SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE PRODUCT

OSIRIS® (Zinc Sulfate) 20mg/5ml Oral Solution

OSIRIS® *Quick* (Zinc Sulfate) 20mg Tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

OSIRIS® 20mg/5ml Oral Solution
Each 5ml contains:
Zinc Sulfate Monohydrate USP 54.9mg
equivalent to Elemental Zinc.....20mg

OSIRIS® *Quick* 20mg Tablet
Each dispersible tablet contains:
Zinc Sulfate Monohydrate USP 54.9mg
eq. to Elemental Zinc.....20mg

3. PHARMACEUTICAL FORM

Tablet / Oral Solution

Appearance:

OSIRIS® 20mg/5ml Oral Solution: Clear colorless to slightly brown liquid having characteristic color.

OSIRIS® *Quick* 20mg Tablet: White color oval shape tablet, plain on both sides.

4. CLINICAL PARTICULARS

4.1. THERAPEUTIC INDICATIONS:

Zinc Sulfate Tablets and Oral Solution are indicated in children suffering from

- Acute and persistent diarrhoea
- Respiratory tract infections
- Common cold
- Malaria
- Acrodermatitis enteropathica
- Sickle cell anaemia
- Wilson's disease

Zinc Sulfate are indicated in the treatment of diarrhoea, always in connection with Oral Rehydration Salts (ORS) of the WHO by giving Zinc as soon as diarrhoea starts, at the same time as ORS. By continuing Zinc supplementation after diarrhoea stops, the Zinc lost in the stools will be replaced. The risk of the child having new episodes of diarrhoea in the following 2 to 3 months is reduced.

4.2. POSOLOGY AND METHOD OF ADMINISTRATION:

Posology:
For Tablet
Children aged less than 6 months: 10mg (½ tablet) once daily for 10–14 days.
Children aged 6 months–5 years: 20mg (1 tablet) once daily for 10–14 days.
Wilson's disease: 25-50mg elemental zinc two to three times daily
Sickle cell anaemia: 10-15mg elemental zinc daily
Acrodermatitis enteropathica: 1-2mg elemental zinc per kg of body weight daily.
For Oral Solution:
Children aged less than 6 months: Half spoonful (2.5ml) once daily (10-14 days) or as directed by the physician.
Children aged 6 months–5 years: One spoonful (5ml) once daily (10-14 days)
It is recommended that doses are given between meals and the dose repeated if the child vomits within 30 minutes. For missed doses, the missing dose can be taken as soon as possible, unless the next dose is due within 6 hours.
Method of administration:
For Tablet: The tablet (or half-tablet) should be dispersed completely in 1 teaspoon (5mL) clean water or breast milk and the entire amount administered orally.

4.3. CONTRAINDICATIONS:

Zinc Sulfate are contraindicated as co-prescription with certain drugs like penicillamine, sodium valproate and ethambutol which inhibit zinc absorption. It is contraindicated to patients with hypersensitivity to the active substances or to any of the Excipients.

4.4. SPECIAL WARNINGS AND PRECAUTIONS FOR USE:

Dosage reduction may be required in patients with renal dysfunction.

4.5. INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORM OF INTERACTIONS:

Antibacterials: When taken together, zinc may reduce the absorption of tetracyclines (but not doxycycline) and quinolone antibacterials. In addition, zinc may also interfere with the absorption of cephalexin or ceftibuten. An interval of at least 3 hours should be allowed between administration of zinc and any of these medicines. Medicines that reduce the absorption of zinc such as penicillamine should not be taken together with Zinc Sulfate. An interval of at least 3 hours should be allowed between administration of zinc and medicines such as penicillamine.
Copper: Zinc may inhibit the absorption of copper.
Calcium salts: The absorption of zinc may be reduced by calcium salts.
Iron: The absorption of zinc may be reduced by oral iron, also the absorption of oral iron may be reduced by zinc.
Trientine: The absorption of zinc may be reduced by trientine, also the absorption of trientine may be reduced by zinc.
Diuretics: Thiazide diuretics have been found to increase urinary zinc excretion. Fiber, found in bran, whole-grain breads and cereals or Phosphorus-containing foods, with zinc supplements may reduce zinc absorption by formation of non-absorbable complexes.
Folic Acid: Some studies have found that folate can decrease the absorption of zinc.
Tetracycline: Oral zinc salts may decrease the absorption of tetracycline by forming insoluble chelates.

4.6. FERTILITY, PREGNANCY AND LACTATION:

Fertility: No data on the effect of zinc on fertility are available.
Pregnancy: This medicine is not intended for adults. There are limited data on the use of zinc sulfate in pregnant women.
Breast-feeding: Zinc is present in breast milk.

4.7. EFFECTS ON ABILITY TO DRIVE AND USE MACHINES:

There is no evidence regarding the effect of zinc on the ability to drive or use machines.

4.8. UNDESIRABLE EFFECTS:

The Adverse reactions considered related to zinc sulfate are listed below by body system, organ class and absolute frequency. Frequencies are defined as very common (≥1/10), common (1/100 to 1/10), uncommon (1/1000 to 1/100), rare (1/10 000 to 1/1000), and very rare (< 1/10 000).
Nervous system disorders: ***Frequency not known:*** Headache.
Gastrointestinal disorders: ***Very common:*** Vomiting. ***Common:*** Regurgitation. ***Frequency not known:*** Abdominal pain, dyspepsia, nausea, gastric irritation and gastritis
General disorders and Administration Site Conditions: ***Frequency not known:*** Irritability, lethargy.

4.9. OVERDOSE

Symptoms: High doses of zinc cause emesis. In addition, zinc sulfate is corrosive at high doses, and may cause irritation and corrosion of the gastrointestinal tract, including ulceration of the stomach and possible perforation. Overdose with zinc has also been associated with acute renal tubular necrosis and interstitial nephritis. Prolonged high-dose zinc supplementation may result in copper deficiency.
Treatment: For acute zinc overdose, treatment is primarily supportive, but giving milk or alkali carbonates and activated charcoal may be useful in cases of substantial ingestions of zinc tablets. Chelating agents such as sodium calcium edetate may be useful.

5. PHARMACOLOGICAL PROPERTIES

5.1. PHARMACODYNAMIC PROPERTIES:

Pharmacotherapeutic group: Anti-diarrhoeal for children mineral supplements, **ATC code:** A12CB01.
Zinc is an essential trace element which is present in a wide range of foods. It is found in all tissues. Zinc sulfate is used for the treatment of acute and persistent diarrhoea in children. Normal growth and tissue repair depend on adequate zinc levels.
Mechanism of action: Zinc is an integral part of several enzymes important for protein and carbohydrate metabolism. Severe zinc deficiency is associated with growth retardation, primary hypogonadism, skin disease, disturbances of taste and smell, and impaired immunity, with increased susceptibility to infection. Zinc supplementation has been shown to reduce the duration and severity of diarrhoea in populations of children with a high incidence of zinc deficiency, and also to reduce the frequency of recurrence in the subsequent 2–3 months. The benefits of zinc are possibly associated with reconstitution of the immune response. Direct inhibitory effects of zinc on enteric pathogens have also been reported.

SUMMARY OF PRODUCT CHARACTERISTICS

5.2. PHARMACOKINETICS:
Absorption: Zinc is incompletely absorbed from the gastrointestinal tract and the absorption is reduced in the presence of some dietary constituents such as phytates.
Distribution: Bioavailability of dietary zinc varies widely between different sources, but is about 20- 30%. Zinc is distributed throughout the body with the highest concentration found in muscle, bone, skin and prostatic fluids.
Biotransformation and Elimination: The majority of zinc is stored in the liver and kidney, chiefly intracellularly, and bound to metalloproteins. It is primarily excreted in the faeces. Small amounts are lost in urine and perspiration.

5.3. PRECLINICAL SAFETY DATA:
Non-clinical data have not revealed significant hazards for human, based on standard studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, and reproductive toxicity. Effects in non-clinical studies were observed only at exposures sufficiently in excess of the maximum human exposure to be of little clinical relevance.

6. PHARMACEUTICAL PARTICULARS

6.1. LIST OF EXCIPIENTS:

OSIRIS® 20mg/5ml Oral Solution:
- Sucrose
- Sucralose
- Sodium benzoate
- Sodium metabisulphate
- Citric acid anhydrous
- Maltodextrin
- Alpha cyclodextrin
- Peach flavour
- Purified water q.s. to

OSIRIS® *Quick* 20mg Tablet:
- Microcrystalline cellulose
- Mannitol
- Sorbitol powder
- Crospovidone Type-A
- Aspartame powder
- Peppermint flavor
- Silicon dioxide fumed
- Magnesium stearate

6.2. INCOMPATIBILITIES:
Not applicable.

6.3. SHELF LIFE:
See expiry on the pack.

6.4. SPECIAL PRECAUTIONS FOR STORAGE:
Avoid exposure to heat, light, humidity and freezing. Store between 15 to 30°C. Improper storage may deteriorate the medicine.
Keep out of reach of children.
For Oral Solution: Medicine should not be used if container is leaking or it contains un-dissolved particle(s).

6.5. NATURE AND CONTENTS OF CONTAINER:
OSIRIS® 20mg/5ml Oral Solution: Amber glass bottle with tamper-proof aluminium cap with PE wad, pack size 60ml.
OSIRIS® *Quick* 20mg Tablet: Alu/Alu blister, pack size is 10's.

6.6. SPECIAL PRECAUTIONS FOR DISPOSAL OF A USED PRODUCT:
No special requirements.

6.7. DRUG PRODUCT SPECIFICATIONS:
OSIRIS® 20mg/5ml Oral Solution: USP Specs.
OSIRIS® *Quick* 20mg Tablet: USP Specs.

7. MARKETING AUTHORISATION HOLDER

Manufactured by:
SAMI Pharmaceuticals (Pvt.) Ltd.
F-95, Off Hub River Road, S.I.T.E., Karachi-Pakistan
www.samipharmapk.com
Mfg. Lic. No. 000072

8. MARKETING AUTHORISATION NUMBER(S)

OSIRIS® 20mg/5ml Oral Solution: 066902
OSIRIS® *Quick* 20mg Tablet: 074898

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

OSIRIS® 20mg/5ml Oral Solution: 18th October, 2010
OSIRIS® *Quick* 20mg Tablet: 7th August, 2015

10. DATE OF REVISION OF THE TEXT

اوسیرس اورل سلوشن/ اوسیرس کوئیک ٹیبلٹ

(زنک سلفیٹ) (زنک سلفیٹ)

ہدایات:

خوراک ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

صرف رجسٹرڈ ڈاکٹر کے نسخے کے مطابق فروخت کریں۔

بچوں کی پہنچ سے دور رکھیں۔

دوا کو گرمی، روشنی، نمی اور منجمد ہونے سے محفوظ ۱۵ سے ۳۰

ڈگری سینٹی گریڈ کے درمیان میں رکھیں ورنہ دوا خراب ہو جائیگی۔

برائے اورل سلوشن: دوا کے لیک ہونے یا اس میں کوئی غیر حل پذیر شے نظر آنے کی صورت میں ہرگز استعمال نہ کریں۔