Bosch

For Medical Professional only

20 | 120mg TABLET
Qmetem
(Artemether + Lumefantrine)

40 | 240mg TABLET
Qmetem DS™
(Artemether + Lumefantrine)

80 | 480mg TABLET
Qmetem DS *Plus*®
(Artemether + Lumefantrine)

80mg/ml INJECTION
Qmetem-P™
(Artemether)

Plus®
Qmetem Dry Suspension
(Artemether + Lumefantrine) 15/90mg (30ml/60ml)

Plus®
Qmetem DS Dry Suspension
(Artemether + Lumefantrine) 30/180mg (30ml)

DESCRIPTION:

Artemether + Lumefantrine provide an important addition to the armamentarium against malaria in the form of a safe and effective combination therapy. To date, it is the only fixed-dose artemisinin-based combination therapy (ACT) combining Artemether, an artemisinin derivative, and lumefantrine, a synthetic antimalarial drug. Artemisinin is a compound derived from the sweet wormwood plant and has been used for centuries in traditional Chinese medicine to treat fever.

COMPOSITION:

Qmetem 20/120mg Tablets: Each tablet contains:
Artemether M.S. .... 20mg, Lumefantrine U.S.P..... 120mg.
(Product Specs.: Bosch)
"Product contains lactose"

Qmetem DS 40/240mg Tablets: Each tablet contains:
Artemether M.S. .... 40mg, Lumefantrine U.S.P..... 240mg.
(Product Specs.: Bosch)
"Product contains lactose"

Qmetem DS Plus 80/480mg Tablets: Each tablet contains:
Artemether M.S. .... 80mg, Lumefantrine U.S.P..... 480mg.
(Product Specs.: Bosch)

Qmetem Plus Dry Suspension: Each 5ml contains:
Artemether M.S. .... 15mg, Lumefantrine U.S.P..... 90mg.
(Product Specs.: Bosch)

Qmetem Plus DS Dry Suspension: Each 5ml contains:
Artemether M.S. .... 30mg, Lumefantrine U.S.P..... 180mg.
(Product Specs.: Bosch)

Qmetem-P 80mg/ml Injection: Each ml contains:
Artemether M.S. .... 80mg.
(Product Specs.: Bosch)

INDICATIONS:

Artemether + Lumefantrine are indicated for the treatment of:

- Standby emergency treatment of adults and children with acute, uncomplicated infections due to P. falciparum or mixed infections including P. falciparum.
- Because Artemether + Lumefantrine are effective against both drug-sensitive and drug-resistant P.falciparum they are also recommended for malarial infections acquired in areas where the parasites may be resistant to other antimalarials.
- Qmetem Injection is used in the treatment of severe and complicated malaria caused by P. falciparum both in adults and children in areas where there is multidrug resistance including the chloroquine-resistant sub tertian malaria. Treatment of uncomplicated malaria in situations where there is widespread prevalence of multi-drug resistant P. falciparum infection.

CONTRAINDICATIONS:

Artemether + Lumefantrine are contraindicated in:

- Patients with hypersensitivity to the active substances to any of the excipients.
- Patients with severe malaria including cerebral malaria, or malaria with pulmonary edema or renal failure.
- First trimester of pregnancy. During the second and third trimester, treatment should only be considered if the expected benefit to the mother outweighs the risk to the fetus.
- During breast-feeding.
- 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, patients with clinically relevant bradycardia or with severe cardiac disease.

- Patients with known disturbances of electrolyte balance, e.g. hypokalaemia or hypomagnesaemia.

- Patients taking any drug that is metabolised by the cytochrome enzyme CYP2D6 (e.g. flecainide, metoprolol, imipramine, amitriptyline, clomipramine).

- Patients taking drugs that are known to prolong the QTc interval such as anti-arrhythmics of class IA and III, neuroleptics, antidepressant agents, certain antibiotics including some agents of macrolides, fluoroquinolones, lmidazole, and triazole antifungal agents, certain non-sedating antihistaminics (terfenadine, astemizole) and cisapride.

SIDE EFFECTS:

Following clinical studies, the following adverse effects were reported:

Gastrointestinal (abdominal pain, anorexia, nausea, vomiting, diarrhoea) and of the central nervous system (headache. dizziness and sleep disturbance). There is no evidence of serious or persistent neurotoxicity. However, a few patients presented with symptoms such as abnormal gait (4 patients), nystagmus (1 adult), ataxia (3 adults), decreased hearing (4 adults), and paraesthesia (15 adults). Pruritus and rash were reported by less than 2% of patients. Over 90% of the reported adverse events, which could also have been attributed to malaria, were rated mild to moderate in intensity. Artemether+Lumefantrine combination did not lead to any clinically relevant alterations of the laboratory parameters.

Drug induced fever has been observed with Qmetem-P Injection. Mild reactions were seen in patients to whom Qmetem-P Injection had been administered intramuscularly. These included nausea, hypotension, dizziness and tinnitus. Slight rise of SGOT and SGPT may occur in individual cases.

PRECAUTIONS:

Administration of Artemether + Lumefantrine with drugs that are metabolized by the cytochrome enzyme CYP2D6 (e.g. flecainide, metoprolol, imipramine, amitriptyline, clomipramine) should be avoided Co-administration of Artemether+Lumefantrine should be with caution in patients taking, drugs that are known to prolong the QTc interval such as anti-arrhythmics of classes IA and III, neuroleptics, antidepressant agents, certain antibiotics Including same agents of macrolides, Fluoroquinolones, imidazole, and triazole antifungal agents, certain non-sedating antihistaminics (terfenadine, astemizole) and cisapride. Pregnant women (especially during 1st trimester) and nursing mothers should not be prescribed Artemether + Lumefantrine.

OVERDOSAGE:

In case of suspected over dosage, symptomatic and supportive therapy should be given as appropriate.

DOSAGE AND ADMINISTRATION:

For adults and children following dosing schedule should be adopted, depending on their weights:

Qmetem, Qmetem-DS & Qmetem DS Plus Tablets.

Body weight (Kg)	Initial dose	Following doses
5 to <15	1 Qmetem tablet at the time of initial diagnosis.	Then 1 Qmetem tablet at 8, 24 and 48 hours thereafter (Total of 4 tablets in all).
15 to <25	2 Qmetem tablets at the time of initial diagnosis. or 1 Qmetem DS tablet at the time of initial diagnosis.	Then 2 Qmetem tablets at 8, 24 and 48 hours thereafter (Total of 8 tablets in all). or Then 1 Qmetem DS tablet at 8, 24 and 48 hours thereafter (Total of 4 tablet in all).
25 to <35	3 Qmetem tablets at the time of initial diagnosis. or 1 1/2 Qmetem DS tablet at the time of initial diagnosis.	Then 3 Qmetem tablets at 8, 24 and 48 hours thereafter (Total of 12 tablets in all). or Then 1 1/2 Qmetem DS tablet at 8, 24 and 48 hours thereafter (Total of 6 tablet in all).
35 and above (Adults and older children)	4 Qmetem tablets at the time of initial diagnosis. or 2 Qmetem DS 40/240 tablet at the time of initial diagnosis. or 1 Qmetem DS plus 80/480 tablet at the time of initial diagnosis.	Then 4 Qmetem tablets at 8, 24 and 48 hours thereafter (Total of 16 tablets in all). or Then 2 Qmetem DS 40/240 tablet at 8, 24 and 48 hours thereafter (Total of 8 tablet in all). or Then 2 Qmetem DS plus 80/480 tablet at 8, 24 and 48 hours thereafter (Total of 4 tablet in all).

Qmetem Plus, Qmetem Plus DS Dry Suspension

Body weight (Kg)	Day 1		Day 2		Day 3	
	Qmetem Plus DS	Qmetem Plus	**Qmetem Plus DS**	Qmetem Plus	**Qmetem Plus DS**	Qmetem Plus
5 kgs	3.5ml	7ml	3.5ml	7ml	3.5ml	7ml
7.5 kgs	5ml	10ml	5ml	10ml	5ml	10ml
10 kg	7ml	14ml	7ml	14ml	7ml	14ml
15 kg	10ml	20ml	10ml	20ml	10ml	20ml

Qmetem Injection

In severe malaria for adult usual starting dose is 2 ampoules of 80mg given IM on day 1, followed by 1 ampoule of 80mg for 2nd to 5th day. Qmetem-P for children, 3.2 mg/kg by the intramuscular route as a loading dose on the first day, followed by 1.6mg/kg for 2nd to 5th day.

Treatment In non-Immune children and multi-drug-resistant areas

(Most tourists and business travelers, considered to be non-immune):

A thorough 3-day course is recommended for the treatment of non-immune children and in areas of multi-drug-resistant malaria, with 1-4 Qmetem 20/120mg tablets and ½-2 of Qmetem DS 40/240mg tablets (depending on bodyweight), given as a single dose at the time of initial diagnosis, again after 8 hours and then twice daily on each of the following two days (entire course comprises 6, 12, 18 or 24 Qmetem 20/120mg tablets or 3, 6, 9 or 12 of Qmetem DS 40/240mg tablets depending on bodyweight).

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Stand-by emergency treatment:

A thorough 3-day course is recommended for stand-by emergency treatment, with1-4 Qmetem 20/120mg tablets or ½-2 Qmetem DS 40/240mg tablets (depending on bodyweight), given as a single dose at the time of start of symptoms, again after 8 hours and then twice daily on each of the following two days (entire course comprises 6, 12, 18 or 24 Qmetem 20/120mg tablets or 3, 6, 9 or 12 Qmetem DS 40/240mg tablets depending on bodyweight).

Dosage In hepatic and renal Impairment:

No special precautions or dosage adjustments are considered in mild to moderate hepatic or renal impairment. Moreover, the side effect profile did not differ in patients with and those without hepatic impairment. Most patients with acute malaria present with some degree of relative hepatic impairment.

Elderly Patients:

No special precautions or dosage adjustments are required.

Concomitant use with food:

The dose should be taken with high-fatty food or drinks such as milk. Patients should be encouraged to resume normal eating as soon as food can be tolerated, since this Improves absorption of Artemether and lumefantrine. In the event of vomiting within 1 hour of administration, a repeat dose should be taken. Note that patients with acute malaria are frequently averse to food.

Reconstitution:

Add small quantity of cool boiled water in the bottle and shake until all powder is dispersed, then slowly add more water upto the mark given on the label and shake vigorously after tighten the cap. Once reconstituted the suspension must be used within 14 days when stored in refrigerator or within 7 days at room temperature.

SHELF LIFE: 2 Years

Storage and Instructions:

Protect from heat, sunlight & moisture, store below 30°C.

The expiration date refer to the product correctly stored at the required condition.

Patients and healthcare professionals can also report suspected adverse drug reaction at ade@bosch-pharma.com.

Keep out of the reach of children.

To be sold on prescription of a registered medical practitioner only.

Presentation:

Qmetem Tablet 20/120 mg Pack of 16's.

Qmetem DS Tablet 40/240mg Pack of 8's.

Qmetem DS Tablet 80/480mg Pack of 6's.

Qmetem Dry Suspension 15/90mg (60ml) in 90ml Glass Bottle.

Qmetem Dry Suspension 15/90mg (30ml) in 60ml Glass Bottle.

Qmetem DS Suspension 30/180mg (30ml) in 60ml Glass Bottle.

Qmetem-P Injection 80mg/ml Pack of 5's.

ہدایات :

دھوپ، گرمی اور نمی سے محفوظ ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔

بچّوں کی پہنچ سے دُور رکھیں۔

صرف مستند ڈاکٹر کے نسخے پر فروخت کے لئے۔

Manufactured by:
Bosch Pharmaceuticals (Pvt) Ltd.
221-223, Sector 23, Korangi Industrial Area,
Karachi - Pakistan

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Qmetem
(Artemether + Lumefantrine)

40 | 240mg TABLET
Qmetem DS TM
(Artemether + Lumefantrine)

80 | 480mg TABLET
Qmetem DS *Plus*®
(Artemether + Lumefantrine)

Qmetem *Plus*®
(Artemether + Lumefantrine) Dry Suspension 15/90mg (30ml/60ml)

Qmetem DS *Plus*®
(Artemether + Lumefantrine) Dry Suspension 30 /180mg (30ml)

80mg/ml INJECTION
Qmetem-P TM
(A r t e m e t h e r)

FIRST & ONLY CERTIFIED HALAAL
RENAISSANCE INSPECTION & CERTIFICATION AGENCY حلال HALAAL
PHARMACEUTICAL COMPANY