



1.5.3 Patient Information Leaflet (PIL)

Package leaflet : Information for the user

AGODAPS-100 TABLETS

(Dapsone Tablets BP 100 mg)

Read all of this leaflet carefully before taking this medicine

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your health care provider or pharmacist
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptom are the same as yours.
- If you get any side effect, talk to your doctor or pharmacist. This includes any possible side effect not listed in this leaflet

What is in this leaflet?

1. What Agodaps-100 tablets are and what they are used for
2. What you need to know before you take Agodaps-100 tablets
3. How to take Agodaps-100 tablets
4. Possible side effects
5. How to store Agodaps-100 tablets
6. Further information

1. What Agodaps-100 tablets are and what they are used for

Dapsone belong to group of antibacterial medicines called sulfones. It is an antibacterial drug that works by stopping the production of folic acid in certain bacteria, therefore preventing them from growing.

Agodaps-100 is used for the treatment of

- Leprosy (Hansen's disease)
- Dermatitis herpetiformis
- Acne vulgaris

2. What do you need to know before you take Agodaps-100 Tablets

Do not take this medicine if

- You are allergic (hypersensitive) to Dapsone, sulfones or any their sulfonamides
- You have a genetic enzyme deficiency called Glucose-6-Phosphate Dehydrogenase deficiency (G6PD Deficiency-a hereditary condition in which red blood cells break down when the body is exposed to certain medicines or infections)
- If you have Porphyria (a genetic or inherited disorder of the red blood pigment, haemoglobin)
- You suffer from severe anaemia
- If you suffer from Methemoglobin Reductase deficiency

Take special care with Agodaps-100 tablets

- If you suffer from heart problems
- If you have lung problems
- If you suffer from liver problems
- If you have blood disorders

Taking with other medicines

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines, including medicines obtained without a prescription.

Tell your doctor if you are taking any of these following medicines

- Probenecid (to treat gouty arthritis)
- Nitrofurantoin (to treat urinary tract infections)
- Rifampicin (to treat certain bacterial infections)
- Primaquine, Pyrimethamine (to treat and prevent malaria)
- Folic Acid (supplement to treat folate deficiency)
- Mefloquine (to treat malaria)
- Nefazodone (to treat depression)
- Apalutamide (to treat prostate cancer)
- Trimethoprim (to treat bacterial infections)
- Saquinavir (to treat or prevent HIV/AIDS)
- Co-Trimoxazole (to treat bacterial infections)
- Lansoprazole (to treat and prevent stomach ulcers)

Taking Agodaps-100 tablet with food and drink

Dapsone tablets can be taken before, during or after meals but it is advised to take it at a fixed time.

Pregnancy and breast-feeding

Talk to your doctor or pharmacist before taking this medicine if you are pregnant or think you might be pregnant or breast-feeding or are planning to have a baby.

Driving and using machine

Use caution while driving or doing anything that requires mental alertness as Agodaps-100

may cause blurred vision or dizziness.

3. How to take Agodaps-100 tablets

Always take Agodaps-100 tablets exactly as your doctor or health care provider has told you. You should check with your doctor or health care provider if you are not sure. Swallow the tablets whole with a glass of water.

Unless otherwise prescribed by the doctor, the recommended doses are:

Adults and Children (aged over 12 years):

For Dermatitis herpetiformis : Initially 50 mg daily which may be gradually increased to 300 mg daily and then reduced back down to the usual maintenance dose of 25-50 mg daily.

For Leprosy: 100 mg daily for at least six months

Children (Aged between 6-12 years): The dose is based on the body weight of the child. Talk to your doctor or healthcare provider for an appropriate dosage for your child.

Children (Aged less than 6 years): The safety and efficacy of Agodaps-100 in children aged less than 6 years has not been established.

Elderly: If you have liver problems, the doctor may give you a lower dose. Consult your doctor or pharmacist if you have further questions on the dosage of this medicine.

If you take more Agodaps-100 tablet than you should

If you have accidentally taken more tablets in one day than your doctor has told you to, contact your doctor or go to nearest hospital emergency department immediately.

If you forget to take Agodaps-100 tablet

Do not take a double dose to make up for a forgotten dose.

If you stop taking Agodaps-100 tablet

Do not stop taking your tablets, even if you feel better. It is important to take the tablets as long as the doctor has told you to, otherwise your medicine might not work properly.

Agodaps-100 contains Lactose

Lactose is a type of sugar. If you have been told by a doctor that you cannot tolerate sugar, talk to your doctor before taking this medicine.

4. Possible side effect

Like all medicines, Agodaps-100 tablets can cause side effects, although not everybody gets them.

Very Common side effect: Numbness or Tingling , Nausea and Vomiting.

Common side effect: Headache, Blurred Vision, Ringing in Ears

Uncommon side effect: Fast heart beat (Tachycardia), Yellowing of the skin or eyes (Jaundice)

Rare side effect: Blue Lips, Mouth and Finger Nails, Low Blood Cell Counts

If any of the side effect gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or health care provider.

5. How to store Agodaps-100 tablet

Keep out of the reach and sight of children.

Do not store above 30°C.

Protect from light.

Store in the original carton.

Do not use this medicine after the expiry date stated on the container (MM/YYYY)

6. Further Information

What Agodaps-100 tablet contains:

Each uncoated tablet contains:

Dapsone BP 100 mg

Excipients q.s.

This product contains 'Lactose'.

What Agodaps-100 tablet looks like and contents of the pack

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

Shelf life: 36 months

Packing/Pack size: Blister Pack of 10 x 10 Tablets
Blister Pack of 100 x 10 Tablets
Jar Pack of 1000 Tablets
Pack of 28 Tablets

Distribution Category: Prescription Only Medicine (POM)

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 Marketing Authorisation Holder and Manufacturer
AGOG PHARMA LTD.
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165 mm

80 mm