Megtite Sus.

(Megestrol Acetate 800mg/20mL)

■ **COMPOSITON**

20 mL of suspension contains

Megestrol acetate ..... 800 mg.

■ **APPEARANCE**

White-cream suspension of orange taste in the opaque bottle or aluminum foil pouch

■ **INDICATION**

Increase your appetite and prevent or reverse significant weight loss (e.g., muscle wasting in cancer or AIDS)

■ **DOSACE & ADMINSTRATION**

The recommended adult initial dosage of Megestrol acetate Oral Suspension is 800 mg/day(20 mL/day). Shake container well before using. In clinical trials, evaluating different dose schedules, daily doses of 400 and 800 mg/day were found to be clinically effective.

■ **PRECAUTIONS**

1. Warning

1) Megestrol may cause harm to your unborn baby

2) High blood sugar (hyperglycemia) and worsening of diabetes and Cushing's syndrome may occur.

3) This drug may decrease adrenal gland activity, adrenocorticotropin (ACTH) stimulation testing has revealed the frequent occurrence of asymptomatic pituitary-adrenal suppression. The possibility of adrenal insufficiency should be considered in any patient who presents with symptoms and signs suggestive of hypoadrenalism (hypotonia, weakness, dizziness, nausea). Failure to recognize inhibition of the hypothalamic-pituitary-adrenal axis may result in death, so consideration should be given to the use of empiric therapy with stress doses of a rapidly acting glucocorticoid.

2. Megestrol Acetate should not administer to the following patients

1) Patients with a history of hypersensitivity to this drug

2) Pregnant woman or suspected pregnancy

3. Should be given cautiously to the following patients

1) Patient with a history of thromboembolic disease

2) diabetic patient(Exacerbation of preexisting diabetes with increased insulin requirements has been reported in association with the use of this drug)

4. Adverse Events

1) Adverse events which occurred in at least 5% of patients in any arm of the two clinical efficacy trials and the open trial are listed below by treatment group.

Adverse events which occurred in at least 5% of patients

Megestrol Acetate, Mg/day No. of Patients	Trial 1 (n=236)				Trial 2 (n=87)		Open Label Trial
	Placebo 0 (N=34)	Megestrol acetate mg/day			Placebo 0 (N=38)	Megestrol acetate mg/day	
		100(N=68)	400(N=69)	800(N=65)		800(N=49)	1200(N=176)
Diarrhea	15	13	8	15	8	6	10
Impotence	3	4	6	14	0	4	7
Rash	9	9	4	12	3	2	6
Flatulence	9	0	1	9	3	10	6
Hypertension	0	0	0	8	0	0	4
Asthenia	3	2	3	6	8	4	5
Insomnia	0	3	4	6	0	0	1
Nausea	9	4	0	5	3	4	5
Anemia	6	3	3	5	0	0	0
Feve	3	6	4	5	3	2	1
Libido Decreased	3	4	0	5	0	2	1
Dyspepsia	0	0	3	3	5	4	2
Hyperglycemia	3	0	6	3	0	0	3
Headache	6	10	1	3	3	0	3
Pain	6	0	0	2	5	6	4
Vomiting	9	3	0	2	3	6	4
Pneumonia	6	2	0	2	3	0	1
Urinary Frequency	0	0	1	2	5	2	1

2) Adverse events which occurred in 1% to 3% of all patients enrolled in the two clinical efficacy trials.

(1) Special Sense : amblyopia

(2) Digestive System: constipation, dry mouth, hepatomegally, increased salivation and oral candidiasis.

(3) Cardiovascular System : cardiomyopathy and palpitation.

(4) Respiratory System : dyspnea, cough, pharyngitis and lung disorder.
(5) Blood : leukopenia
(6) Urogenital System : albuminuria, urinary incontinence, urinary tract infection and gynecomastia.
(7) Nervous System : paresthesia, confusion convulsion, depression, neuropathy, hypesthesia and abnormal thinking.
(8) Skin : alopecia, herpes, pruritus, vesiculobullous rash, sweating and skin disorder.
(9) Metabolism : LDH increased, edema and peripheral edema.
(10) Body as a Whole : abdominal pain, chest pain, infection, candidiasis and sarcoma.

3) Abnormal reaction reported in PMS
(1) In PMS, thromboembolic symptoms, pulmonary embolism and glucose intolerance is reported with thrombotic phlebitis
(2) In the interior of a country for 5 years, an object of 694 peoples, tested after marketing, additional abnormal reactions is following that is reported over the 2 cases, it is not uncovered with cause and effect of drugs.
- anxiety, stomatitis, mucositis, omodynia

5. General caution

1) Treatment for reduction of weight is should have decided after finding base of weight loss possibility
2) This medication is to be used as directed by the physician
3) Long term treatment with this may increase the risk of respiratory infections.

6. Use in pregnancy

1) This medication must not be used during pregnancy. Megestrol may cause harm to your unborn baby.
2) Women of child-bearing age should use an effective form of birth control while using this medication.

7. Use in lactation

Megestrol may pass into breast milk and could have undesirable effects on a nursing infant. therefore, breast-feeding is not recommended while using this drug

8. Use in HIV-infected Woman

All 10 women in the clinical trials reported breakthrough bleeding.

9. Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

10. The others.

1) In animal toxicology the reproductive capability of male offspring of megestrol acetate-treated females was impaired.
2) In animal toxicology pregnant female treated with megestrol acetate showed a reduction in fetal weight and number of live births, and feminization of male fetuses.

11. Treatment of overdosage

1) No serious unexpected side effects have resulted from studies involving Megestrol Acetate administered in dosages as high as 1200mg/day.
2) Due to its low solubility it is postulated that dialysis would not be an effective means of treating overdose.

12. Precaution of storage and treatment

1) Keep out of reach of children.
2) Should not substitute other container in order to maintain quality of the drug and avoid misapplication.

■ **STORAGE**

Store Megestrol Acetate Suspension between 15℃–25℃ and dispense in a tight container, Protect from heat.

■ **PACKAGE :** 20mL x 20 Sachets / Box

■ **SHELF LIFE :** 24 months

This drug is manufactured in accordance with Korea Good Manufacturing Practice (KGMP) as recommended by WHO.