

PATIENT INFORMATION LEAFLET

GVITHER PLUS 20/120

Artemether and Lumefantrine Powder for Oral Suspension

Read all of this leaflet carefully before you start taking or giving this medicine to your child.

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

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1. WHAT GVITHER PLUS 20/120 IS AND WHAT IT IS USED FOR

GVITHER PLUS 20/120 is used to treat malaria infections caused by *Plasmodium falciparum* (a particular type of malaria parasite). It contains two active substances, artemether and lumefantrine. It works by killing the malaria parasites.

Infection with malaria occurs when the *Anopheles* mosquito bites a person's skin and transfers the malaria parasite (*Plasmodium*). Manifestations of malaria do not appear until at least one week after the bite (see section 3: How to take GVITHER PLUS 20/120). GVITHER PLUS 20/120 is used to treat infants and children up to 12 years of age who weigh between 5 kg and less than 35 kg.

GVITHER PLUS 20/120 may be given to persons travelling to regions in which malaria is prevalent for use as emergency self-medication (e.g. persons travelling to isolated areas

where prompt medical help may not be available.) In such cases, prescribing physicians are advised to prescribe GVITHER PLUS 20/120 so that it may be kept by parents or caregivers for administration to the travelling child (“stand-by emergency treatment”).

Please note that such treatment is a first-aid measure, i.e. it must not be given unless malaria is suspected and even then, medical help must be sought as quickly as possible.

GVITHER PLUS 20/120 may not be used unless it has been prescribed by a doctor.

Emergency treatment with GVITHER PLUS 20/120 cannot substitute for the following preventive measures: Protect your child from mosquito bites. Anopheles mosquito bites are most likely to occur in the hours between dusk and dawn.

During this time you should therefore:

- Use mosquito repellents.
- Make sure that as much skin as possible is covered by clothing.
- At night, use a mosquito net in sleeping areas not protected from mosquitoes.

Remember that GVITHER PLUS 20/120 is not effective against all malaria parasites or in all endemic areas.

GVITHER PLUS 20/120 is also recommended for malaria infections acquired in areas where malaria parasites may be resistant to other antimalarial medicines

In order to avoid problems caused by taking the wrong type or the wrong dose of antimalarial medication, you must not give GVITHER PLUS 20/120 to your child without first consulting a doctor or pharmacist. This also applies to later trips to an endemic area.

GVITHER PLUS 20/120 is not suitable either for malaria prevention or for the treatment of severe malaria (e.g. malaria affecting the child’s brain, kidneys or lungs).

2. BEFORE YOU TAKE GVITHER PLUS 20/120

Do not give GVITHER PLUS 20/120 to your child

- If your child is allergic (hypersensitive) to artemether, lumefantrine or any of the other ingredients of GVITHER PLUS 20/120.

If you think your child might be allergic, ask your doctor for advice.

- If your child has severe liver or kidney impairment.
- If there is severe malaria affecting the brain, lungs or kidneys.

- During the first 3 months of pregnancy, or if your daughter may become pregnant, insofar as the doctor can provide another medicine to treat malaria.
- If your child has a heart condition, such as arrhythmia, slow heartbeat or severe heart disease or, for example, an abnormal electrical signal in the ECG referred to as “prolongation of the QT interval”.
- If one of the child’s family members (such as parents, grandparents, brothers and sisters) died suddenly due to a problem with heart rate, or already had problems with heart rate at birth.
- If your child is being treated with medicines that affect the heartbeat (antiarrhythmic medicines).
- If your child has low blood levels of electrolytes such as potassium or magnesium.
- If there is severe water loss or problems with eating.

In such cases, you must go to the nearest hospital.

Take special care with GVITHER PLUS 20/120

- If your child’s condition gets worse, or if your child feels too sick to eat or drink, contact your child’s doctor immediately. Your doctor may carry out a test called an electrocardiogram (ECG) before and during treatment, and test your child’s blood levels of electrolytes such as potassium and magnesium
- Inform your doctor or pharmacist if your child is suffering from any other conditions or,
- If your child has any allergies.

Taking other medicines

Tell your doctor if your child is taking any other medicines (for internal or external use), including any bought without a prescription.

Tell your doctor if your child is taking, or has taken, other antimalarial medicines, because some of these medicines must not be given concurrently with GVITHER PLUS 20/120. Other antimalarial medications, containing the active substances halofantrine or quinine, should not be taken concurrently with GVITHER PLUS 20/120.

Also tell your doctor if your child is taking antiretroviral medicines or a protease inhibitor (to treat HIV infections or AIDS).

GVITHER PLUS 20/120 must not be taken concurrently with certain other medicines, such as those belonging to the following classes: antiarrhythmic medicines (medicines used to treat arrhythmia, such as flecainide and metoprolol), blood-pressure medicines (beta-blockers), neuroleptics, antidepressants (such as imipramine, amitriptyline, clomipramine), antibiotics and antifungals (such as macrolides, fluoroquinolones, imidazoles and triazoles), non-sedating antiallergic medicines (such as terfenadine, astemizole) and medicines containing the active substance cisapride (such as Prepulsid®).

Therefore, tell your doctor if your child is taking other medicines.

Taking GVITHER PLUS 20/120 with food and drink

After opening the vial (breaking the seal), drinking water is added and carefully brought to the mark point indicating 60 ml level. When adding water the mixture turns yellow. After adding the water the mixture is vigorously shaken until all powder has disappeared from the bottom and an oral suspension is being formed. The composition of the powders is such that this process takes only a few seconds. It may be necessary to readjust the volume to the 60 ml or mark. This oral suspension is stable for several days. It is advisable to shake the vial before use.

A subunit of 5 ml contains 20 mg artemether and 120 mg lumefantrine. For each patient it will be calculated how many millilitres should be administered. It is recommended to round off the dosage to the nearest subdivision.

Pregnancy and breast-feeding

Ask your doctor, health care provider or pharmacist for advice before taking any medicine.

Women who are pregnant or breastfeeding should take GVITHER PLUS 20/120 only after consulting with their doctors.

GVITHER PLUS 20/120 may have serious consequences for the fetus, and therefore must not be used during the first 3 months of pregnancy if the doctor can provide your daughter with another medicine to treat malaria. Your daughter should not take GVITHER PLUS 20/120 in the later stages of pregnancy unless it is clearly necessary.

Tell your daughter's doctor if your daughter is pregnant, if pregnancy is suspected, or if your daughter has become pregnant during treatment with GVITHER PLUS 20/120.

GVITHER PLUS 20/120 must not be used during the first 3 months of pregnancy. Women of childbearing advised potential who have GVITHER PLUS 20/120 with them as emergency medication for use during travelling are therefore to use an effective means of birth-control

during their journey, during the time they use GVITHER PLUS 20/120, and until the start of their next menstruation following treatment.

Your daughter should not breastfeed while taking GVITHER PLUS 20/120. After discontinuing use of GVITHER PLUS 20/120, she should resume breastfeeding no sooner than 4 weeks after she has taken the last dose.

Driving and using machines

Dizziness and/or fatigue may occur after GVITHER PLUS 20/120 is taken.

The patient must not drive because the ability to drive or use machines may be adversely affected.

The patient must not use any tools or machines.

3. HOW TO TAKE GVITHER PLUS 20/120

Always take GVITHER PLUS 20/120 exactly as your doctor or health care provider has told you. You should check with your doctor, health care provider or pharmacist if you are not sure.

Malaria caused by *Plasmodium falciparum* is a serious, life-threatening disease that must be fully treated. It is therefore very important that GVITHER PLUS 20/120 be taken as prescribed by the doctor, and that all prescribed 20/120 be taken, even if your child feels better beforehand. Symptoms might return if your child stops taking the GVITHER PLUS 20/120 too soon.

If the doctor or pharmacist has given your child GVITHER PLUS 20/120 prior to a visit to an endemic area, recommending that GVITHER PLUS 20/120 be used (as emergency medication) if malarial symptoms develop, it is important to remember the following:

Always suspect malaria if your child develops fever inexplicably, with or without further signs and symptoms such as headache, muscle pain, weakness, nausea, vomiting, diarrhoea, stomach pains and cough. These symptoms may develop any time after the end of the first week following the first possible contact with malaria (i.e. following arrival in the endemic area), and up to 2 months after the last possible contact. In some cases it may take even longer than 2 months. Your child should always consult a doctor immediately if he/she experiences any of the symptoms described.

Only use GVITHER PLUS 20/120 as self-medication if it is not possible to get medical help within the next 24 hours.

Moreover, self-medication should not be undertaken unless your child has spent at least 8 days in an area where malaria is prevalent.

Even after self-medication, you must contact a doctor as soon as possible so that he or she can determine whether your child is suffering from malaria or another disease, and can begin any appropriate additional treatment.

Your doctor will tell you exactly how many GVITHER PLUS 20/120 doses to give your child. If you are not sure how much GVITHER PLUS 20/120 you should give, or when you should give it, ask your doctor or pharmacist.

How much to give

- Six doses are given over 3 days.
- The first dose should be taken as soon as possible and should be followed by five further doses at 8, 24, 36, 48 and 60 hours after the first dose, as described in the next section.
- When you give first dose, work out the times you will need to give the rest of the doses at and write them down.
- All doses must be taken and at the right times, to gain the full benefits of this medicine.

Body weight	Number of millilitres					
	DAY 1		DAY 2		DAY3	
	0 Hrs	8 Hrs	24 Hrs	36 Hrs	48 Hrs	60 Hrs
5 to <14 kg	5 ml	5 ml	5 ml	5 ml	5 ml	5 ml
15 to < 24 kg	10 ml	10 ml	10 ml	10 ml	10 ml	10 ml

If your child vomits within one hour of taking the dose, give the prescribed dose again and inform your doctor or pharmacist immediately

Strictly adhere to the dosage prescribed by the doctor.

If your child takes more GVITHER PLUS 20/120 than he/she should

If you have accidentally given your child more doses than your doctor has prescribed, you should immediately take your child to a doctor or to the nearest hospital emergency room, or make sure that someone consults an emergency doctor on your child's behalf. Take the medicine or the empty package with you.

If your child forgets to take GVITHER PLUS 20/120

If your child forgets a dose, give the child the dose as soon as you realize this. The next dose should be given at the scheduled time.

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

If the symptoms recur after treatment

If manifestations of malaria recur after the end of treatment, you should consult a doctor immediately.

Your child's doctor will decide on further treatment of malaria.

Do not change the prescribed dosage yourself. If you think that the treatment is having too strong or too weak an effect, talk to your child's doctor or pharmacist.

If you have any further questions on the use of this product, ask your doctor, health care provider or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, GVITHER PLUS 20/120 can cause side effects, although not everybody gets them.

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

Most side effects are mild to moderate and usually resolve a few days or weeks after treatment.

These side effects were very common: Loss of appetite, coughing, vomiting.

These side effects were common: Headache, dizziness, stomach ache, diarrhoea, nausea, rash, muscle and joint pain, fatigue and general exhaustion, symptoms such as inexplicable, persistent nausea, stomach problems, loss of appetite or unusual fatigue or weakness (signs of liver problems), QT prolonged in electrocardiogram.

These side effects were uncommon: Sleep disturbances, drowsiness, palpitations, pruritus (itching).

These side effects were rare: Allergic reaction (such as rash, itching, trouble breathing or swallowing, dizziness).

Some side effects may be serious. Contact your child's doctor immediately as soon as you notice the following side effect in your child: Rash and/or reddening of the face (signs of allergy).

The other side effects mentioned do not normally need to be treated but you should contact your child's doctor if any of them persists for a long time or is particularly unpleasant.

The following side effects have been uncommonly reported in adults, but not in infants or children: Disturbances of movement, abnormal gait, tingling sensation or reduced sensation.

You should inform your child's doctor or pharmacist if you notice side effects in your child that are not described here.

5. HOW TO STORE GVITHER PLUS 20/120

- Keep out of the reach and sight of children.
- Store in dry place, below 30°C. Protect from light.
- Do not use GVITHER PLUS 20/120 after the expiry date stated on the bottle and the carton after EXP. The expiry date refers to the last day of that month.
- Do not use GVITHER PLUS 20/120 if the pack is damaged or shows signs of tampering.

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 GVITHER PLUS 20/120 contains

- The active substances are: artemether and lumefantrine.
Each 5 ml of reconstituted suspension contains 20 mg artemether and 120 mg lumefantrine.
- The other ingredients are Sucrose, Methyl Paraben, Propyl Paraben, Colloidal Anhydrous Silica (Aerosil), Citric Acid (Anhydrous), Xanthan Gum, Saccharin Sodium, Sunset Yellow Supra, and Powderome Orange 4153.

What GVITHER PLUS 20/120 looks like and contents of the pack

GVITHER PLUS 20/120 suspension is Yellow coloured granular powder, after reconstitution orange coloured viscous suspension having pleasant orange flavour.

Packs containing - 60 ml HDPE bottle packed in a carton along with pack insert;

Marketing Authorisation Holder

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