Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product:
FUCLEAR V TABLET

2. Qualitative and quantitative composition
Each uncoated vaginal tablet contains:
Clotrimazole BP.....100 mg
Metronidazole BP.....500 mg
Lactobacillus Sporogens...150 million spores

Excipient with known effect: Each tablet contains Lactose.

For a full list of excipients, see section 6.1

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 Effects on ability to drive and use machines

This medication has no or negligible influence on the ability to drive or use machinery.

4.8 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.

Reporting of suspected adverse reactions: Healthcare professionals are requested to report any suspected adverse reactions via National Pharmacovigilance Electronic Reporting Systems' to the respective National Regulatory Authorities.

4.9 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.
ATC Code: J01CE30

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 m^2.

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.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on studies of repeated dose toxicity, genotoxicity and carcinogenicity.

Clotrimazole was not teratogenic in reproductive toxicity studies in mice, rats and rabbits. In rats high oral doses were associated with maternal toxicity, embryotoxicity, reduced foetal weights and decreased pup survival.

In rats clotrimazole and/or its metabolites were secreted into milk at levels higher than in plasma by a factor of 10 to 20 at 4 hrs after administration, followed by a decline to a factor of 0.4 by 24 hrs.

6. Pharmaceutical Particulars

6.1 List of Excipients

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

None known.

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 Content 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 Authorization Holder

Saga Laboratories
Ahmedabad
Gujarat, India.
E-mail: info@sagalabs.com
URL: www.sagalabs.com

8. Marketing Authorization Number

H2022/CTD8484/15208

9. Date of first authorization/renewal of the authorization

11/11/2022

10. Date of revision of the text

11/11/2022