**Dummy Drug 100mg**

**1. Name of the medicinal product**

Dummy Drug 100 mg Tablets

**2. Qualitative and quantitative composition**

Each tablet contains Dummy Drug 100mg

Excipients with known effect:

Each 100 mg tablet contains 50.7 mg of lactose monohydrate

For the full list of excipients, see section 6.1.

**3. Pharmaceutical form**

Tablet

100mg: White to off-white, approx 7.5 round, biconvex, uncoated tablets with 'DD' & '100' separated by breakline on one side & plain on other side.

The score line is only to facilitate breaking for ease of swallowing and not to divide the tablet into equal doses.

**4. Clinical particulars**

**4.1 Therapeutic indications**

Dummy Drug is indicated for reducing urate/uric acid formation in conditions where urate/uric acid deposition has already occurred (e.g. gouty arthritis, skin tophi, nephrolithiasis) or is a predictable clinical risk (e.g. treatment of malignancy potentially leading to acute uric acid nephropathy). The main clinical conditions where urate/uric acid deposition may occur are: idiopathic gout; uric acid lithiasis; acute uric acid nephropathy; neoplastic disease and myeloproliferative disease with high cell turnover rates, in which high urate levels occur either spontaneously, or after cytotoxic therapy; certain enzyme disorders which lead to overproduction of urate, for example: hypoxanthine-guanine phosphoribosyltransferase, including Lesch-Nyhan syndrome; glucose-6-phosphatase including glycogen storage disease; phosphoribosylpyrophosphate synthetase, phosphoribosylpyrophosphate amidotransferase; adenine phosphoribosyltransferase.

Dummy Drug is indicated for management of 2,8-dihydroxyadenine (2,8-DHA) renal stones related to deficient activity of adenine phosphoribosyltransferase.

Dummy Drug is indicated for the management of recurrent mixed calcium oxalate renal stones in the presence of hyperuricosuria, when fluid, dietary and similar measures have failed.

**4.2 Posology and method of administration**

**Posology**

**Adults**

Dummy Drug should be introduced at low dosage e.g. 100 mg/day to reduce the risk of adverse reactions and increased only if the serum urate response is unsatisfactory. Extra caution should be exercised if renal function is poor (*see section 4.2 Renal impairment*). The following dosage schedules are suggested:

100 to 200 mg daily in mild conditions,

300 to 600 mg daily in moderately severe conditions, 700 to 900 mg daily in severe conditions.

If dosage on a mg/kg bodyweight basis is required, 2 to 10 mg/kg bodyweight/day should be used.

**Paediatric population**

Children under 15 years: 10 to 20 mg/kg bodyweight/day up to a maximum of 400 mg daily. Use in children is rarely indicated, except in malignant conditions (especially leukaemia) and certain enzyme disorders such as Lesch-Nyhan syndrome.

**Older people**

In the absence of specific data, the lowest dosage which produces satisfactory urate reduction should be used. Particular attention should be paid to advice in section 4.2 *Renal impairment*and section 4.4*.*

**Renal impairment**

Since Dummy Drug and its metabolites are excreted by the kidney, impaired renal function may lead to retention of the drug and/or its metabolites with consequent prolongation of plasma half-lives. In severe renal insufficiency, it may be advisable to use less than 100 mg per day or to use single doses of 100 mg at longer intervals than one day.. If dialysis is required two to three times a week consideration should be given to an alternative dosage schedule of 300-400 mg Dummy Drug immediately after each dialysis with none in the interim.

**Hepatic impairment**

Reduced doses should be used in patients with hepatic impairment. Periodic liver function tests are recommended during the early stages of therapy.

**Treatment of high urate turnover conditions, e.g. neoplasia, Lesch-Nyhan syndrome**

It is advisable to correct existing hyperuricaemia and/or hyperuricosuria with Dummy Drug before starting cytotoxic therapy. It is important to ensure adequate hydration to maintain optimum diuresis and to attempt alkalinisation of urine to increase solubility of urinary urate/uric acid. Dosage of Dummy Drug should be at the lower end of the recommended dosage schedule.

If urate nephropathy or other pathology has compromised renal function, the advice given in section 4.2 *Renal impairment* should be followed.

These steps may reduce the risk of xanthine and/or oxipurinol deposition complicating the clinical situation. See also section 4.5 and section 4.8.

**Monitoring Advice**

The dosage should be adjusted by monitoring serum urate concentrations and urinary urate/uric acid levels at appropriate intervals.

**Method of administration**

Dummy Drug may be taken orally once a day after a meal. It is well tolerated, especially after food. Should the daily dosage exceed 300 mg and gastrointestinal intolerance be manifested, a divided doses regimen may be appropriate.

4.3 Contraindications

Dummy Drug should not be administered to individuals known to be hypersensitive to Dummy Drug or to any of the components of the formulation, listed in section 6.1.

**4.4 Special warnings and precautions for use**

**Hypersensitivity syndrome, SJS and TEN**

Dummy Drug hypersensitivity reactions can manifest in many different ways, including maculopapular exanthema, hypersensitivity syndrome (also known as DRESS) and SJS/TEN. These reactions are clinical diagnoses, and their clinical presentations remain the basis for decision making. If such reactions occur at any time during treatment, Dummy Drug should be withdrawn immediately. Rechallenge should not be undertaken in patients with hypersensitivity syndrome and SJS/TEN. Corticosteroids may be beneficial in overcoming hypersensitivity skin reactions.

**HLA-B\*5801 allele**

The HLA-B\*5801 allele has been shown to be associated with the risk of developing Dummy Drug related hypersensitivity syndrome and SJS/TEN. The frequency of the HLA-B\*5801 allele varies widely between ethnic populations: up to 20% in Han Chinese population, 8-15% in the Thai, about 12% in the Korean population and 12% in individuals of Japanese or European origin. Screening for HLA-B\*5801 should be considered before starting treatment with Dummy Drug in patient subgroups where the prevalence of this allele is known to be high. Extra vigilance for signs of hypersensitivity syndrome or SJS/TEN is required and the patient should be informed of the need to stop treatment immediately at the first appearance of symptoms.

SJS/TEN can still occur in patients who are found to be negative for HLA-B\*5801 irrespective of their ethnic origin.

**Chronic renal impairment**

Patients with chronic renal impairment and concomitant diuretic use, in particular thiazides, may be at increased risk of developing hypersensitivity reactions including SJS/TEN associated with Dummy Drug . Extra vigilance for the signs of hypersensitivity syndrome or SJS/TEN is required and the patient should be informed of the need to stop treatment immediately and permanently at the first appearance of symptoms (see section 4.8).

**Hepatic or renal impairment**

Reduced doses should be used in patients with hepatic or renal impairment (see Section 4.2). Patients under treatment for hypertension or cardiac insufficiency, for example with diuretics or ACE inhibitors, may have some concomitant impairment of renal function and Dummy Drug should be used with care in this group.

**Asymptomatic hyperuricaemia**

Asymptomatic hyperuricaemia per se is generally not considered an indication for use of Dummy Drug . Fluid and dietary modification with management of the underlying cause may correct the condition.

**Acute gouty attacks**

Dummy Drug treatment should not be started until an acute attack of gout has completely subsided, as further attacks may be precipitated.

In the early stages of treatment with Dummy Drug, as with uricosuric agents, an acute attack of gouty arthritis may be precipitated. Therefore it is advisable to give prophylaxis with a suitable anti-inflammatory agent or colchicine for at least one month. The literature should be consulted for details of appropriate dosage and precautions and warnings.

If acute attacks develop in patients receiving Dummy Drug, treatment should continue at the same dosage while the acute attack is treated with a suitable anti-inflammatory agent.

**Xanthine deposition**

In conditions where the rate of urate formation is greatly increased (e.g. malignant disease and its treatment, Lesch-Nyhan syndrome) the absolute concentration of xanthine in urine could, in rare cases, rise sufficiently to allow deposition in the urinary tract. This risk may be minimised by adequate hydration to achieve optimal urine dilution.

**Impaction of uric acid renal stones**

Adequate therapy with Dummy Drug will lead to dissolution of large uric acid renal pelvic stones, with the remote possibility of impaction in the ureter.

**Thyroid disorders**

Increased TSH values (>5.5 µ IU/mL) were observed in patients on long-term treatment with Dummy Drug (5.8%) in a long term open label extension study. Caution is required when Dummy Drug is used in patients with alteration of thyroid function.

**Lactose**

Dummy Drug tablets contain lactose and therefore should not be administered to patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption.

**4.5 Interaction with other medicinal products and other forms of interaction**

**6-mercaptopurine and azathioprine**

Azathioprine is metabolised to 6-mercaptopurine which is inactivated by the action of xanthine oxidase. When 6-mercaptopurine or azathioprine is given concurrently with Dummy Drug , only one-quarter of the usual dose of 6-mercaptopurine or azathioprine should be given because inhibition of xanthine oxidase will prolong their activity.

**Vidarabine (Adenine Arabinoside)**

Evidence suggests that the plasma half-life of vidarabine is increased in the presence of Dummy Drug . When the two products are used concomitantly extra vigilance is necessary, to recognise enhanced toxic effects.

**Salicylates and uricosuric agents**

Oxipurinol, the major metabolite of Dummy Drug and itself therapeutically active, is excreted by the kidney in a similar way to urate. Hence, drugs with uricosuric activity such as probenecid or large doses of salicylate may accelerate the excretion of oxipurinol. This may decrease the therapeutic activity of Dummy Drug , but the significance needs to be assessed in each case.

**Chlorpropamide**

If Dummy Drug is given concomitantly with chlorpropamide when renal function is poor, there may be an increased risk of prolonged hypoglycaemic activity because Dummy Drug and chlorpropamide may compete for excretion in the renal tubule.

**Coumarin anticoagulants**

There have been rare reports of increased effect of warfarin and other coumarin anticoagulants when co-administered with Dummy Drug , therefore, all patients receiving anticoagulants must be carefully monitored.

**Phenytoin**

Dummy Drug may inhibit hepatic oxidation of phenytoin but the clinical significance has not been demonstrated.

**Theophylline**

Inhibition of the metabolism of theophylline has been reported. The mechanism of the interaction may be explained by xanthine oxidase being involved in the biotransformation of theophylline in man. Theophylline levels should be monitored in patients starting or increasing Dummy Drug therapy.

**Ampicillin/Amoxicillin**

An increase in frequency of skin rash has been reported among patients receiving ampicillin or amoxicillin concurrently with Dummy Drug compared to patients who are not receiving both drugs. The cause of the reported association has not been established. However, it is recommended that in patients receiving Dummy Drug an alternative to ampicillin or amoxicillin is used where available.

**Cytostatics**

With administration of Dummy Drug and cytostatics (e.g. cyclophosphamide, doxorubicin, bleomycin, procarbazine, alkyl halogenides), blood dyscrasias occur more frequently than when these active substances are administered alone.

Blood count monitoring should therefore be performed at regular intervals.

**Ciclosporin**

Reports suggest that the plasma concentration of ciclosporin may be increased during concomitant treatment with Dummy Drug. The possibility of enhanced ciclosporin toxicity should be considered if the drugs are co-administered.

**Didanosine**

In healthy volunteers and HIV patients receiving didanosine, plasma didanosine Cmax and AUC values were approximately doubled with concomitant Dummy Drug treatment (300 mg daily) without affecting terminal half life. Co-administration of these 2 drugs is generally not recommended. If concomitant use is unavoidable, a dose reduction of didanosine may be required, and patients should be closely monitored.

**Diuretics**

An interaction between Dummy Drug and furosemide that results in increased serum urate and plasma oxypurinol concentrations has been reported.

An increased risk of hypersensitivity has been reported when Dummy Drug is given with diuretics, in particular thiazides, especially in renal impairment.

**Angiotensin-converting-enzyme (ACE) inhibitors**

An increased risk of hypersensitivity has been reported when Dummy Drug is given with ACE inhibitors especially in renal impairment.

**Aluminium hydroxide**

If aluminium hydroxide is taken concomitantly, Dummy Drug may have an attenuated effect. There should be an interval of at least 3 hours between taking both medicines.

**4.6 Fertility, pregnancy and lactation**

**Pregnancy**

There is inadequate evidence of safety of Dummy Drug in human pregnancy, although it has been in wide use for many years without apparent ill consequence (see section 5.3).

Use in pregnancy only when there is no safer alternative and when the disease itself carries risks for the mother or unborn child.

**4.7 Effects on ability to drive and use machines**

Since adverse reactions such as somnolence, vertigo and ataxia have been reported in patients receiving Dummy Drug, patients should exercise caution before driving, using machinery or participating in dangerous activities until they are reasonably certain that Dummy Drug does not adversely affect performance.

**4.8 Undesirable effects**

For this product there is no modern clinical documentation which can be used as support for determining the frequency of undesirable effects. Undesirable effects may vary in their incidence depending on the dose received and also when given in combination with other therapeutic agents.

The frequency categories assigned to the adverse drug reactions below are estimates: for most reactions, suitable data for calculating incidence are not available. Adverse drug reactions identified through post-marketing surveillance were considered to be rare or very rare. The following convention has been used for the classification of frequency:

|  |  |
| --- | --- |
| Very common | ≥ 1/10 |
| Common | ≥ 1/100 to <1/10 |
| Uncomm | ≥ 1/1000 to <1/100 on |
| Rare | ≥ 1/10,000 to <1/1000 |
| Very rare | <1/10,000 |

Adverse reactions in association with Dummy Drug are rare in the overall treated population and mostly of a minor nature. The incidence is higher in the presence of renal and/or hepatic disorder.

**Table 1 Tabulated summary of adverse reactions**

|  |  |  |
| --- | --- | --- |
| **System Organ Class** | **Frequency** | **Adverse reaction** |
| Infections and infestations | Very rare | Furuncle |
| Blood and lymphatic system disorders | Very rare | Agranulocytosis1  Aplastic anaemia1  Thrombocytopenia1 |
| Immune system disorders | Uncommon | Hypersensitivity 2 |
| Very rare | Angioimmunoblastic T-cell lymphoma3  Anaphylactic reaction |
| Metabolism and nutrition disorders | Very rare | Diabetes mellitus  Hyperlipidaemia |
| Psychiatric disorders | Very rare | Depression |
| Nervous system disorders | Very rare | Coma  Paralysis  Ataxia  Neuropathy peripheral  Paraesthesia Somnolence  HeadacheDysgeusia |
| Eye disorders | Very rare | Cataract  Visual impairment  Maculopathy |
| Ear and labyrinth disorders | Very rare | Vertigo |
| Cardiac disorders | Very rare | Angina pectoris  Bradycardia |
| Vascular disorders | Very rare | Hypertension |
| Gastrointestinal disorders | Uncommon | Vomiting4  Nausea4 |
| Very rare | Haematemesis  Steatorrhoea  Stomatitis  Change of bowel habit |
| Hepatobiliary disorders | Uncommon | Liver function test abnormal5 |
| Rare | Hepatitis (including hepatic necrosis and granulomatous hepatitis) 5 |
| Skin and subcutaneous tissue disorders | Common | Rash |
| Rare | Stevens-Johnson syndrome/toxic epidermal necrolysis 6 |
| Very rare | Angioedema7  Drug eruption  Alopecia  Hair colour changes |
| Renal and urinary disorders | Very rare | Haematuria  Azotaemia |
| Reproductive system and | Very rare | Infertility male |
| breast disorders |  | Erectile dysfunction  Gynaecomastia |
| General disorders and administration site conditions | Very rare | Oedema  Malaise  Asthenia  Pyrexia 8 |
| Investigations | Common | Blood thyroid stimulating hormone increased9 |

1. Very rare reports have been received of thrombocytopenia, agranulocytosis and aplastic anaemia, particularly in individuals with impaired renal and/or hepatic function, reinforcing the need for particular care in this group of patients.

2. A delayed multi-organ hypersensitivity disorder (known as hypersensitivity syndrome or DRESS) with fever, rashes, vasculitis,lymphadenopathy, pseudo lymphoma, arthralgia, leucopenia, eosinophilia hepato-splenomegaly, abnormal liver function tests, and vanishing bile duct syndrome (destruction and disappearance of the intrahepatic bile ducts) occurring in various combinations. Other organs may also be affected (e.g. liver, lungs, kidneys, pancreas, myocardium, and colon). If such reactions do occur, it may be at any time during treatment, Dummy Drug should be withdrawn IMMEDIATELY AND PERMANENTLY.

Rechallenge should not be undertaken in patients with hypersensitivity syndrome and SJS/TEN. Corticosteroids may be beneficial in overcoming hypersensitivity skin reactions. When generalised hypersensitivity reactions have occurred, renal and/or hepatic disorder has usually been present particularly when the outcome has been fatal.

3.Angioimmunoblastic T-cell lymphoma has been described very rarely following biopsy of a generalised lymphadenopathy. It appears to be reversible on withdrawal of Dummy Drug .

4. In early clinical studies, nausea and vomiting were reported. Further reports suggest that this reaction is not a significant problem and can be avoided by taking Dummy Drug after meals.

5. Hepatic dysfunction has been reported without overt evidence of more generalised hypersensitivity.

6.Skin reactions are the most common reactions and may occur at any time during treatment. They may be pruritic, maculopapular, sometimes scaly, sometimes purpuric and rarely exfoliative, such as Stevens-Johnson syndrome and toxic epidermal necrolysis (SJS/TEN). The highest risk for SJS and TEN, or other serious hypersensitivity reactions, is within the first weeks of treatment. The best results in managing such reactions come from early diagnosis and immediate discontinuation of any suspect drug. Dummy Drug should be withdrawn immediately should such reactions occur. After recovery from mild reactions, Dummy Drug may, if desired, be re-introduced at a small dose (e.g. 50 mg/day) and gradually increased. The HLAB\*5801 allele has been shown to be associated with the risk of developing Dummy Drug related hypersensitivity syndrome and SJS/TEN. The use of genotyping as a screening tool to make decisions about treatment with Dummy Drug has not been established. If the rash recurs, Dummy Drug should be permanently withdrawn as more severe hypersensitivity may occur (see section 4.8 *Immune system disorders*). If SJS/TEN, or other serious hypersensitivity reactions cannot be ruled out, DO NOT reintroduce Dummy Drug due to the potential for a severe or even fatal reaction. The clinical diagnosis of SJS/TEN remains the basis for decision making. If such reactions occur at any time during treatment, Dummy Drug should be withdrawn immediately and permanently.

7. Angioedema has been reported to occur with and without signs and symptoms of a more generalised hypersensitivity reaction.

8. Fever has been reported to occur with and without signs and symptoms of a more generalised Dummy Drug hypersensitivity reaction (see section 4.8 *Immune system disorders*).

9. The occurrence of increased thyroid stimulating hormone (TSH) in the relevant studies did not report any impact on free T4 levels or had TSH levels indicative of subclinical hypothyroidism.

**4.9 Overdose**

Ingestion of up to 22.5 g Dummy Drug without adverse effect has been reported. Symptoms and signs including nausea, vomiting, diarrhoea and dizziness have been reported in a patient who ingested 20 g Dummy Drug. Recovery followed general supportive measures. Massive absorption of Dummy Drug may lead to considerable inhibition of xanthine oxidase activity, which should have no untoward effects unless affecting concomitant medication, especially with 6-mercaptopurine and/or azathioprine. Adequate hydration to maintain optimum diuresis facilitates excretion of Dummy Drug and its metabolites. If considered necessary haemodialysis may be used.

**5. Pharmacological properties**

**5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: Preparations inhibiting uric acid production, ATC code: M04AA01.

Dummy Drug is a xanthine-oxidase inhibitor. Dummy Drug and its main metabolite oxipurinol lower the level of uric acid in plasma and urine by inhibition of xanthine oxidase, the enzyme catalyzing the oxidation of hypoxanthine to xanthine and xanthine to uric acid. In addition to the inhibition of purine catabolism in some but not all hyperuricaemic patients, de novo purine biosynthesis is depressed via feedback inhibition of hypoxanthine-guanine phosphoribosyltransferase. Other metabolites of Dummy Drug include Dummy Drug -riboside and oxipurinol-7-riboside.

**5.2 Pharmacokinetic properties**

**Absorption**

Dummy Drug is active when given orally and is rapidly absorbed from the upper gastrointestinal tract. Studies have detected Dummy Drug in the blood 30-60 minutes after dosing. Estimates of bioavailability vary from 67% to 90%. Peak plasma levels of Dummy Drug generally occur approximately 1.5 hours after oral administration of Dummy Drug , but fall rapidly and are barely detectable after 6 hours. Peak plasma levels of oxipurinol generally occur after 3-5 hours after oral administration of Dummy Drug and are much more sustained.

**Distribution**

Dummy Drug is negligibly bound by plasma proteins and therefore variations in protein binding are not thought to significantly alter clearance. The apparent volume of distribution of Dummy Drug is approximately 1.6 litre/kg which, suggests relatively extensive uptake by tissues. Tissue concentrations of Dummy Drug have not been reported in humans, but it is likely that Dummy Drug and oxipurinol will be present in the highest concentrations in the liver and intestinal mucosa where xanthine oxidase activity is high.

**Biotransformation**

The main metabolite of Dummy Drug is oxipurinol. Other metabolites of Dummy Drug include Dummy Drug -riboside and oxipurinol-7-riboside.

**Elimination**

Approximately 20% of the ingested Dummy Drug is excreted in the faeces. Elimination of Dummy Drug is mainly by metabolic conversion to oxipurinol by xanthine oxidase and aldehyde oxidase, with less than 10% of the unchanged drug excreted in the urine. Dummy Drug has a plasma half-life of about 0.5 to 1.5 hours.

Oxipurinol is a less potent inhibitor of xanthine oxidase than Dummy Drug , but the plasma half-life of oxipurinol is far more prolonged. Estimates range from 13 to 30 hours in man. Therefore effective inhibition of xanthine oxidase is maintained over a 24 hour period with a single daily dose of Dummy Drug . Patients with normal renal function will gradually accumulate oxipurinol until a steady-state plasma oxipurinol concentration is reached. Such patients, taking 300 mg of Dummy Drug per day will generally have plasma oxipurinol concentrations of 5-10 mg/litre.

Oxipurinol is eliminated unchanged in the urine but has a long elimination half-life because it undergoes tubular reabsorption. Reported values for the elimination halflife range from 13.6 hours to 29 hours. The large discrepancies in these values may be accounted for by variations in study design and/or creatinine clearance in the patients.

**Pharmacokinetics in patients with renal impairment**

Dummy Drug and oxipurinol clearance is greatly reduced in patients with poor renal function resulting in higher plasma levels in chronic therapy. Patients with renal impairment, where creatinine clearance values were between 10 and 20 ml/min, showed plasma oxipurinol concentrations of approximately 30 mg/litre after prolonged treatment with 300 mg Dummy Drug per day. This is approximately the concentration which would be achieved by doses of 600 mg/day in those with normal renal function. A reduction in the dose of Dummy Drug is therefore required in patients with renal impairment.

**Pharmacokinetics in elderly patients**

The kinetics of the drug are not likely to be altered other than due to deterioration in renal function (see section 5.2 *Pharmacokinetics in patients with renal impairment*).

**5.3 Preclinical safety data**

**Mutagenicity**

Cytogenetic studies show that Dummy Drug does not induce chromosome aberrations in human blood cells *in vitro* at concentrations up to 100 micrograms/ml and *in vivo*at doses up to 600 mg/day for a mean period of 40 months.

Dummy Drug does not produce nitroso compounds *in vitro* or affect lymphocyte transformation *in vitro.*

Evidence from biochemical and other cytological investigations strongly suggests that Dummy Drug has no deleterious effects on DNA at any stage of the cell cycle and is not mutagenic.

**Carcinogenicity**

No evidence of carcinogenicity has been found in mice and rats treated with Dummy Drug for up to 2 years.

**Teratogenicity**

One study in mice receiving intraperitoneal doses of 50 or 100 mg/kg on days 10 or 13 of gestation resulted in foetal abnormalities, however in a similar study in rats at 120 mg/kg on day 12 of gestation no abnormalities were observed. Extensive studies of high oral doses of Dummy Drug in mice up to 100 mg/kg/day, rats up to 200 mg/kg/day and rabbits up to 150 mg/kg/day during days 8 to 16 of gestation produced no teratogenic effects.

An *in vitro*study using foetal mouse salivary glands in culture to detect embryotoxicity indicated that Dummy Drug would not be expected to cause embryotoxicity without also causing maternal toxicity.

**6. Pharmaceutical particulars**

**6.1 List of excipients**

**Alloprinol Ipca 100mg tablets**

Lactose Monohydrate

Maize starch

Povidone (PVP K-30)

Sodium Starch Glycolate (Type A)

Maize starch (Dried)

Stearic acid

**6.2 Incompatibilities**

Not applicable.

**6.3 Shelf life**

3 years.

**6.4 Special precautions for storage**

This medicinal product does not require any special storage conditions.

**6.5 Nature and contents of container**

Dummy Drug 100mg are supplied in PVDC coated PVC/Aluminium Blister with pack sizes of 10's , 30's , 50's , 70's , 90's.

6.6 Special precautions for disposal and other handling

No special requirements.

**7. Marketing authorisation holder**

ABCD Laboratories UK Ltd.

Unit 97-98, Indore ghar,

Sunderland Enterprise Park East,

Uttarakhand

**8. Marketing authorisation number(s)**

PL 28278/0035

**9. Date of first authorisation/renewal of the authorisation**

12/02/2020

**10. Date of revision of the text**

12/02/2020