1.3 PRESCRIBING INFORMATION

1.3.1 PRODUCT INFORMATION (SUMMARY OF PRODUCTS CHARACTERISTICS)

FUCLEAR V
(Clotrimazole,Metronidazole and Lactobacillus Sporogenes Vaginal Tablets)

1. NAME OF THE MEDICINAL PRODUCT

Clotrimazole,Metronidazole and Lactobacillus Sporogenes Vaginal Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each uncoated vaginal tablet contains:
Clotrimazole BP……....100 mg
Metronidazole BP……..500 mg
Lactobacillus Sporogens...150 million spores
Excipients…….. Q.S.

3. PHARMACEUTICAL FORM

Tablet
For vaginal administration.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Vaginal candidiasis, Acute ulcerative gingivitis (Vincent's), Giardiasis, Bacterial dysbiosis, Bloating, Constipation, Gas, Gastrointestinal system, Geriatric and glucose metabolism support, High cholesterol, Lactose intolerance, Vaginitis.

4.2 Posology and method of administration

The usual dose is one tablet three times daily. This dosage may be increased to two tablets three times daily if infections are not adequately suppressed. The treatment should generally be continued for at least 48 hours after clinical cure to prevent relapse.

4.3 Contraindications

Contraindicated to patients hypersensitive to any of the ingredients.

4.4 Special warnings and precautions for use

Not for oral use.
Use only if you have already had a vaginal yeast infection diagnosed by a medical practitioner and you have the same symptoms now, otherwise consult your doctor. These symptoms include itching and burning of the vagina and sometimes a white discharge.

If there is no improvement in 3 days or if symptoms have not disappeared within 7 days, then consult a medical practitioner as not all vaginal infections are caused by yeasts.
Consult a medical practitioner if you have abdominal pain, fever or a foul-smelling vaginal discharge before or during use of this medication.
If symptoms recur within 2 months, consult a medical practitioner.
If you are pregnant or think you may be pregnant or are nursing, do not use this medication except on the advice of a medical practitioner.
Do not use in girls under 12 years of age, except on the advice of a medical practitioner.
If skin rash or new irritation occurs, discontinue use.
Pseudomembranous colitis has been reported with the use of metronidazole.

4.5 Interaction with other medicinal products and other forms of interaction

Alcoholic beverages should not be consumed during metronidazole therapy and for at least one day afterward because abdominal cramps, nausea, vomiting, headaches, and flushing may occur.
Psychotic reactions have been reported in alcoholic patients who are using metronidazole and disulfiram concurrently. Metronidazole should not be given to patients who have taken disulfiram within the last two weeks.
Antibiotic drugs interacts with Lactobacillus.
Medications that decrease the immune system (Immunosuppressants) interacts with Lactobacillus

4.6 Pregnancy and lactation

Because of the potential for tumorigenicity, shown for metronidazole in mouse and rat studies, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother. Metronidazole is secreted in human milk in concentrations similar to those found in plasma.
If you are pregnant, breast-feeding or trying for a baby, tell your doctor or midwife before using Clotrimazole.
To treat internal thrush, your doctor may recommend that you use the pessary without the help of an applicator.

4.7 Undesirable effects

Local reactions, Contact allergic dermatitis, Lower abdominal cramps, increase in urinary frequency or skin rash may occur.
There have been reports of peculiar taste in the mouth, furred tongue, nausea, vomiting and gastro-intestinal upset. Drowsiness, headache, vertigo, ataxia, disorientation, skin rashes and pruritus have been reported.
Alcohol should be avoided during treatment with metronidazole.
No adverse side effects have been reported during or after supplementation.

4.8 Overdose

Gastro-intestinal disturbances and central nervous system depression may follow accidental oral ingestion.
Treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Clotrimazole is a broad spectrum antimycotic with fungicidal properties.

Metronidazole is an anti-protozoal agent effective against Trichomonas vaginalis, Entamoeba histolytica and in giardiasis. Metronidazole is useful for the treatment of infections caused by various anaerobic bacteria, particularly Bacteroides fragilis.

5.2 Pharmacokinetic properties

Metronidazole

Disposition of metronidazole in the body is similar for both oral and intravenous dosage forms, with an average elimination half-life in healthy humans of eight hours.

The major route of elimination of metronidazole and its metabolites is via the urine (60 to 80% of the dose), with fecal excretion accounting for 6 to 15% of the dose. The metabolites that appear in the urine result primarily from side-chain oxidation [1-(β-hydroxyethyl)-2-hydroxymethyl-5- nitroimidazole and 2-methyl-5-nitroimidazole-1-yl-acetic acid] and glucuronide conjugation, with unchanged metronidazole accounting for approximately 20% of the total. Renal clearance of metronidazole is approximately 10 mL/min/1.73 m2.

Clotrimazole

metronidazole is well absorbed; Following vaginal administration, C max and T max are 281 ng/mL and 9.5 h, respectively.

Metronidazole appears in cerebrospinal fluid, saliva, and breast milk in concentrations similar to those found in plasma. Less than 20% is protein bound.

Metabolites are 2–hydroxymethyl and acidic metabolite.

Routes of elimination are via urine (60% to 80%) and feces (6% to 15%). Renal Cl is approximately 10 mL/min per 1.73 m 2 . The half-life is 8 h in healthy adults, and the hydroxy-metabolite half-life is 15 h.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose	BP
Maize Starch	BP
Croscarmellose Sodium	BP
Microcrystalline Cellulose	BP
Colloidal Anhydrous Silica	BP
Povidone	BP
Polyethylene Glycol – 6000	BP
Purified water	BP
Magnesium Stearate	BP
Croscarmellose Sodium	BP
Polacrilin Potassium (Kyron T-314)	USP-NF

6.2 Incompatibilities

NA

6.3 Shelf life

36 Months

6.4 Special precautions for storage

Store below 30°C.
KEEP OUT OF REACH OF CHILDREN

6.5 Nature and contents of container

1X 6 Tablets of Alu/Alu strip is packed in a printed carton along with package insert.

6.6 Special precautions for disposal and other handling

No special requirements.

7. MARKETING AUTHORISATION HOLDER

saga LABORATORIES
Ahmedabad
Gujarat, India.
E-mail: info@sagalabs.com
URL: www.sagalabs.com

8. MARKETING AUTHORISATION NUMBER(S)

G/25/1877