the formation of uric acid.

Allopurinol is used to treat hyperuricemia associated with chronic gout, acute uric acid nephropathy, as well as to treat uric acid crystal formations, uric lithiasis, and calcium renal lithiasis in patients with hyperuricemia and/or hyperuricosuria. It is an anti-gout agent, which acts by competitively inhibiting xanthine oxidase.

It is not used for asymptomatic hyperuricemia, it is used to treat gout and primary hyperuricemias, as well as those secondary caused by blood dyscrasias, neoplastic diseases or therapies thereof and in the overproduction of urate.

It can be associated with classic anti-gout medicines (uricosuric and anti-inflammatory).

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6. DOSAGE

Allopurinol may be administered:

- Orally:
 - Initial doses: 100–300 mg/day.
 - Maintenance dose: 200–600 mg/day.
 - Severe cases: Up to 900 mg/day.
 - Hyperuricaemia and prevention of urate nephropathy, associated with cancer: 600–800 mg/day, for 2 or 3 days.
 - In paediatrics, it can be used to treat hyperuricaemia associated with cancer or chemotherapy in doses of 10–20 mg/kg/day. The maximum amount administered will depend on age.

7. REMARKS

Storage: Store at room temperature ($25\pm 2^{\circ}\text{C}$), in a cool, dry place, away from sunlight, in a tightly closed container.

8. BIBLIOGRAPHY

European Pharmacopeia latest edition.

"Martindale. The Extra Pharmacopoeia". 30th Edition. Ed. The Pharmaceutical Press. London. (1993).

Monografías Farmacéuticas, COFA, 1998.