SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Solvazinc® 45mg Effervescent Tablets.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 45mg of elemental zinc (equivalent to 125mg of zinc sulfate monohydrate).

Excipient(s) with known effect: each tablet contains 115.5mg of sorbitol (E420) and 106mg of sodium.

For the full list of the excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Effervescent tablet.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Zinc sulfate is a source of zinc which is an essential trace element and involved in a number of body enzyme systems.

Solvazinc®is indicated in adults and children for the treatment of zinc deficiency.

4.2 Posology and method of administration

Method of administration: oral after dissolution in water.

Adults: One tablet, dissolved in water, once to three times daily after meals.

Children:

More than 30kg:	One tablet, dissolved in water, once to three times daily after meals.
10 - 30kg:	½ tablet, dissolved in water, once to three times daily after meals.
Less than 10kg:	½ tablet, dissolved in water, once daily after meals

4.3. Contraindications

Hypersensitivity to the active substance or any of the excipients listed in section 6.1.

Copper deficiency (see section 4.5).

4.4. Special warnings and precautions for use

Accumulation of zinc may occur in cases of renal failure.

This product contains sorbitol (E420), therefore patients with rare hereditary problems of fructose intolerance should not take this medicine.

This medicinal product contains 106mg sodium per tablet, equivalent to 5.3% of the WHO recommended maximum daily intake of 2g sodium for an adult.

Therapy should continue until clinical improvement occurs and Solvazinc can be replaced by dietary measures unless there is severe malabsorption, metabolic disease or continuing zinc loss. Continued long-term treatment with Solvazinc if zinc deficiency is no longer present may lead to copper deficiency (see section 4.8).

4.5. Interaction with other medicinal products and other forms of interaction

Copper:
Zinc may inhibit the absorption of copper (see section 4.3).

Tetracycline Antibacterials:
Zinc may reduce the absorption of concurrently administered tetracyclines, also the absorption of zinc may be reduced by tetracyclines; when both are being given an interval of at least three hours should be allowed.

Quinolone Antibacterials:
Zinc may reduce the absorption of quinolones; ciprofloxacin, levofloxacin, moxifloxacin, norfloxacin and ofloxacin.

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.

Penicillamine:
The absorption of zinc may be reduced by penicillamine, also the absorption of penicillamine 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.

4.6. Fertility, pregnancy and lactation

The safety of this product in human pregnancy has not been established. Zinc crosses the placenta and is present in breast milk.

4.7. Effects on ability to drive and use machines

Solvazinc® has no influence on the ability to drive and use machines.

4.8. Undesirable effects

Zinc salts may cause abdominal pain, dyspepsia, nausea, vomiting, diarrhoea, gastric irritation and gastritis. There have also been cases of irritability, headache and lethargy observed.

Zinc may interfere with the absorption of copper, leading to reduced copper levels, and potentially copper deficiency. The risk of copper deficiency may be greater with long-term treatment (e.g. if zinc deficiency is no longer present; see Section 4.4) and/or with higher doses of zinc. Signs of copper deficiency can include neurological symptoms e.g. polyneuropathy (symptoms of which can include gait disturbances, ataxia and paraesthesia and/or hypoaesthesia) and haematological symptoms e.g. anaemia, neutropenia, leucopenia and pancytopenia.

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 professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9. Overdose

Zinc sulfate is corrosive in overdosage. Symptoms are corrosion and inflammation of the mucous membrane of the mouth and stomach; ulceration of the stomach followed by perforation may occur. Gastric lavage and emesis should be avoided. Demulcents such as milk should be given. Chelating agents such as sodium calcium edetate may be useful.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic Group: Mineral Supplement, ATC Code: A12CB01

Zinc is an essential trace element involved in many enzyme systems. Severe deficiency causes skin lesion, alopecia, diarrhoea, increased susceptibility to infections and failure to thrive in children. Symptoms of less severe deficiency include distorted or absent perceptions of taste and smell and poor wound healing.

5.2 Pharmacokinetic properties

Zinc is absorbed from the gastrointestinal tract and distributed throughout the body. The highest concentrations occur in hair, eyes, male reproductive organs and bone. Lower levels are present in liver, kidney and muscle.

In blood 80% is found in erythrocytes. Plasma zinc levels range from 70 to 110µg/dl and about 50% of this is loosely bound to albumin. About 7% is amino-acid bound and the rest is tightly bound to alpha 2-macroglobulins and other proteins.

5.3 Preclinical safety data

None stated.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Solvazinc® contains the following excipients:

Sorbitol (E420), mannitol (E421), sodium hydrogen carbonate, citric acid, saccharin sodium, povidone K25, sodium citrate and sodium carbonate anhydrous.

6.2 Incompatibilities

None

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store below 25°C, protect from moisture.

6.5 Nature and contents of container

Polypropylene containers with polyethylene caps and packed in cartons of three containers. Each tablet container contains 30 tablets. The tablet containers also contain a desiccant capsule.

6.6 Special precautions for disposal

None.

7 MARKETING AUTHORISATION HOLDER

Galen Limited
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BT63 5UA
UK

8 MARKETING AUTHORISATION NUMBER

PL 27827/0003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

01/09/1998

10 DATE OF REVISION OF THE TEXT

10/10/2023