

## Patient Information Leaflet

**P-ALAXIN DISPERSIBLE Dispersible** (Dihydroartemisinin 20/40 mg & Piperaquine 160/320 mg Tablets)

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have questions about the medicine, ask your health care provider.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness seem to be the same as yours.
- If you get any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. See section 4.

### What is in this leaflet

1. What **P-ALAXIN DISPERSIBLE Dispersible** is and what it is used for
2. What you need to know before you take **P-ALAXIN DISPERSIBLE Dispersible**
3. How to take **P-ALAXIN DISPERSIBLE Dispersible**
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#### 1. What **P-ALAXIN DISPERSIBLE Dispersible** is and what it is used for

**P-ALAXIN DISPERSIBLE Dispersible** contains the active substances piperaquine phosphate and dihydroartemisinin. It is used to treat uncomplicated malaria when use of a medicine given by mouth is appropriate.

Malaria is caused by infection with a parasite called *Plasmodium*, spread by the bite of an infected mosquito. There are different types of *Plasmodium* parasite. **P-ALAXIN DISPERSIBLE Dispersible** kills all types of *Plasmodium* parasite.

#### 2. What you need to know before you take **P-ALAXIN DISPERSIBLE**

**Do not take P-ALAXIN DISPERSIBLE if you or your child:**

- is allergic (hypersensitive) to the active substances, piperaquine tetraphosphate or dihydroartemisinin, or to any of the other ingredients of **P-ALAXIN DISPERSIBLE** (see section 6 for a list of these);
- has a severe type of malaria infection which has affected parts of the body such as the brain, lungs or kidneys;

- has a heart condition, such as changes to the rhythm or rate of the heartbeat, or heart disease;
- knows that any member of your family (parents, grandparents, brothers or sisters) died suddenly due to a heart problem or was born with heart problems;
- suffers from changes to the levels of salts in the body (electrolyte imbalances);
- is taking other medicines that can have an effect on heart rhythm, such as:
  - quinidine, disopyramide, procainamide, amiodarone, dofetilide, ibutilide, hydroquinidine or sotalol;
  - medicines used to treat depression;
  - medicines used to treat mental health problems such as phenothiazines, sertindole, sultopride, chlorpromazine, haloperidol, mesoridazine, pimozide, or thioridazine;
  - medicines used to treat infections. These include some of the types of medicines used to treat bacterial infections (macrolides [such as erythromycin or clarithromycin] and fluoroquinolones [such as moxifloxacin and sparfloxacin]) or fungal infections (including fluconazole and imidazole) as well as pentamidine (used to treat a specific type of pneumonia) and saquinavir (for treatment of HIV);
  - antihistamines used to treat allergies or inflammation such as terfenadine, astemizole or mizolastine;
  - certain medicines used to treat stomach problems such as cisapride, domperidone or droperidol;
  - other medicines such as vinca alkaloids and arsenic trioxide (used to treat certain cancers), bepridil (used to treat angina), diphemanil (used to treat stomach disturbances), levomethadyl and methadone (used to treat drug addiction), and probucol (used to treat high blood cholesterol levels).
- has recently (for example within about one month) been treated for malaria with certain medicines or has taken certain medicines to prevent malaria. These medicines include: mefloquine, halofantrine, lumefantrine, chloroquine or quinine.

If any of the above applies to you or your child or if you are unsure, tell your health care provider before taking or giving P-ALAXIN DISPERSIBLE .

### **Take special care with P-ALAXIN DISPERSIBLE**

Check with your health care provider before taking this medicine if you or your child:

- has liver or kidney problems;
- is taking or has taken any other medicines for the treatment of malaria (other than those mentioned above);

- is pregnant or breastfeeding (see below);
- is female, elderly (over 65 years) or vomiting;
- is taking certain other medicines which could interact with P-ALAXIN DISPERSIBLE
- Examples are listed in the section “Taking other medicines”.

If you are not sure about any of the above, please ask your health care provider.

### **Use in children**

P-ALAXIN DISPERSIBLE can be used in infants and children. The dose depends on the weight of the child. Your health care provider will tell you how many tablets of P-ALAXIN DISPERSIBLE to give your child.

### **Taking other medicines**

Please tell your health care provider if you or your child is taking or has recently taken any other medicines, including medicines obtained without a prescription. Some medicines can affect the way P-ALAXIN DISPERSIBLE works and your health care provider may decide that P-ALAXIN DISPERSIBLE is not suitable or that extra checks are needed while you or your child is taking certain medicines which may interact with P-ALAXIN DISPERSIBLE . Examples are listed below (but there are several others):

- some medicines used to treat high cholesterol in the blood (such as atorvastatin, lovastatin, simvastatin);
- medicines used to treat high blood pressure and heart problems (such as diltiazem, nifedipine, nitrendipine, verapamil, felodipine, amlodipine);
- some medicines used to treat HIV (antiretroviral medicinal products): protease inhibitors (such as amprenavir, atazanavir, indinavir, nelfinavir, ritonavir), non-nucleoside reverse transcriptase inhibitors (such as efavirenz, nevirapine);
- some medicines used to treat microbial infections (such as telithromycin, rifampicin, dapson);
- medicines used to help you fall asleep: benzodiazepines (such as midazolam, triazolam, diazepam, alprazolam), zaleplon, zolpidem;
- medicines used to prevent/treat epileptic seizures (fits): barbiturates (such as phenobarbital), carbamazepine or phenytoin;
- medicines used after organ transplantation and in autoimmune diseases (such as cyclosporin, tacrolimus);
- sex hormones, including those contained in hormonal contraceptives (such as gestodene, progesterone, estradiol), testosterone;
- glucocorticoids (hydrocortisone, dexamethasone);
- omeprazole (used to treat diseases related to gastric acid production);

- paracetamol (used to treat pain and fever);
- theophylline (used to make breathing easier);
- nefazodone (used to treat depression);
- aprepitant (used to treat nausea); - some gases (such as enflurane, halothane and isoflurane) used to give a general anaesthetic.

### **Taking P-ALAXIN DISPERSIBLE without food and drink**

You should take P-ALAXIN DISPERSIBLE with water only.

You should take this medicine on an empty stomach. You should take each dose no less than 3 hours after the last food intake, and no food should be taken within 3 hours after each dose of P-ALAXIN DISPERSIBLE . You can drink water at any time. You should not take P-ALAXIN DISPERSIBLE with grapefruit juice due to possible interactions.

### **Pregnancy and breast-feeding**

Tell your health care provider if you are pregnant, think you may be pregnant or become pregnant, or if you are breast-feeding.

P-ALAXIN DISPERSIBLE must not be used in pregnancy if your health care provider can give you an alternative medicine. If you receive P-ALAXIN DISPERSIBLE while pregnant, please note that a pregnancy registry is in place to monitor the pregnancy outcomes.

You should not breast-feed your baby while taking this medicine.

If you are taking folate supplements to prevent possible neural tube birth defects, you can continue taking them at the same time as P-ALAXIN DISPERSIBLE

Ask your health care provider for advice before taking any medicine during pregnancy or breast-feeding.

### **Driving and using machines**

You can drive or use machines after taking P-ALAXIN DISPERSIBLE

### 3. How to take P-ALAXIN DISPERSIBLE

Always take P-ALAXIN DISPERSIBLE exactly as your doctor has told you to. You should check with your health care provider if you are not sure.

Take this medicine with water and on an empty stomach. You or your child should take each dose at least 3 hours after your last meal. You should also avoid eating until 3 hours after taking P-ALAXIN DISPERSIBLE . You can drink water at any time.

If the tablets are difficult to swallow, you can crush and mix them with water; drink the mixture immediately.

A course of P-ALAXIN DISPERSIBLE lasts 3 consecutive days. Take one dose on each day.

You should try to take the dose at about the same time on each of the three days.

The daily dose depends on the patient's **body weight**. Your health care provider should have prescribed a dose that is appropriate for your weight or your child's weight as follows:

<b>Body weight</b>	<b>Dose</b>
5 kg to less than 8 kg	1 tablet per day for 3 days
8 kg to less than 11 kg	1½ tablets per day for 3 days
11 kg to less than 17 kg	2 tablets per day for 3 days
17 kg to less than 25 kg	3 tablets per day for 3 days

If your weight or your child's weight is less than 25 kg, you should use a lower strength tablet.

If you cannot swallow the tablet, break or crush the tablet (by using the tip of a spoon) and add it to a small amount of liquid or semi-solid food. Swallow all the mixture immediately.

#### **Vomiting when taking this medicine:**

If this happens within:

- 30 minutes of taking P-ALAXIN DISPERSIBLE , the whole dose must be taken again.
- 31-60 minutes, half the dose must be taken again.

If you or your child vomit also the second dose, do not take or give your child another dose. Contact your health care provider urgently to obtain an alternative treatment for malaria.

#### **Taking this medicine, if the malaria infection returns:**

- If you or your child gets another attack of malaria you may take a second course of P-ALAXIN DISPERSIBLE within one year if your health care provider thinks this is a suitable treatment. You or your child must not take more than two courses within one year. If this happens, talk to your health care provider. You or your child should not take a second course of P-ALAXIN DISPERSIBLE within 2 months of the first course.

- If you or your child is infected more than twice in a year, your health care provider will prescribe an alternative treatment.

**If you or your child takes more P-ALAXIN DISPERSIBLE than you should:**

If you or your child takes more than the recommended dose, tell your health care provider. Your health care provider may suggest special monitoring for you or your child because doses higher than those recommended may have an unwanted, severe effect on your heart

**If you or your child forgets to take P-ALAXIN DISPERSIBLE :**

If you or your child forgets to take the second dose of P-ALAXIN DISPERSIBLE at the right time, take it as soon as you remember. Then take the third (last) dose approximately 24 hours after the second dose. If you or your child forgets to take the third (last) dose at the right time, take it as soon as you remember.

Never take more than one dose on the same day to make up for a missed dose. Check with your health care provider if you are not sure.

**If you or your child stops taking P-ALAXIN DISPERSIBLE**

For the medicine to work effectively, you or your child should take the tablets as instructed and should complete the 3 days course of treatment. If you or your child is not able to do this, talk to your health care provider.

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

**4. Possible side effects**

Like all medicines, P-ALAXIN DISPERSIBLE can cause side effects, although not everybody gets them. Most of the side effects are not severe and normally disappear within a few days or weeks after treatment.

If you or your child gets a rash, swelling of the face, lips, tongue or throat with difficulty in swallowing or breathing, these may be signs of an allergic reaction. Tell your health care provider immediately or go immediately to the emergency department of your nearest hospital, taking this leaflet with you.

**A heart problem called QT prolongation can occur in some people who take P-ALAXIN DISPERSIBLE , particularly those who have a heart condition or are taking another medication that can cause the same problem. Tell your health care provider if you or your child have a heart condition or are taking any medications. Your health care provider can advise you about using P-ALAXIN DISPERSIBLE .**

**If you notice anything different about your or your child's heart rhythm or have symptoms (such as palpitations or irregular heart beat) you should contact your health care provider as soon as possible and before the next dose is due.**

**Side effects in adults:**

*Common (affecting less than 1 in 10 patients but more than 1 in 100):*

Low red blood cell counts (anaemia), headache, heart rhythm disturbances (ECG changes or noticing unusually fast heart beats or palpitations), fever, general weakness.

*Uncommon (affecting less than 1 in 100 patients but more than 1 in 1000):*

Influenza, respiratory infections, poor appetite or loss of appetite, dizziness, convulsions (fits), irregular or slow heart rate, cough, vomiting, abdominal pain, diarrhoea, nausea, inflammation or enlargement of the liver, abnormal liver function tests, itching, pain in the muscles or joints.

**Side effects in children:**

*Very common (affecting more than 1 in 10 patients):*

Influenza, cough, fever.

*Common (affecting less than 1 in 10 patients but more than 1 in 100):*

Respiratory infections, ear infection, low red blood cell counts (anaemia), abnormalities in various types of blood cells (white blood cells and platelets), poor appetite or loss of appetite, eye infection, heart rhythm disturbances (change as in adults, ECG changes), abdominal pain, vomiting, diarrhoea, skin inflammation, rash, general weakness.

*Uncommon (affecting less than 1 in 100 patients but more than 1 in 1000):*

Abnormalities in red blood cells, excessive numbers of platelets, enlargement of some organs (such as liver or spleen), swollen lymph glands, convulsions (fits), headache, abnormal heart sounds (heard by your doctor with a stethoscope), nose bleeds, runny nose, nausea, inflammation of the mouth, inflammation or enlargement of the liver, jaundice, abnormal liver function blood tests, skin itching and inflammation, pain in the joints.

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

**5. How to store P-ALAXIN DISPERSIBLE**

Store in a dry place, below 30°C. Protect from light.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date stated on the label after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines in wastewater or household waste. Ask your health care provider how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What P-ALAXIN DISPERSIBLE contains**

- The active substances are Dihydroartemisinin and piperaquine (as phosphate)
- The other ingredients of P-ALAXIN DISPERSIBLE are excipients:

*Pregelatinised Starch, Microcrystalline cellulose , Crospovidone, Sucralose, Dextrine, Powdarome Strawberry Premium Flavour, Colloidal anhydrous silica, Magnesium Stearate.*

### **What P-ALAXIN DISPERSIBLE looks like and contents of the pack**

#### **P-ALAXIN Dispersible 20/160:**

White to off White coloured, round shaped, beveled edge, flat faced tablet, debossed with “TT” “21” separated with break line on one side and plain on other side.

#### **P-ALAXIN Dispersible 40/320:**

White to off White coloured, round shaped, beveled edge, flat faced tablet, debossed with “TT” “22” separated with break line on one side and plain on other side.

### **Marketing Authorization Holder**

Bliss GVS Pharma Ltd.,

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