

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Diartem[®] IG Adultes

Dihydroartemisinin 120 mg /
Piperazine Phosphate 960 mg

Read all of this leaflet carefully before you start using this medicine

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. What Diartem[®] IG Adultes is and what it is used for
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1. WHAT DIARTEM[®] IG ADULTES IS AND WHAT IT IS USED FOR

Diartem[®] IG Adultes contains the ingredients piperazine tetraphosphate 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. Diartem[®] IG Adultes kills the Plasmodium falciparum parasite. The medicine can be taken by adults and children who weigh 36 kilograms or more.

2. BEFORE YOU OR YOUR CHILD TAKE DIARTEM[®] IG ADULTES

- Do not take Diartem[®] IG Adultes if you or your child:**
- Is allergic (hypersensitive) to the active substances, piperazine or dihydroartemisinin, or to any of the other ingredients of Diartem[®] IG Adultes;
 - Has a severe type of malaria infection which has affected parts of your body such as the brain, lungs or kidneys;
 - Has a heart condition, such as changes to the rhythm or rate of your heart beat, 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 your 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, sertraline, sulopride;
 - 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 doctor or pharmacist before taking or giving Diartem[®] IG Adultes.

Take special care with Diartem[®] IG Adultes

- Check with your doctor or pharmacist before taking this medicine if you or your child:
- Has liver or kidney problems;
 - Has a malaria infection caused by a parasite other than Plasmodium falciparum;
 - 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 cause possible metabolic interactions. Examples are listed in the section "Taking other medicines".
- If you are not sure about any of the above, please ask your doctor or pharmacist.

Use in children

Do not give this medicine to children below 36 kg in weight.

Taking other medicines

- Please tell your doctor or pharmacist 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 Diartem[®] IG Adultes works and your doctor may decide that Diartem[®] IG Adultes is not suitable or that extra checks are needed while you or your child is taking the medicinal products which could cause possible interactions. 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 hypertension and heart problems (such as diltiazem, nifedipine, nitrendipine, verapamil, felodipine, amlodipine);
 - Some medicines used to treat HIV (antiretroviral medicinal products): protease inhibitors (such as ampreviravir, abacavir, didanosine, didanosine, ritonavir), non nucleoside reverse transcriptase inhibitors (such as efavirenz, nevirapine);
 - Some medicines used to treat microbial infections (such as telithromycin, rifampicin, dapsone);
 - Medicines used to help you fall asleep: benzodiazepines (such as midazolam, triazolam, diazepam, alprazolam), zolpidem, zolpidem;
 - Medicines used to prevent/treat epileptic seizures: 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 improve bronchial air flow);
 - Mefazodone (used to treat depression);
 - Aprepitant (used to treat nausea);
 - Some gases (such as enflurane, halothane and isoflurane) used to give a general anaesthetic.

Taking Diartem[®] IG Adultes with food and drink

You should take Diartem[®] IG Adultes tablets 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 Diartem[®] IG Adultes. You can drink water at any time. You should not take Diartem[®] IG Adultes with grapefruit juice due to possible interactions.

Pregnancy and breast-feeding

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

Diartem[®] IG Adultes must not be used in pregnancy if your doctor can give you an alternative medicine. If you receive Diartem[®] IG Adultes 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 Diartem[®] IG Adultes.

Ask your doctor or pharmacist for advice before taking any medicine during pregnancy or breast-feeding.

Driving and using machines

You can drive or use machines after taking Diartem[®] IG Adultes.

3. How to take Diartem[®] IG Adultes

Always take Diartem[®] IG Adultes exactly as your doctor has told you to. You should check with your doctor or pharmacist 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 Diartem[®] IG Adultes. 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 Diartem[®] IG Adultes 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 doctor should have prescribed a dose that is appropriate for your weight or your child's weight as follows:

Weight	Diartem [®] IG Adultes 960/120mg	Total number of tablets for treatment of 3 days
36 to < 75 Kg	1 tablet	3

Diartem[®] IG Adultes tablet is not suitable for weight group other than that mentioned in table. If you weigh more than 100 kg then follow the dose that your doctor has prescribed.

Vomiting when taking this medicine

- If this happens within:
- 30 minutes of taking Diartem[®] IG Adultes, 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 doctor 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 Diartem[®] IG Adultes within one year if your doctor 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 doctor. You or your child should not take a second course of Diartem[®] IG Adultes within 2 months of the first course.
- If you or your child is infected more than twice in a year, your doctor will prescribe an alternative treatment.

If you or your child takes more Diartem[®] IG Adultes tablets than you should
If you or your child takes more than the recommended dose, tell your doctor. Your doctor may suggest special monitoring for you or your child because doses higher than those recommended may have an unwanted, severe effect on your heart (see also section 4).

If you or your child forgets to take Diartem[®] IG Adultes

If you or your child forgets to take the second dose of Diartem[®] IG Adultes 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 doctor or pharmacist if you are not sure.

If you or your child stops taking Diartem[®] IG Adultes

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 doctor or pharmacist. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

All medicines, Diartem[®] IG Adultes 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 doctor 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 while taking Diartem[®] IG Adultes and for some days after taking the last dose. This can cause a life-threatening abnormality of the heart rhythm.

Your doctor may take electrical recordings of your heart (electrocardiogram, ECG) while you are being treated and after the last dose is given. Your doctor will advise you when these readings will be taken.

If you notice anything different about your heart rhythm or have symptoms (such as palpitations or irregular heart beat) you should contact your doctor 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)*
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), regular 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)*
Influenza, respiratory infections, ear infection, 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 various types of 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 doctor or pharmacist.

5. HOW TO STORE DIARTEM[®] IG ADULTES

Store below 30°C, protect from light and moisture. Keep out of reach and sight of children.

Do not take Diartem[®] IG Adultes after the expiry date which is stated on the package after EXP. The expiry date refers to the last day of that month.

Do not use Diartem[®] IG Adultes if you notice the blister package is open.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Diartem[®] IG Adultes tablet contains
Composition:
Each film coated tablet contains
Dihydroartemisinin 120 mg
Piperazine Phosphate 960 mg
Excipients q.s.
Colours: Brilliant blue, Indigo carmine & Titanium dioxide.

Excipients: Pregelatinised Starch, Maltodextrin, Croscarmellose Sodium, Magnesium Stearate and Talc: Blue TC – 505027.

What Diartem[®] IG Adultes tablet looks like and contents of the pack
Blue colour, capsule shape film coated tablets having score line on one side and plain on other side of each tablet.

Pack Contents: Carton contains one blister of 3 tablets along with leaflet.

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If you have any questions about this product or would like to report an adverse reaction contact us by phone: + 225 21 25 32 36.

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