NALIS® YEAST TABLETS

SUBMITTED BY

NALIS PHARMACEUTICALS LTD

ADDRESS:

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SUMMARY OF PRODUCT CHARACTERISTICS

(SmPC)

1. NAME OF THE DRUG PRODUCT

Name of product: NALIS® YEAST TABLETS (Yeast Powder 300mg)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Yeast Powder 300mg

Excipients……**...q.s**

Excipients with known effect
For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Oral tablets

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Nalis® Yeast Tablets is used as a superfood supplement for the improvement of vision heath of diabetic patients, luxuriant skin and general well-being.

4.2 Posology and method of administration

Posology

Nalis® Yeast Tablets is intended to be used by adults (including the elderly) and children.

Adults: 20 tablets to be taken at once or in divided doses preferably in between meals.

Children: 10 tablets to be taken at once or in divided doses preferably in between meals.

Method of Administration

For oral administration

4.3 Contradindications

Nalis® Yeast Tablets is contraindicated in people that have:

- **Yeast allergy**
- **Recurrent vaginal yeast infections**
- **Ulcerative colitis**
- **Crohn disease: Yeast can make Crohn disease worse; people with the disease should not use.**
- **Weakened immune system for an organ transplant or advanced HIV (It may trigger fungal infection)**

4.4 Special warnings and precautions for use

Nalis® Yeast Tablets should be taken short-term as it is the period possibly safe for most people. There is not enough information to know whether yeast tablets are safe to use long-term.

Diabetic patients using Nalis® Yeast Tablets should monitor their blood sugars carefully if they are on diabetes medications as it may cause dangerously low blood sugar.

4.5 Interaction with other drug products and other forms of interaction

Monoamine Oxidase Inhibitors (MAIOs) work by keeping the body from breaking down tyramine (a substance in some foods). Yeast has large amounts of the tyramine, thus taking yeast tablets with an MAOI could lead to a tyramine spike that can cause a sudden rise in blood pressure known as hypertensive crisis.
The narcotic, Demerol (meperidine) is used to treat moderate to severe pain. It can cause hypertensive crisis when taken with yeast.
Yeast may interfere with antifungal drugs such as Diflucan (fluconazole), Lamisil (terbinafine), Sporanox (itraconazole).

4.6 Fertility, pregnancy and lactation

There is not enough reliable information to know whether yeast tablets are safe to use during pregnancy or breast-feeding. It is therefore safer to avoid use.

4.7 Effects on ability to drive and use machines

Nalis® Yeast Tablets have no influence on the ability to drive and use machines.

4.8 Undesirable effects

Nalis® Yeast Tablets may cause headaches, stomach upset, gas.

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 to the regulatory bodies such as NAFDAC.

4.9 Overdose

It should be kept in mind that natural products are not always necessarily safe and dosages can be important. Be sure to follow relevant directions on product labels and consult your healthcare provider before using.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Yeast tablets are a rich source of minerals, B-complex vitamins and chromium.

Mechanism of action

Due to the chromium content of Yeast, it helps the body insulin more effectively to lower blood sugar levels. It also seems to stimulate chemicals (intestinal enzymes) that could help relieve diarrhea. Yeast also might help to fight bacteria that cause infections in the intestine as well as improve the body's defenses against viral lung infections such as flu and the common cold.

5.2 Pharmacokinetic properties

The absorption of yeast is more effective in individuals with poor chromium status. All the B Vitamins are water soluble vitamins. Quantities in excess of the bodies requirements are excreted either unchanged or as metabolites, mainly in the urine but to a lesser extent also in the faeces.

5.3 Preclinical safety data

Not available

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose Monohydrate B.P

Maize Starch B.P

Purified talc B.P

Magnesium Stearate B.P

Sodium Starch Glycollate B.P

Methyl Paraben B.P

Propyl Paraben B.P

6.2 Incompatibilities

Refer to section 4.5

6.3 Shelf life

Five years

6.4 Special precautions for storage

Keep container tightly closed in a dry and well-ventilated place. Store in a cool place. Recommended storage temperature is 2 – 8 °C.

6.5 Nature and contents of container

Plastic jars containing 100 tablets packed into cardboard cartons.

6.6 Special precautions for disposal of used medicinal product or waste materials derived from such medicinal product and other handling of the product

Dispose to a licensed disposal company.

7. APPLICANT/HOLDER OF CERTIFICATE OF PRODUCT REGISTRATION

NAME:
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8. DRUG PRODUCT MANUFACTURER

NAME:
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9. NAFDAC REGISTRATION NUMBER(S):

Not available