SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product
ZINCAT-OD Syrup

2. Qualitative and quantitative composition
Each 5 ml contains:
Zinc Sulphate Monohydrate USP e.q to elemental Zinc Sulphate…….20 mg

For the full list of excipients, see section 6.1.

3. Pharmaceutical form
Oral syrup

Description: Colourless to slightly yellow syrup free from foreign matter.

4. Clinical particulars
4.1 Therapeutic indications
Zincat-OD syrup is indicated in infants and children for all kinds of diarrhoea e.g.,
- Acute diarrhoea
- Persistent diarrhoea
- Chronic diarrhoea
- Recurrent diarrhoea

4.2 Posology and method of administration
Children: (1-2 years) one spoon full (5ml) once daily (10-14 days)

Infants: (Under six months) half spoonful (2.5ml) once daily (10-14 days) or as directed by the physician.

And adequately marked 5 ml measuring spoon is provided in the carton.

4.3 Contraindication
Zincat-OD syrup is contraindicated in patients with hypersensitivity to Zinc.

4.4 Special warnings and precautions for use
Dosage reduction may be required in patients with renal dysfunction.

4.5 Interaction with other medical products and other forms of interaction
Absorption of Zinc may be reduced by iron supplements, penicillamine and tetracycline. Zinc supplements reduce absorption of Floroquinolones, iron and tetracycline.

4.6 Pregnancy and lactation
Pregnancy
The safety of Zincat-OD syrup in pregnancy has not been established.

Lactation
Zinc crosses the placenta and is present in breast milk. The safety of Zincat-OD syrup in lactation has not been established.

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, however Zincat-OD syrup is not expected to have any effect on the ability to drive and use machines.

4.8 Undesirable effects
At the recommended dosage no side effects are observed. However, large doses of Zinc may cause nausea, vomiting, heart burn, abdominal pain, dyspepsia and gastric irritation.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare providers are asked to report any suspected adverse reactions to the marketing authorization holder or if available via the national reporting system (See details below);

Paper based reporting: TMDA yellow card
Online reporting: https://sqrt.tmda.go.tz/
*USSD reporting: send a simple short text message to report any suspected Adverse Drug Reaction by dialing *152*00# and follow the instructions.*

4.9 Overdose
In acute over dosage, Zinc salts are corrosive due to formation of Zinc Chloride which is treated by administration of milk and alkali carbonates.

5. Pharmacological properties
There is sufficient evidence to recommend the inclusion of Zinc as adjunctive therapy to oral rehydration salt in the standard management of both dysentery and non-dysenteric acute diarrhoea. Chronic diarrhoea can be a sign of Zinc deficiency and diarrhoea can lead to excess Zinc losses and Zinc deficiency. A WHO report conclude that administration of the Zinc at a dose of about 10 to 20 mg daily for 14 days is efficacious is significantly reducing the severity and duration of diarrhoea in children. The low osmolarity of Zincat-OD avoids osmotic diarrhoea. The timely use of Zincat-OD for 10-14 days as recommended not only. Zinc is incompletely absorbed from gastrointestinal tract. 90% Zinc is excreted through faeces and 25 in urine.

5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Other mineral supplements, ATC code: A12CB01.

Zinc sulfate is a zinc salt used for the treatment of acute and persistent diarrhoea in children. Zinc is an essential trace element which is present in a wide range of foods. It is found in all tissues. Normal growth and tissue repair depend upon adequate zinc levels. Zinc acts as an integral part of several enzymes important to 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 diarrhea in populations of children with a high incidence of zinc deficiency, and also to reduce the frequency of recurrences in the subsequent 2-3 months. The beneficial effects of zinc are likely associated with reconstitution of the immune response, however direct inhibitory effects of zinc on enteric pathogens have also been reported.

5.2 Pharmacokinetic properties
Absorption Zinc is incompletely absorbed from the small bowel, with between 10 and 40% of an ingested dose absorbed. Numerous dietary components can interfere with zinc absorption, particularly phytates and fibre, which bind to zinc, resulting in poorly absorbed zinc complexes. The absorption of zinc from Zincat-OD was examined in 10 healthy, zinc replete, adult male volunteers (baseline mean plasma zinc level ± SD of 15.1 ± 3.5 mmol/L). Absorption of zinc from 1½ Zincat-OD (i.e., a 30 mg dose) was rapid, with a maximal increase in mean plasma zinc level (± SD) of 11.6 (± 6.0) mmol/L observed within approximately 2 hours of administration. Distribution Approximately 60% of circulating zinc is bound to albumin and roughly 30% is bound to macroglobulin. The majority of zinc is stored in the liver and kidney, chiefly intracellularly, and bound to metalloproteins. Elimination In adults, it has been estimated that approximately 0.5 to 1.0 mg/day is secreted in the biliary tract and excreted in the stool, while 0.5 to 0.8 mg/day is excreted in the urine.

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
Sucralose
Sodium Benzoate
Vanillin
Sodium Metabisulphite
Citric acid Monohydrate
Maltodextrin
Sucrose
Alpha Cyclodextrin
Purified Water

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
24 months

6.4 Special precautions for storage
Keep out of reach of children.
Protect from light and heat.
Do not store above 30°C.
Replace cap securely after use.
To be used under medical device.

6.5 Nature and contents of container
60 ml amber coloured glass bottle, packed in a printed carton.

6.6 Special precautions for disposal and other handing

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 Name of the Marketing Authorization Holder

M/s ATCO Laboratories
B-18, S.I.T.E, Karachi, 75700
Pakistan.

8 Marketing Authorisation Number

TAN 20 HM 0453

9 Date of First Authorisation / Renewal of The Authorisation

25/09/2020

10 DATE OF REVISION / APPROVAL OF THE TEXT