1. NAME OF THE MEDICINAL PRODUCT

Artefan 20/120*
Artemether 20 mg + Lumefantrine 120 mg

Artefan 40/240*
Artemether 40 mg + Lumefantrine 240 mg

Artefan 60/360*
Artemether 60 mg + Lumefantrine 360 mg

Artefan 80/480*
Artemether 80 mg + Lumefantrine 480 mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Artefan is a fixed dose combination of artemether and lumefantrine.

Each Artefan 20/120 tablet contains 20 milligrams of artemether and 120 milligrams of lumefantrine

Each Artefan 40/240 tablet contains 40 milligrams of artemether and 240 milligrams of lumefantrine

Each Artefan 60/360 tablet contains 60 milligrams of artemether and 360 milligrams of lumefantrine

Each Artefan 80/480 tablet contains 80 milligrams of artemether and 480 milligrams of lumefantrine

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablets :

Artefan 20/120 is a "Yellow coloured circular flat uncoated tablet".

Artefan 40/240 is a "Yellow coloured, circular, flat, uncoated tablet with breakline on one side".

Artefan 60/360 is a "Yellow coloured, capsule shaped, biconvex, uncoated tablet".

Artefan 80/480 is a "Yellow coloured, capsule shaped, biconvex, uncoated tablet with breakline on one side".

The breakline is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

4. CLINICAL PARTICULARS

4.1 Therapeutic indication

Artefan is indicated for the treatment of uncomplicated cases of malaria due to *Plasmodium falciparum* in adults, children and infants of 5 kg and above.

The most recent official guidelines on the appropriate use of antimalarial agents and local information on the prevalence of resistance to antimalarial drugs must be taken into consideration for deciding on the appropriateness of therapy with Artefan.
Official guidance will normally include WHO (http://whqlibdoc.who.int/publications/2010/9789241547925_eng.pdf) and local health authorities' guidelines (see also sections 4.4 and 5.1).

4.2 Posology and method of administration

Tablets for oral administration.

Table 1: Number of Artefan for treatment according to weight bands

Weight range	1st day of treatment	2nd day of treatment	3rd day of treatment
≥ 5 kg to < 15 kg	1 tablet twice daily (2 x 20mg/120mg A/L)	1 tablet twice daily (2 x 20mg/120mg A/L)	1 tablet twice daily (2 x 20mg/120mg A/L)
15 kg to < 25 kg	1 tablet twice daily (2 x 40mg/240mg A/L)	1 tablet twice daily (2 x 40mg/240mg A/L)	1 tablet twice daily (2 x 40mg/240mg A/L)
25 kg to < 35 kg	1 tablet twice daily (2 x 60mg/360mg A/L)	1 tablet twice daily (2 x 60mg/360mg A/L)	1 tablet twice daily (2 x 60mg/360mg A/L)
≥ 35 kg (or ≥ 12 years of age)	1 tablet twice daily (2 x 80mg/480mg A/L)	1 tablet twice daily (2 x 80mg/480mg A/L)	1 tablet twice daily (2 x 80mg/480mg A/L)

Treatment should be administered at the time of initial diagnosis or at the onset of symptoms. It is preferable that the patient has a positive diagnostic test before administration.
The first dose should be followed by a second dose after 8 hours. The following two days the doses of Artefan should be given twice daily, morning and evening (i.e. 12 hours apart).

To increase absorption, Artefan should be taken with food or a milky drink (see section 5.2). If a patient is unable to tolerate food, Artefan should still be administered, but the systemic exposure may be reduced. Patients who vomit within 1 hour of taking the medication should repeat the dose.

For very young children, the tablets may be crushed and added to a small amount of semi-solid food or liquid, all of which should be consumed immediately.

Renal or hepatic impairment
No dose adjustments are necessary in patients with renal or hepatic impairment. However, caution is advised when administering Artefan to patients with severe renal or hepatic problems (see section 4.4).

Elderly
No special precautions or dosage adjustments are necessary in such patients.

4.3 Contraindications

Hypersensitivity to artemether, lumefantrine or to any of the excipients.

4.4 Special warnings and precautions for use

Pregnancy: Artefan should not be used in the first trimester of pregnancy in situations where other suitable and effective antimalarials are available (see section 4.6).

Prolongation of the QT-interval: Artefan may prolong the QTc interval and increase the risk of cardiac arrhythmias (see sections 4.5, 4.8 and 5.1). Therefore Artefan should be avoided in patients:

- with a family history of congenital prolongation of the QTc interval or sudden death, or with any other clinical condition known to prolong the QTc interval, such as patients with a history of symptomatic cardiac arrhythmias, clinically relevant bradycardia or congestive heart failure.
- with known disturbances of electrolyte balance, e.g. hypokalaemia or hypomagnesaemia.
- taking drugs that prolong the QTc interval, such as class IA and III antiarrhythmics, certain neuroleptics and antidepressants, certain antibiotics (some macrolides and fluoroquinolones), certain non-sedating antihistamines (terfenadine, astemizole) and cisapride.
- taking drugs with narrow therapeutic index which are metabolized by cytochrome CYP2D6 (e.g. flecainide, metoprolol, imipramine, amitriptyline, clomipramine).

In these patients, ECG- and serum potassium-monitoring is advised.

Renal/hepatic dysfunction: Artefan has not been studied in patients with severe renal or hepatic problems

Severe malaria: Artefan has not been evaluated for the treatment of severe malaria, including cases of cerebral malaria or other severe manifestations such as pulmonary oedema or renal failure. Use of Artefan in such cases is also inadvisable on pharmacokinetic grounds, as it is uncertain if exposure of artemether and, in particular, of lumefantrine is adequate in these patients with high parasitaemia and little or no food intake.

Malaria prophylaxis: Artefan has not been evaluated for malaria prophylaxis.

Malaria not caused by P. falciparum: Artefan has not been evaluated for the treatment of malaria due to *P. vivax*, *P. malariae* , *P. ovale* or *P. knowlesi* (see section 5.1).
Following treatment of mixed infections including *P. vivax*, follow-up treatment must be given in order to eradicate the exoerythrocytic forms of *P. vivax*.

Other antimalarials:
Unless there is no other treatment option, Artefan should not be given concurrently with any other antimalarial agent due to limited data on safety and efficacy (see section 4.5).

If a patient deteriorates while taking Artefan, alternative treatment for malaria should be started without delay. In such cases, monitoring of the ECG is recommended and steps should be taken to correct any electrolyte disturbances.

Due to the potential of additive/synergistic QT-prolongation, close ECG-monitoring is advised when quinine is given after Artefan (see section 5.1).

If Artefan is given after mefloquine, close monitoring of food intake is advised (see section 4.5).

In patients previously treated with halofantrine, Artefan should not be administered earlier than one month after the last halofantrine dose (see section 4.5).

Hormonal contraceptives: Artefan may reduce the effectiveness of hormonal contraceptives. Patients should be advised to use an additional non-hormonal method of birth control.

Intake with food and drinks: Patients who remain averse to food during treatment should be closely monitored, as the risk of recrudescence may be greater.

4.5 Interaction with other medicinal products and other forms of interaction

Artefan should not be used in patients taking drugs that are known to prolong the QTc interval (see section 4.4), as effects may be additive and increase the risk of cardiac arrhythmia.

Interaction with other antimalarials
Artefan should not be given concurrently with any other antimalarial agent *(see section 4.4)*. In addition, due to the propensity of some antimalarial agents to prolong the QTc interval, caution is advised when administering Artefan to patients in whom there may still be detectable concentrations of these drugs in the plasma following prior treatments.

Administration of a six-dose regimen of artemether/lumefantrine (over 60 hours) starting 12 hours after completion of a three-dose regimen of mefloquine or placebo in healthy volunteers showed no effect of mefloquine on plasma concentrations of artemether or the artemether/dihydroartemisinin ratio, but a 30-40% reduction in plasma levels of lumefantrine. These are possibly due to lower absorption secondary to a mefloquine-induced decrease in bile production. Patients that have been pretreated with mefloquine should be encouraged to eat at dosing times to compensate for the decrease in bioavailability. Plasma mefloquine concentrations from the time of addition of artemether/lumefantrine were not affected compared with a group that received mefloquine followed by placebo.

In patients previously treated with halofantrine, Artefan should be dosed at least one month after the last halofantrine dose due to the long elimination half-life of halofantrine and the potential additive/synergistic effects on the QT-interval.

<u>Interaction with CYP450 enzymes</u>
Studies in humans have demonstrated that artemisinins have some capacity to induce CYP3A4 and CYP2C19 and inhibit CYP2D6 and CYP1A2. Although the magnitude of the changes was generally low it is possible that these effects could alter the therapeutic response or safety profile of drugs that are predominantly metabolised by these enzymes (see sections

4.4 and 5.2).

Lumefantrine was found to inhibit CYP2D6 in vitro. This may be of particular clinical relevance for compounds with a low therapeutic index (see section 4.3).

Interaction with CYP450 3A4 inhibitors

Ketoconazole: both artemether and lumefantrine are metabolised predominantly by the cytochrome enzyme CYP3A4, and do not inhibit this enzyme at therapeutic concentrations. The concurrent oral administration of ketoconazole with artemether/lumefantrine led to a modest increase (2 fold) in artemether, DHA, and lumefantrine exposure in healthy adult subjects. This increase in exposure to the antimalarial combination was not associated with increased side effects or changes in electrocardiographic parameters. Dose adjustment of Artefan is not considered necessary when administered concomitantly with ketoconazole or other azole antifungals, but such combinations should be used with caution.

HIV protease inhibitors: When co-administered with lopinavir and ritonavir, the AUC of lumefantrine increased by 193% and the Cmax by 82%. Artemether and lumefantrine did not significantly affect lopinavir exposure. Data for other protease inhibitors are not available. Artefan and HIV protease inhibitors should be co-administered with caution.

4.6 Pregnancy and lactation

Pregnancy

There is insufficient data from the use of artemether and lumefantrine in pregnant women. In animal studies Artemether + Lumefantrine tablets, as well as other artemisinin derivates, have been shown to cause post-implantation losses and serious birth defects when administered during the first trimester of pregnancy (see sections 4.4 and 5.3). Therefore, should not be used during the first trimester of pregnancy in situations where other suitable and effective anti-malarials are available (see section 4.4). Nonetheless, it may be used when it is the only treatment immediately available.

Lactation

The amounts of artemether, dihydroartemisinin and lumefantrine in breast milk are small. Therefore, lactating women can receive artemisinin-based combination therapies (including Artefan) for malaria treatment.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed. Patients receiving Artefan should be warned that dizziness, fatigue or asthenia may occur, in which case their ability to drive or operate machines may be impaired.

4.8 Undesirable effects

The safety of artemether/lumefantrine has been evaluated in clinical trials with more than 3500 patients. A total of 1810 adults and adolescents above 12 years of age as well as 1788 infants and children of 12 years of age and below have received artemether/lumefantrine in clinical trials.

Adverse reactions reported from clinical studies and post-marketing experience are listed below according to system organ class.

Adverse reactions are ranked under headings of frequency using the MedDRA frequency convention:
Very common (≥ 1/10)
Common (≥ 1/100 to < 1/10)
Uncommon (≥ 1/1,000 to < 1/100)
Rare (≥ 1/10,000 to < 1/1,000)
Very rare (< 1/10,000)
Not known (cannot be estimated from available data).

Table 2: Frequency of undesirable effects

	Adults and adolescents above 12 years of age	**Infants and children of 12 years of age and below (incidence estimates*)**
Cardiac disorders		
Palpitations	Very common	Common
Electrocardiogram QT prolonged	Common	Common
Nervous system disorders		
Headache	Very common	Very common
Dizziness	Very common	Common
Paraesthesia	Common	--
Gait disturbance	Common	--
Ataxia, hypoaesthesia	Uncommon	--
Clonic movements, somnolence	Uncommon	Uncommon
Respiratory, thoracic and mediastinal disorders		
Cough	Common	Very common
Gastrointestinal disorders		
Vomiting	Very common	Very common
Abdominal pain	Very common	Very common
Nausea	Very common	Common
Anorexia	Very common	Very common
Diarrhoea	Common	Common
Skin and subcutaneous tissue disorders		
Rash	Common	Common
Pruritus	Common	Uncommon
Urticaria, angioedema*	Not known	Not known
Arthralgia	Very common	Common
Myalgia	Very common	Common
General disorders and administration site conditions		
Asthenia	Very common	Common
Fatigue	Very common	Common
Immune system disorders		
Hypersensitivity	Not known	Rare
Hepatobiliary disorders		
Liver function tests increased	Uncommon	Common
Psychiatric disorders		
Sleep disorders	Very common	Common
Insomnia	Common	Uncommon

* These adverse reactions were reported during post-marketing experience. Because these spontaneously reported events are from a population of uncertain size, it is difficult to

estimate their frequency.

4.9 Overdose

Experience of overdosage with artemether and lumefantrine is limited. In cases of suspected overdosage symptomatic and supportive therapy should be given as appropriate, which should include monitoring of ECG and serum electrolytes.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antimalarials, Artemisinin and derivatives, combinations, ATC code: P01BF01

Pharmacodynamic effects

Artefan comprises a fixed ratio of 1:6 parts of artemether and lumefantrine, respectively. The site of antiparasitic action of both components is the food vacuole of the malarial parasite, where they are thought to interfere with the conversion of haem, a toxic intermediate produced during haemoglobin breakdown, to the nontoxic haemozoin, malaria pigment. Lumefantrine is thought to interfere with the polymerisation process, while artemether generates reactive metabolites as a result of the interaction between its peroxide bridge and haem iron. Both artemether and lumefantrine have a secondary action involving inhibition of nucleic acid- and protein synthesis within the malarial parasite.

The antimalarial activity of the combination of lumefantrine and artemether in Artefan is greater than that of either substance alone. In a double-blind comparative study in adults in China (n=157), the 28-day cure rate of artemether/lumefantrine when given at four doses was 94% compared with 90% for lumefantrine and 46% for artemether based on intent-to-treat (ITT) population, when given as monotherapy. For the evaluable population, 28-day cure rates were 100% for artemether/lumefantrine, compared with 92% for lumefantrine and 55% for artemether when given as monotherapy.

In areas where multi-drug-resistant strains of *P. falciparum* malaria are common and in the resident population, 28-day cure rates with the 6 dose regimen (given over 60 to 96 h) were 81% and 90% for artemether/lumefantrine versus 94% and 96% for mefloquine/artesunate, based on the ITT population. For the evaluable population, 28-day cure rates were 97% and 95% for artemether/lumefantrine and 100% for mefloquine/artesunate.

In an open, multicenter clinical study conducted in Africa in 310 children weighing 5 kg to less than 25 kg and receiving a six-dose artemether/lumefantrine regimen according to their body weight range, the mean 28-day parasitological cure rate (PCR-corrected) was 93.9% for the ITT population and 96.7% for the evaluable population.

In non-immune patients living in regions free of malaria but with malaria acquired when travelling in endemic regions, a similar efficacy and safety profile was shown. In an open study (n=165) in adults the 28-day cure rate for artemether/lumefantrine given as the six-dose regimen was 96% (119/124) for the evaluable and 74.1% (120/162) for the ITT population. The main causes of the difference between the evaluable and ITT cure rates were "lost to follow up" (33 patients) or protocol violations (intake of prohibited concomitant medications). These two groups were considered as treatment failures in the ITT analysis.

Arthemether/lumefantrine is active against blood stages of *Plasmodium vivax*, but is not active against hypnozoites.

QT/QTc Prolongation:

For information on the risk of QT/QTc prolongation in patients see section 4.4.

In a healthy adult volunteer parallel group study including a placebo and moxifloxacin control group (n = 42 per group), the administration of the six dose regimen of artemether/lumefantrine with food was associated with a moderate prolongation of QtcF (QT interval corrected by Fridericias formula). The mean changes from baseline at 68, 72, 96, and 108 hours post first dose were 7.45, 7.29, 6.12 and 6.84 msec, respectively. At 156 and 168 hours after first dose, the changes from baseline for QTcF had no difference from zero. No subject had a > 30 msec increase from baseline nor an absolute increase to > 500 msec. Moxifloxacin control was associated with a QTcF increase as compared to placebo for 12 hours after the single dose with a maximal change at 1 hour after dose of 14.1 msec.

5.2 Pharmacokinetic properties

Artemether

Absorption

Artemether is absorbed fairly rapidly and dihydroartemisinin (DHA), the active metabolite of artemether, appears rapidly in the systemic circulation with peak plasma concentrations of both compounds reached about 2 hours after dosing. The absolute bioavailability is unknown.

In healthy volunteers the relative bioavailability of artemether was increased more than two-fold when taken with food.

Distribution

Artemether is 95.4% bound to human serum proteins in vitro. The active metabolite dihydroartemisinin (DHA) is also bound to human serum proteins (47-76%).

Metabolism

Artemether is rapidly and extensively metabolised with substantial first-pass metabolism.
Artemether is metabolised in the liver to the biologically active main metabolite DHA (demethylation), predominantly through the isoenzyme CYP3A4/5. The pharmacokinetics of artemether in adults is time-dependent. During repeated administration of arthemether/lumefantrine, plasma artemether levels decreased significantly, while levels of the active metabolite (dihydroartemisinin) increased, although not to a statistically significant degree. The ratio of day 3/day 1 AUC for artemether was between 0.19 and 0.44, and was between 1.06 and 2.50 for dihydroartemisinin. This suggests that there was induction of the enzyme responsible for the metabolism of artemether. DHA is further converted to inactive metabolites, primarily by glucuronidation. In vivo data indicate that artemisinins have some capacity to induce cytochrome isoenzymes CYP2C19 and CYP3A4.

Elimination

Artemether and dihydroartemisinin are rapidly cleared from plasma with an elimination half-life of about 2 hours.
No urinary excretion data are available for humans. In rats and dogs unchanged artemether has not been detected in faeces and urine due to its rapid and high-first-pass metabolism, but several metabolites (unidentified) have been detected in both faeces and urine.

Lumefantrine

Absorption
Absorption of lumefantrine, a highly lipophilic compound, starts after a lag-time of up to 2 hours, with peak plasma concentration about 6-8 hours after dosing. The absolute bioavailability is unknown.
In healthy volunteers the relative bioavailability of lumefantrine, when was taken after a high-fat meal, was increased sixteen-fold compared with fasted conditions. Food has also been shown to increase the absorption of lumefantrine in patients with malaria, although to a lesser extent (approximately two-fold), most probably due to the lower fat content of the food ingested by acutely ill patients. The food interaction data indicate that absorption of lumefantrine under fasted conditions is very poor. Patients should therefore be encouraged to take the medication with a normal diet as soon as food can be tolerated.

Distribution
Lumefantrine is 99.7% bound to human serum proteins in vitro.

Metabolism
Lumefantrine is N-debutylated, mainly by CYP3A4, in human liver microsomes. The systemic exposure to the metabolite desbutyl-lumefantrine, for which the in vitro antiparasitic effect is 5 to 8 fold higher than lumefantrine, was less than 1% of the exposure to the parent drug. Desbutyl-lumefantrine data is not available specifically for an African population. In vitro, lumefantrine significantly inhibits the activity of CYP2D6 at therapeutic plasma concentrations. In humans, the exposure to lumefantrine increases with repeated administration of artemether/lumefantrine over the 3-day treatment period, consistent with the slow elimination of the compound.

Elimination
Lumefantrine is eliminated very slowly with a terminal half-life of approximately 3 days. No urinary excretion data are available for humans. Lumefantrine is eliminated via the bile in rats and dogs, with excretion primarily in the faeces. After oral dosing in rats and dogs qualitative and quantitative recovery of metabolites in bile and faeces was relatively low, most of the dose being recovered as parent drug.

Pharmacokinetics in special patient populations
Specific pharmacokinetic studies have not been performed in patients with hepatic or renal insufficiency. No pharmacokinetic studies are available in elderly patients.

Paediatric population
In paediatric malaria patients, mean Cmax (CV%) of artemether (observed after first dose) were 223 (139%), 198 (90%) and 174 ng/ml (83%) for body weight groups 5-<15, 15-<25 and 25-<35 kg, respectively, compared to 186 ng/ml (67%) in adult malaria patients. The associated mean Cmax of DHA were 54.7 (108%), 79.8 (101%) and 65.3 ng/ml (36%), respectively compared to 101 ng/ml (57%) in adult malaria patients.
AUC of lumefantrine (population mean, covering the six doses of artemether/lumefantrine) were 577, 699 and 1150 µg•h/ml for paediatric malaria patients in body weight groups 5-<15, 15-<25 and 25-<35 kg, respectively, compared to a mean AUC of 758 µg•h/ml (87%) in adult malaria patients.
The elimination half-lives of artemether and lumefantrine in children are unknown.

5.3 Preclinical safety data

General toxicity
The main changes observed in repeat-dose toxicity studies were associated with the expected

pharmacological action on erythrocytes, accompanied by responsive secondary haematopoiesis.

Mutagenicity

No evidence of mutagenicity was detected in in vitro or in vivo tests with an artemether:lumefantrine combination (consisting of 1 part artemether:6 parts lumefantrine). In the micronucleus test myelotoxicity was seen at all dose levels (500, 1,000 and 2,000 mg/kg), but recovery was almost complete 48 hours after dosing.

Carcinogenicity

Carcinogenicity studies with the artemether/lumefantrine combination were not conducted.

Reproductive toxicity studies

Reproductive toxicity studies performed with the artemether/lumefantrine combination caused maternal toxicity and increased post-implantation loss in rats and rabbits at doses 50 mg/kg/day (corresponding to approximately 7 mg/kg/day artemether) and 175 mg/kg/day (corresponding to 25 mg/kg/day artemether) respectively. These effects were not observed at lower doses.

Lumefantrine alone caused no sign of reproductive or development toxicity at doses up to 1,000 mg/kg/day in rats and rabbits.

Embryotoxicity has been observed in rat and rabbit reproductive toxicity studies conducted with artemether, a derivative of artemisinin. Artemisinins (e.g. artesunate) are known to be embryotoxic.

Artemether caused increases in post-implantation loss and teratogenicity (characterised as a low incidence of cardiovascular and skeletal malformations) in rats at 19.4 mg/kg, and in rabbits at 30 mg/kg. Maternal toxicity was also observed in rabbits at 30 mg/kg/day. No other adverse effects were observed at lower doses in rabbits. The no observed effect dose was 3 mg/kg/day in rats and 25 mg/kg/day in rabbits.

The embryotoxic artemether dose, 20 mg/kg/day in the rat, yields artemether and dihydroartemisinin exposures similar to those achieved in humans.

Artesunate, a structurally related compound, also caused increases in post-implantation loss and teratogenicity (low incidence of cardiovascular and skeletal malformations) in rats at 6 mg/kg and in the lowest dose tested in the rabbits, 5 mg/kg/day.

Cardiovascular Pharmacology

In toxicity studies in dogs at doses $\geq$ 600 mg/kg/day only, there was some evidence of prolongation of the QTc interval, at higher doses than intended for use in man. In an in vitro assay of HERG channels, lumefantrine and the main metabolite desbutyl-lumefantrine showed some inhibitory potential in one of the currents responsible for cardiac repolarization. From the estimated IC_{50} values, the order of potency of HERG current block was halofantrine (IC_{50} = 0.04 μM) > chloroquine (2.5 μM) > mefloquine (2.6 μM) > desbutyl-lumefantrine (5.5 μM) > lumefantrine (8.1 μM). Clinical studies show, that prolongation of QTcF can occur with standard dosing of artemether/lumefantrine (see sections 4.4 and 5.1).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Colloidal silicon dioxide
Crospovidone
Magnesium stearate

Microcrystalline cellulose
Sodium lauryl sulphate
Purified Talc

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24 months

6.4 Special precautions for storage

Do not store above 30°C, protect from light.

6.5 Nature and contents of container

Artefan 20/120 tablets

The tablets are provided in clear PVC/PVdC-Alu blisters.
Aluminium/PVC-PVdC blister of 1x6's, 1x12's, 1x18's, 1x24's 30x6's, 30x12's, 30x18's, 30x24's, 3x8's tablets packed in a carton with pack insert.

6.6 Special precautions for disposal

No special requirements.
Any unused product or waste material should be disposed of in accordance with local requirements.

7. SUPPLIER

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