Summary of Product Characteristics (SmPC)

NEVAX®

SULPHADOXINE 500MG / PYRIMETHAMINE 25MG

This information is intended for use by health professional

1. Name of the medicinal product

NEVAX® caplet

2. Qualitative and quantitative composition

Each uncoated tablet contains

Sulfadoxine .....500 mg

Pyrimethamine .....25 mg

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Uncoated Caplet.

4. Clinical particulars

4.1 Therapeutic indications.

Nevax® is indicated in Intermittent prevention of malaria in pregnant women during the 2nd and 3rd trimesters of pregnancy. Also indicated in the Treatment of acute, uncomplicated P. falciparum in combination with artesunate is recommended by WHO.

4.2 Posology and method of administration

Pregnancy

The usual dose is 3 tablets of NEVAX® which corresponds to 75 mg of pyrimethamine and 1500mg of sulfadoxine.

Doses should be given at each planned visit to your health care provider, from the beginning of the second trimester of your pregnancy until delivery. The doses of NEVAX® are given at least one month apart.

Children

The correct dosage of NEVAX® depends on the weight of your child. Each dose will be at least a month apart.

Adults	2 to 3 tablets taken as a single dose
Pediatric patients (> 2months to 18	The dosage for treatment should be based on body weight:

years)	
Weight (kg)	Number of tablets taken as a single dose
> 45	3
31 - 45	2
21- 30	1 and half tablets
11-20	1
5-10	Half tablet
For children weighing less than 5kg, appropriate dose adjustments cannot be made and your health care provider will choose another formulation.	

Dosage for Prevention of Malaria

	Once weekly	Once Every 2 weeks
Adults	1 tablet	2 tablets
Pediatric patients (> 2months to 18 years)	The dosage for treatment should be based on body weight:	
Weight (kg)	Number of tablets taken once weekly	
> 45	1 1/2	
31 - 45	1	
22- 30	3/4	
11-20	1/2	
5-10	1/4	
For children weighing less than 5kg, appropriate dose adjustments cannot be made and your health care provider will choose another formulation.		

Method of administration

Nevax ® is for oral use.

NEVAX® is a tablet to be taken by mouth either on an empty stomach or with food. Your health care provider will prepare the dose andgive it to you or your child.

For use in infants:

The tablet should be divided into half and the half tablet crushed.

The crushed half tablet can be added to a small amount of semi-solid food and given to the child straight away.

Alternatively, around 10m l of clean drinking water should be taken in a small and clean cup orglass, and the crushed half of the tablet added.

The cup should be gently swirled until the half tablet disperses and the entire mixture is given to thechild to drink straight away.

The container should be rinsed with an additional 5-10 mL of water, and given to the child to drinkto ensure the whole dose is taken.

If your child vomits the dose within 30 minutes, they should be allowed to rest for 30 minutes and then begiven a second half-tablet. If they vomit a second time, no further dose should be attempted.

If you have any questions on the use of this medicine, ask your health care provider.

If you or child take more NEVAX® than you should

Because this medicine is normally given under the supervision of your health care provider, you or yourchild should be given the right dose. If you think you or your child have taken too much NEVAX®, tell your health care provider.

If you forget to take NEVAX® or to give it to your child at the right time

You and your child should take the medicines at the right time to have the best chance of preventing malaria.

Missing a dose reduces protection but you or your child can still receive the next dose.

4.3 Contraindications

Nevax® is contraindicated in the following cases:

• Known hypersensitivity to sulfonamides or pyrimethamine or any other ingredient

• Severe hepatic or renal insufficiencies (except when no alternative treatment is available).

• History of hepatitis due to sulfadoxine or pyrimethamine intake

4.4 Special warnings and precautions for use

Skin reactions, blood disorders or marrow failure (angina, oral ulcers) require immediate and definitive discontinuation of the treatment (see section 4.8).

Due to accumulated risk of bone marrow toxicity, Nevax® should not be associated with other anti-folinic nor drugs containing pyrimethamine.

4.5 Interaction with other medicinal products and other forms of interaction

Interactions related to pyrimethamine Special precautions with the following drugs + Didanosine Decrease in pyrimethamine digestive absorption due to an increased stomach pH (antacid contained in the DDI tablet). Whenever possible, a 2 hours interval should be respected between pyrimethamine and didanosine administrations. + Trimethoprim (alone or in association) Megaloblastic anaemia, particularly when both substances are administered at a high dosage (folic acid deficiency due to the association of two 2-4 diaminopyrimidine compounds). Frequent haemogram monitoring and association with a folinic acid treatment (regular IM or IV injections). + Zidovudine Increase in haematologic toxicity by dihydrofolate

reductase inhibition. Frequent haemogram monitoring is required. Interactions related to sulfadoxine Special precautions with the following drugs + Methotrexate Increase in haematologic methotrexate toxicity (increase in free methotrexate plasma concentration due to displacement from plasmatic proteins by some sulfonamides). Level of free methotrexate should be monitored and dosage should be adapted during and after treatment with Nevax®

4.6 Fertility, pregnancy and lactation

Pregnancy The use during pregnancy involves a specific prenatal monitoring. Lactation Both pyrimethamine and sulfadoxine pass into breast milk, this medicine must therefore not be used during breastfeeding.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

• Rare gastro-intestinal disorders • Signs of skin allergic reactions: rash, itching, exceptionally severe reactions, including Stevens-Johnson and Lyell syndromes. • Blood disorders (megaloblastic anaemia, leukopenia, agranulocytosis, thrombopenia), which require treatment discontinuation and a possible IM or IV folinic acid administration. • Renal disorders: some cases of renal function alterations have been reported with sulfonamides. • Hepatic function disorders: rare cases of transaminase level increase and hepatitis have been reported Skin reactions or blood disorders require an immediate and definitive discontinuation of the treatment

4.9 Overdose

High doses of pyrimethamine are potentially fatal. Prominent symptoms of overdose are anorexia, vomiting and seizures. Induction of emesis or gastric lavage is of value if undertaken within a few hours after ingestion. Convulsions may be controlled with parenteral diazepam. Blood dyscrasia that may be induced by large doses of pyrimethamine should be treated with folinic acid.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Antimalarial Combining An Antifolinic Sulfonamide And An Antifolinic Diaminopyrimidine. (P: Parasitology) The association has a schizonticide activity by inhibiting the metabolism of folic acid (it blocks the dihydrofolate reductase) needed by the haematozoa to grow. Nevax may also be effective against strains of P. falciparum resistant to other antimalarial drugs. However, some trains of Plasmodium falciparum are resistant to the association. The efficacy of sulfonamides against Plasmodium ovale and Plasmodium vivax is weak.

5.2 Pharmacokinetic properties

Both pyrimethamine and sulfadoxine are well absorbed after oral administration. Half-life is about 4 days for pyrimethamine and about 8 days for sulfadoxine. Both pyrimethamine and sulfadoxine are excreted mostly via the kidneys; pyrimethamine is partly eliminated as metabolites.

5.3 Preclinical safety data

Not available

6. Pharmaceutical particulars

6.1 List of excipients

Tablet core:

Lactose Monohydrate, Corn starch, Povidone, Magnesium stearate.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

5 years

6.4 Special precautions for storage

Store in the original package to protect from moisture.

Do not store above 30°C.

6.5 Nature and contents of container

Caplets are packed in Aluminum/Aluminum (Alu-Alu) blisters of 3 caplets per blister. 1 of such blister packed in an inner packet accompanied by a patient information leaflet.

6.6 Special precautions for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements.

7. Marketing authorisation holder

NEMEL Pharmaceuticals Limited

Plot 35 Emene Industrial Layout

Enugu, Nigeria.

8. Marketing authorisation number(s)

A11-1002.

9. Date of first authorisation/renewal of the authorisation

28th November,2019.

10. Date of revision of the text

29th November, 2024.