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10. Date of revision of the text

RWANDA FDA
Rwanda Food and Drugs Authority

1. NAME OF THE MEDICINAL PRODUCT

Ped Zinc Tablets

1.1 Strength

Each dispersible tablet contains Zinc Sulphate Monohydrate 54.9mg equivalent to Elemental Zinc 20mg

1.2 Pharmaceutical Form

Tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

2.1 Qualitative declaration

Zinc Sulphate Monohydrate

2.2 Quantitative declaration

Each dispersible tablet contains Zinc Sulphate Monohydrate 54.9mg equivalent to elemental Zinc 20mg

For full list of excipients, see section 6.1

2.3 Salts and hydrates

Zinc Sulphate Monohydrate contains Sulphate, which is a salt

2.4 Esters and pro-drugs

Zinc Sulphate Monohydrate is not neither an ester nor a pro-drug

2.5 Oral powders for solution or suspension

Ped Zinc Tablets are dispersible tablets. The tablets do not involve any reconstitution.

2.6 Parenterals excluding powders for reconstitution

Ped Zinc Tablets contain Zinc Sulphate Monohydrate which is used by oral administration. Because of this, Ped Zinc Tablets is not a parenteral.

2.7 Powders for reconstitution prior to parenteral administration

Ped Zinc Tablets contain Zinc Sulphate Monohydrate which is used by oral administration. Because of this, Ped Zinc Tablets is not a parenteral.

2.8 Concentrates

Ped Zinc Tablets do not contain any concentrate and does not require any dilution.

2.9 Transdermal patches

Ped Zinc Tablets is used by oral administration

2.10 Multidose solid or semi-solid products

Ped Zinc Tablets contain only Zinc Sulphate as the API

2.11 Biological medicinal products

Ped Zinc Tablets is a generic product that contains Zinc Sulphate Monohydrate. During the manufacture of the product, no human materials were used and Zinc Sulphate Monohydrate does not involve any biological origin.

3. PHARMACEUTICAL FORM

Tablet

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Zinc Sulphate Monohydrate Tablets are indicated in children suffering from acute and persistent diarrhea, respiratory tract infections, common cold, malaria, acrodermatitis enteropathica, sickle cell anaemia and wilsons disease.

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

4.2 Posology

As directed by the physician or

Acute diarrhea: For children below 6 months: 10mg elemental Zinc daily for 10-14 days. For children above 6 months: 20mg elemental Zinc 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 enteropanthica: 1-2mg elemental zinc per kg of body weight daily.

Ped Zinc Tablets should be taken between meals but if GI upset occurs, it can be taken with food. In case of vomiting within half an hour following the intake of tablet, give another tablet.

Place the tablet in a teaspoon/tablespoon. Add about 5ml water or breast milk. Let the tablet disperse (around 45 seconds). Give the entire spoonful to the child.

4.3 Method of Administration

Oral Administration

4.4 Contraindications

Zinc Sulphate Monohydrate Tablets 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.

4.5 Special Warnings and Precautions for Use

Problems in human beings and especially for pediatrics have not been documented with intake of normal daily recommended amounts of Zinc. Keep the medicine out of reach of children.

4.6 Paediatric Population

There are no specific special warnings and precautions for children under 3 years. However, if there are children who are hypersensitive or allergic should avoid using Opele Lotion.

4.7 Interaction with other medicinal products and other forms of interaction

Combinations containing any of the following depending on the amount present may interact with Zinc.

Diuretics: Thiazide diuretics have been found to increase urinary Zinc excretion. Fiber found in bran, whole grain breads and cereals or phosphorus-containing food, with Zinc supplement 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.

4.8 Additional information on special populations

The contraindications, special warnings and precautions and interaction with other medicinal products of Ped Zinc Tablets does not affect any special populations.

4.9 Paediatric Population

Ped Zinc Tablets can be administered to children below 6 months and above 6 months

4.10 Fertility, pregnancy and lactation

Problems in humans have not been documented with intake of normal daily recommended amounts.

Use extreme caution during pregnancy.

4.11 Effects on ability to drive and use machines

Effects on ability to drive and use machines have not been documented.

4.12 Undesirable effects

Adverse reactions are rare but if excessive doses of Zinc are used it may cause copper deficiency. Nausea and vomiting may occur. If GI upset occurs, Zinc Sulphate Monohydrate Tablets can be taken with food, but foods high in calcium, phosphorus and phytates must be avoided.

4.13 Overdose

Symptoms: Overdosage includes dizziness or fainting, yellow eyes or skin, chest pain or shortness of breath, vomiting etc.

Treatment

Dilute with milk or water. For specific treatment intramuscular or intravenous edetate calcium disodium at a dose of 50 to 75 mg per kg of body weight per day in 3 to 6 divided doses for up to 5 days shall be given.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacological Properties

Pharmacotherapeutic group and ATC Code

Pharmacotherapeutic group: **Anti - diarrhoeal for children**

ATC Code: **A12CB01**

Pharmacodynamic Properties - Zinc Sulphate Monohydrate is a Zinc salt used for the treatment of Zinc deficiency. Zinc Sulphate Monohydrate contains 23 percentage of elemental Zinc. Zinc Sulphate Monohydrate is absorbed over a broad pH range and may cause mild GI irritation. Zinc is an essential element of nutrition and traces are present in wide range of foods. It is a constituent of many enzyme systems and is present in all the tissues.

Normal growth and tissue repair depend upon adequate Zinc. Zinc acts as an integral part of several enzymes important to protein and carbohydrates metabolism. Features of zinc deficiency include growth retardation and defects of rapidly dividing tissues such as the skin and the intestinal mucosa. Zinc facilitates wound healing and helps maintain normal growth rates, normal skin hydration and senses of taste and smell.

Mechanism of Action – Zinc improves absorption of water electrolytes. Zinc supplements prevent subsequent episodes of diarrhea. WHO and UNICEF recommend daily zinc supplements for children with acute diarrhea to curtail the severity of the episode and prevent further occurrences in the ensuing 2-3 months. Zinc deficiency in human alters several aspects of immune function. Immune defects associated with zinc deficiency include impaired function of lymphocytes, natural killer cells and neutrophils. Zinc deficiency has also been hypothesized to exacerbate malaria and other diseases(infection with human immunodeficiency virus and tuberculosis) that rely on macrophage killing of infected cells.adequate intakes of zinc shorten the duration of respiratory tract infections including common cold.

5.2 Pharmacokinetic Properties

Zinc is incompletely absorbed from the gastrointestinal tract and the absorption is reduced in the presence of some dietary constituents such as phytates. 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. It is primarily excreted in the faeces. Small amounts are lost in urine and perspiration.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber in addition to that included in other sections of the summary of product characteristics.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Microcrystalline Cellullose, Colloidal Anhydrous Silica, Maize Starch, Aspartame, Croscarmellose Sodium, Raspberry Flavor, Sodium Starch Glycolate, Magnesium Stearate.

6.2 Incompatibilities

None known

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store in a dry place below 30^0C

Protect from light

6.5 Nature and contents of container

Ped Zinc Tablets are packed in blister packs of 10 tablets in 10 inner boxes (dispenser cartons) along with leaflets then packed in an outer box (dispenser carton) made of chipboard material.

6.6 Special precautions for disposal and other handling

No special requirements

7. MARKETING AUTHORIZATION HOLDER & MANUFACTURING SITE ADDRESSES

Manufacturing Authorization Holder (MAH)

Name: SHELYS PHARMACEUTICALS LIMITED

Address: Plot No. 696, New Bagamoyo Road, Mwenge

P.O. BOX 32781, Dar es Salaam

Country: Tanzania

Telephone: +255 22 2771715/6/7

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E-Mail: info@tz.betashelys.com

Manufacturing Site(s)

Name: SHELYS PHARMACEUTICALS LIMITED

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Country: Tanzania

Telephone: +255 22 2771715/6/7

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AND

Name: BETA HEALTHCARE INTERNATIONAL LTD

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P.O. BOX 42569-00100 GPO Nairobi

Country: KENYA

Telephone: +254202652042/89

Telefax: +25420556198 / 2944

E-Mail: info@ke.betashelys.com

8. MARKETING AUTHORIZATION NUMBER

6919/27/10

9. DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

Date of first authorization: 8/4/2010
Date of latest renewal: 22/11/2019

10. DATE OF REVISION OF THE TEXT

November 2020

RWANDA FDA
Rwanda Food and Drugs Authority