SUMMARY OF PRODUCT CHARACTERISTICS.

1. **Name of the medicinal product**
   Dawastin Suspension.
2. **Qualitative and quantitative composition**
   Each mL contains: Nystatin 100,000 IU.

3.0 Pharmaceutical form: Suspension for oral administration.

Yellow suspension, free from visible evidence of contamination.

4.0 Clinical particulars

4.1 Therapeutic indications

Nystatin is used in the prophylaxis and treatment of candidiasis of the mucous membranes, intestinal or oesaphageal candidiasis. Nystatin has also been administered with antibiotics in various regimens to suppress the overgrowth of gastrointestinal flora. Nystatin is also used for the treatment of lesions of the mouth.

4.2 Posology and method of administration:

Method of administration: Oral route of administration.

2ml of Dawastin (200,000 units of Nystatin) four times daily (1ml in each side of the mouth).

Note: Limited clinical studies in premature and low birth weight infants indicate that 1ml four times daily is effective.

Children and adults:

4-6ml of Dawastin (400,000 to 600,000 units nystatin) four times daily (one half of dose in each side of the mouth). The preparation should be retained in the mouth for as long as possible before swallowing.

4.3 Contraindications

Nystatin is contraindicated in patients with a history of hypersensitivity to any of its components.

4.4 Special warnings and precautions for use

Nystatin Oral Suspension contains sodium metabisulphite (E223) which may rarely cause severe hypersensitivity reactions and bronchospasm.

Nystatin Oral Suspension contains propyl p-hydroxybenzoate and methyl p-hydroxybenzoate which may cause allergic reactions (possibly delayed).

Nystatin oral preparations should not be used for treatment of systemic mycoses.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

4.6. Pregnancy and lactation

Pregnancy: Animal reproductive studies have not been conducted with Nystatin.

It is not known whether Nystatin can cause foetal harm when administered to a pregnant woman or can affect reproductive capacity; however absorption of nystatin from the gastro-intestinal tract is negligible. Nystatin should be prescribed during pregnancy only if the potential benefits to be derived outweigh the possible risks involved.

Breastfeeding: It is not known whether Nystatin is excreted in human milk. Although gastrointestinal absorption is insignificant, caution should be exercised when Nystatin is prescribed for a breast-feeding woman.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

Nausea, vomiting, and diarrhoea have occasionally been reported after oral use of nystatin. Oral irritation or sensitisation may occur. Rashes, including urticaria, have occurred and Stevens-Johnson syndrome has been

reported rarely. Irritation may occur rarely after the topical use of nystatin. Generalized pustular eruptions were reported in 3 patients after oral nystatin. Subsequent sensitivity testing revealed delayed (type IV) hypersensitivity to nystatin.

4.9 Overdose and treatment

Oral doses of Nystatin in excess of five million units daily have caused nausea and gastrointestinal upsets. There have been no reports of serious toxic effects or super infections. In case of overdosage, symptomatic therapy (e.g. gastric lavage) and general supportive measures are recommended.

5. 0 Pharmacological properties

5.1 Pharmacodynamic properties.

Pharmacotherapeutic group: Antifungals for topical use, **ATC code**: D01AA01**.**

Pharmacology:

Nystatin is a polyene antifungal antibiotic which is both fungistatic and fungicidal in vitro against a wide spectrum of yeasts and yeast like fungi. It acts by binding to sterols in the cell membrane of the fungus with a resultant change in membrane permeability allowing leakage of intracellular components. Nystatin is obtained from streptomyces noursei and is the first well tolerated antifungal antibiotic of dependable efficacy for the treatment of cutaneous, oral and intestinal infections caused by candida (monilia) albicans and other candida species. It exhibits no appreciable activity against bacteria. Nystatin provides specific therapy for all localized forms of candidiasis. Symptomatic relief is rapid, often occurring within 24 to 72 hours after the initiation of treatment. Cure is affected both clinically and mycologically in most cases of localized candidiasis.

5.2 Pharmacokinetic properties

Gastrointestinal absorption of nystatin is insignificant. Most orally administered nystatin is passed unchanged in the stool. Significant concentrations of nystatin may appear occasionally in the plasma of patients with renal insufficiency during oral therapy with conventional dosage forms. Mean nystatin concentrations in excess of those required in vitro to inhibit growth of clinically significant candida persisted in saliva for approximately 2 hours after the start of oral dissolution of 400,000 units of nystatin administered simultaneously to 12 healthy volunteers.

5.3 Preclinical safety data

No additional data of relevance.

6. Pharmaceutical particulars

6.1 List of excipients

Sodium Saccharin,
Sodium CMC,
Sorbitol solution
Sodium methyl paraben
Sodium propyl paraben,
Glycerin,
Sodium Metabisulphite
Pineapple liquid flavour,
Tartrazine colour
Citric acid,
Bronopol,
Sodium citrate,
Disodium edetate,
Propylene glycol
Purified water

6.2 Incompatibilities

None known.

6.3 Shelf life

24 months from the date of manufacture. (2 years)

6.4 Special precautions for storage

Store in a dry place, below 30°C. Protect from light.

6.5 Nature and contents of container

30 mL and 12mL pack in amber coloured PET bottle in a unit box along with a literature insert.

6.6 Special precautions for disposal and other handling

None applicable.

7. Marketing authorization holder/Registrant.

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9. Date of revision of the text:

December 2019.