Summary of Product Characteristics

P-ALAXIN Tablets

Dihydroartemisinin 40 mg & Piperaquine 320 mg Tablets

1. NAME OF THE MEDICINAL PRODUCT

P-ALAXIN Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Each film coated tablet contains

Dihydroartemisinin	40 mg
Piperaquine Phosphate	320 mg

Excipients: q.s.
Colour: Permissible

3. PHARMACEUTICAL FORM:

Oral tablet
Blue circular biconvex, film coated tablets having "BG" embossed on one side and brealine on other side of each tablet.

4. CLINICAL PARTICULARS:

4.1 Therapeutic Indications

Treatment of clinical attacks of Malaria caused by P. falciparum, P. Vivax and P. malariae

4.2 Posology and Method of Administration:

Oral Administration
Patient should follow doctor's instruction. The recommended dosages are in the following table.

Weight in Kg	**11 to < 17 kg**	**17 to < 25 kg**	**25 to < 36 kg**	**36 to < 60 kg**	**60 to < 80 kg**	**> 80 kg**
Day 1	1 Tablet	1.5 Tablets	2 Tablets	3 Tablets	4 Tablets	5 Tablets
Day 2	1 Tablet	1.5 Tablets	2 Tablets	3 Tablets	4 Tablets	5 Tablets
Day 3	1 Tablet	1.5 Tablets	2 Tablets	3 Tablets	4 Tablets	5 Tablets
Total	3 Tablets	4.5 Tablets	6 Tablets	9 Tablets	12 Tablets	15 Tablets

- 3 day treatment regimen with once a day dosing.
- No dosage adjustment is required in pregnant woman.
- Avoid for patients who are on medications that prolong QT intervals.
- High fat meals should be avoided during the treatment.
- In case patient vomits the dose after half an hour, repeat half the administered dosage immediately.
- In case of vomiting after repeat dose, clinician should change the medication.

4.3 Contraindications:

P-ALAXIN is contraindicated in patients hypersensitive to Dihydroartemisinin, Piperaquine phosphate, any of its derivatives or other ingredients of the product.
The product is not recommended for use in women during the first 3 months of pregnancy.

4.4 Special warnings and Precautions for use:
The specified dosage should not be exceeded.
No other precautions are mentioned for this product

4.5 Interaction with other medicinal products and other forms of interactions
Concomitant administration of mefloquine and dihydroartemisinin leads to a modest increase in mefloquine absorption rate

4.6 Pregnancy and Lactation:
The World Health Organization currently advises against the use of artemisinins in the first trimester of pregnancy, unless in a lifesaving situation. In the second and third trimesters of pregnancy, artemisinin and its derivatives are not recommended unless alternative drug treatments are unsuitable.
There are no established results for the safe use of Dihydroartemisinin in lactating mothers. Since many drugs are excreted in human breast milk, P-ALAXIN should be used in lactating mothers only if clearly required and the advantages outweigh the risk to infants

4.7 Effects on ability to drive and use machines
Effects are unlikely.

4.8 Undesirable effects
Nausea or vomiting may occur occasionally with incidence of less than 6%.
No noticeable side effect of Dihydroartemisinin is reported. The Dihydroartemisinin would, for certain individuals, bring effects of greater or lesser severity, for example, a reversible reduction in reticulocyte counts.
Possible side-effect of PQP includes mild dizziness, vertigo, headache, nausea, vomiting and abdominal discomfort. Reversible leucopenia was infrequently reported; dyspnea and palpitations were also reported but not further specified.

4.9 Overdose
Cases of overdose are not known. Acute overdosage should be treated symptomatically.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
P-ALAXIN is a combination of 2 ingredients Dihydroartemisinin & Piperaquine phosphate
Dihydroartemisinin:
Dihydroartemisinin mainly interferes with the membrane structures of trophozoites (erythrocytic asexual forms), i.e. whorled food vacuole membrane, distended mitochondria, swollen nuclear membranes, dissociation of ribosomes from endoplasmic reticulum leading to cytoplasmic vacuolization and autophagocytosis. In addition, biochemical depression of protein synthesis and nucleic acid synthesis are exhibited.
Piperaquine Phosphate:
PQP interferes with physiological function of the food vacuole membrane of the trophozoites leading to autophagocytosis of the parasites. It has no marked effect on the ring forms, immature or mature schizonts and the male or female gametocytes.

5.2 Pharmacokinetic properties

Dihydroartemisinin:

Upon oral administration Dihydroartemisin is rapidly absorbed and maximum blood concentration attained 1 hour afterwards, with a half-life of about 4 hours. It is widely distributed in the liver, kidneys and bile. Approximately 80% is excreted through the urine and feces within 24 hrs after administration. It is metabolized to two inactive metabolites, deoxydihydroartemisinin and dihydroxydihydroartemisinin.

Piperaquine phosphate:

Upon oral administration about 80-90% is absorbed within 24 hrs. It is widely distributed in the body mainly in the liver, kidneys, lungs and spleen. About 25% of the total dose is partitioned in the liver within 8 hrs of intake. Elimination is very slow with the half life of about 9.4 days. It is excreted through bile by hepatoenteral circulation.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Pregelatinised Starch, Maltodextrin, Croscarmellose Sodium, Magnesium Stearate, wincoat WT-01215 Blue, Isopropyl Alcohol, dichloromethane, Purified talc.

6.2 Incompatibilities

None known.

6.3 Shelf Life

3 Years

6.4 Special warnings for storage

Store in a dry place, below 30^{o}C. Protect from light.

6.5 Nature and contents of the package

9 Tablets packed in Aluminium and PVC blister, one such blister packed in a carton along with a leaflet.

6.6 Special precautions for disposal and other handling

For the treatment of children and infants, the 9-tablets pack should be prescribed. The prescriber and pharmacist should instruct the parent or care giver on the posology for their child and that a variable number of tablets (depending on the child's body weight) will be requested for the full treatment. Therefore, the whole pack may not be used. After successful treatment the remaining tablets should be discarded or returned to the pharmacist.

7. MARKETING AUTHORISATION HOLDER

Bliss GVS Pharma Ltd., Saki Vihar Road, Andheri (East), Mumbai - 400 072.

8. DATE OF REVISION OF THE TEXT

July 2015