AGOG Pharma Ltd.
(WHO - GMP CERTIFIED - GOVT RECOGNISED EXPORT HOUSE)
Regd. Office & Factory : Plot No. 33, Sector II, The Vasai Taluka Industrial Co-op. Estate Ltd. Gauraipada, Vasai (E), Dist. Thane - 401 208. INDIA.
Tel. : 95250 - 2455801 / 2452714 / 2453525 • Fax : 95250 - 2452074 (0091 - 250 - 2452074) • Email : agog@vsnl.net & agogpharma@rediffmail.com

1.5 PRODUCT INFORMATION

1.5.1 Prescribing Information (Summary of Products Characteristics)

1. NAME OF DRUG PRODUCT

1. Name of drug product

DAPSONE BP 100 MG TABLETS

1.1 (Trade) name of product

AGODAPS-100 TABLETS

1.2 Strength

Each uncoated tablet contains:
DAPSONE BP 100 mg

1.3 Pharmaceutical Dosage Form

Uncoated tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITIONS

2.1 Qualitative Declaration

Each uncoated tablet contains:
DAPSONE BP 100 mg

2.2 Quantitative Declaration

Ingredients	Specification	Label Claim	Qty. / Tab.
ACTIVE			
Dapsone	BP	100 mg	102.00 mg
INACTIVE			
2. Maize Starch	BP	-	26.40 mg
3. Lactose	BP	-	38.00 mg
4. Methyl paraben sodium	BP	-	0.200 mg
5. Propyl paraben sodium	BP	-	0.020 mg
6. Sodium starch glycolate	BP	-	5.000 mg
7. Cross carmellose sodium	BP	-	3.000 mg
8. Colloidal Silicon Dioxide	BP	-	2.000 mg
9. Talcum	BP	-	4.000 mg
10. Magnesium stearate	BP	-	2.000 mg

BP = British Pharmacopoeia.

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3. PHARMACEUTICAL DOSAGE FORM

Uncoated tablets

White, circular, uncoated tablet having a breakline on one side and other side is plain of each tablet.

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4. CLINICAL PARTICULARS

4.1 Therapeutic indications

1) As part of a multi-drug regimen in the treatment of all forms of leprosy.

2) Treatment of dermatitis herpetiformis and other dermatoses.

3) Prophylaxis of malaria in combination with pyrimethamine.

4) Prophylaxis of Pneumocystis carinii pneumonia in immunodeficient subjects, especially AIDS patients.

4.2 Posology and method of administration

Posology

Adults and children over 12 years:

Multibacillary leprosy (3-drug regimen): 100mg daily for at least two years.

Paucibacillary leprosy (2-drug regimen): 100mg daily for at least six months.

Malaria prophylaxis: 100mg weekly with 12.5mg pyrimethamine.

Dermatitis herpetiformis: Initially 50mg daily, gradually increased to 300mg daily if required. Once lesions have begun to subside, the dose should be reduced to a minimum as soon as possible, usually 25-50mg daily, which may be continued for a number of years. Maintenance dosage can often be reduced in patients receiving a gluten-free diet.

Pneumocystis carinii pneumonia: In combination with trimethoprim, 50-100mg daily; 100mg twice weekly or 200mg once weekly.

Children 6-12 years:

Multibacillary leprosy (3-drug regimen): 50mg daily for at least two years.

Paucibacillary leprosy (2-drug regimen): 50mg daily for at least six months.

Elderly: Dosage should be reduced in the elderly where there is an impairment of hepatic function.

Method of Administration

For oral administration.

4.3 Contraindications

Known hypersensitivity to sulfonamides, sulfones, or any of the excipients; severe anaemia; porphyria; severe glucose-6-phosphate dehydrogenase deficiency.

Dapsone contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactose deficiency or glucose-galactose malabsorption should not take this medicine.

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4.4 Special warnings and precautions for use

Dapsone should be used with caution in patients with cardiac or pulmonary disease.

It is recommended that regular blood counts be performed during treatment with dapsone. Patients deficient in glucose-6-phosphate dehydrogenase, or methaemoglobin reductase, or with haemoglobin M are more susceptible to the haemolytic effects of dapsone.

Dapsone should be used with caution in anaemia. Severe anaemia should be treated before starting Dapsone.

4.5 Interaction with other medicinal products and other forms of interaction

Excretion of dapsone is reduced and plasma concentrations are increased by concurrent administration of probenecid. Rifampicin has been reported to increase the plasma clearance of dapsone.

Increased dapsone and trimethoprim concentrations have been reported following concurrent administration in AIDS patients.

4.6 Pregnancy and lactation

It is now generally considered that the benefits of dapsone in the treatment of leprosy outweigh any potential risk to the pregnant patient. Some leprologists recommend 5mg folic acid daily for leprosy patients receiving dapsone during pregnancy.

Dapsone diffuses into breast milk and there has been a report of haemolytic anaemia in a breast fed infant. While some feel that dapsone should not be used in lactating mothers, in general treatment for leprosy is continued in such patients.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Dapsone should be discontinued or reduced in dosage if severe lepra reactions affecting the eyes or nerve trunks occur.

Varying degrees of dose-related haemolysis and methaemoglobinaemia are the most frequently reported adverse effects of dapsone and occur in most subjects given more than 200mg daily; doses of up to 100mg daily do not cause significant haemolysis but subjects deficient in glucose-6-phosphate dehydrogenase are affected by doses above about 50mg daily. Hypoalbuminaemia and haemolytic anaemia has also been reported.

Although agranulocytosis has been reported rarely with dapsone when used alone, reports have been more common when dapsone has been used with other agents in the prophylaxis of malaria.

Rash, photosensitivity and pruritis may develop. Serious cutaneous hypersensitivity reactions occur rarely and include maculopapular rash, exfoliative dermatitis, toxic

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epidermal necrolysis, and Stevens-Johnson syndrome. Fixed drug eruptions have occurred.

A "dapsone syndrome" may occur after 3-6 weeks therapy; symptoms include rash, which is always present, fever, and eosinophilia. If dapsone is not stopped immediately, the syndrome may progress to exfoliative dermatitis, hepatitis, albuminuria and psychosis. Deaths have been recorded. Most patients require steroid therapy for several weeks, possibly due to the prolonged elimination time of the drug.

Peripheral neuropathy with motor loss has been reported in patients on dapsone for dermatological conditions. Peripheral neuropathy may occur as part of leprosy reaction states and it is not an indication to discontinue dapsone. Other adverse effects occur infrequently and include anorexia, headache, hepatitis, jaundice, changes in liver function tests, insomnia, nausea, psychosis, tachycardia and vomiting.

4.9 Overdose

Symptoms are hypoxia, methaemoglobinaemia and haemolytic anaemia.

In severe overdosage the stomach should be emptied by gastric lavage. Administration of activated charcoal by mouth has been shown to enhance the elimination of dapsone and its monoacetyl metabolite. Methaemoglobinaemia has been treated with slow IV injections of methylene blue 1-2mg/kg bodyweight, repeated after one hour if necessary. Methylene blue should not be administered to patients with glucose-6-phosphate dehydrogenase deficiency since it will not be effective. Haemolysis has been treated by infusion of concentrated human red blood cells to replace the damaged cells.

Supportive therapy includes oxygen to alleviate hypoxia, and administration of fluids to maintain renal flow and promote the elimination of dapsone.

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5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmaco-Kinetic Properties

Dapsone is almost completely absorbed from the GI tract with peak plasma concentrations occurring about 2-8 hours after a dose. Steady-state concentrations are not obtained until after at least 8 days of daily administration; doses of 100mg daily provide trough concentrations of 0.5 micrograms/ml. About 50-80% of dapsone in the circulation is bound to plasma proteins and nearly 100% of its monoacetylated metabolite is bound. Dapsone undergoes enterohepatic recycling. It is widely distributed; is present in saliva, breast milk and crosses the placenta. The half-life ranges from 10-80 hours. Dapsone is acetylated to monoacetyldapsone, the major metabolite, and other mono and diacetyl derivatives. Acetylation exhibits genetic polymorphism. Hydroxylation is the other major metabolite pathway resulting in hydroxylamine dapsone which may be responsible for dapsone-associated methaemoglobinaemia and haemolysis. Dapsone is mainly excreted in the urine, only 20% of a dose as unchanged drug.

5.2 Pharmaco-dynamic properties

Dapsone is a sulfone active against a wide range of bacteria.

Dapsone's mechanism of action is probably similar to that of the sulfonamides which involves inhibition of folic acid synthesis in susceptible organisms. It is usually considered to be bacteriostatic against *M leprae* although it may also possess weak bactericidal activity. It is also active against *Plasmodium* and *Pneumocystis carinii*. As with sulfonamides, antibacterial activity is inhibited by *p*-aminobenzoic acid.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

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6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Maize Starch	BP	26.40 mg
Lactose	BP	38.00 mg
Methyl paraben sodium	BP	0.200 mg
Propyl paraben sodium	BP	0.020 mg
Sodium starch glycolate	BP	5.000 mg
Cross carmellose sodium	BP	3.000 mg
Colloidal Silicon Dioxide	BP	2.000 mg
Talcum	BP	4.000 mg
Magnesium stearate	BP	2.000 mg

6.2 Incompatibilities

None reported

6.3 Shelf-Life

36 months from the date of manufacture.

6.4 Special Precautions for Storage

Do not store above 30°C. Protect from light.

6.5 Nature and Contents of Container

Blister pack of 10X10 tablets.
Material of construction of primary packaging material is attached.

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Date : 23/09/2024
Director of the manufacturer
(Signature, Full name, Stamp)

Date :23/09/2024
Director of applicant company
(Signature, Full name, Stamp)