

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

AMINORAL 1.5 Film-Coated Caplet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated caplet contains:

α -Ketoisoleucine, Calcium salt	100.5 mg
α -Ketoleucine, Calcium salt	151.5 mg
α -Ketophenylalanine, Calcium salt	102 mg
α -Ketovaline, Calcium salt	129 mg
α -Hydroxymethionine, Calcium salt	88.5 mg
Lysine Acetate	157.5 mg
Threonine	79.5 mg
Tryptophan	34.5 mg
Histidine	57 mg
Tyrosine	45 mg

3. PHARMACEUTICAL FORM

Film-coated caplet; yellow with thin glossy coating; plain

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Therapy of chronic renal insufficiency in connection with high calory-low protein diet 40 g/day or less in compensated or decompensated retention i.e generally in patients with a glomerular filtration rate (GFR) between 5 and 50 ml/minutes

4.2 Posology and method of administration

For oral use.

If not otherwise prescribed, 8 – 16 caplets in total per day during meals divided into three times.

Swallow whole.

This dosage applies to adults (70 kg/body weight)

Aminoral 1.5 film-coated caplets are given as long as the glomerular filtration rate is between 5 and 50 ml/minute, and concomitantly, dietary should contain 40 g/day protein or less (adults).

4.3 Contraindications

Hypercalcaemia, disturbances of amino acid metabolism.

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1

4.4 Special warning and precautions for use

- It is important to ensure sufficient calories provided to the patient
- Precautions shall be taken in case of concomitant administration of calcium preparations which may cause hypercalcaemia. The serum calcium level should be monitored regularly.
- In the presence of hereditary phenylketonuria, attention should be given to the fact that Aminoral 1.5 contains phenylalanine.
- Monitoring of the serum phosphate levels is needed in case of concomitant administration of aluminium hydroxide
- There is no experience in children and pregnant women from the use of Aminoral.

4.5 Interaction with other medicinal products and other forms of interaction

- Concomitant administration of calcium-containing drugs may cause or aggravate elevated serum calcium levels.
- Drugs that form hardly soluble compounds with calcium (e.g. tetracyclines, quinolones such as ciprofloxacin and norfloxacin as well as drugs containing iron, fluoride or estramustine) should not be taken at the same time with Aminoral 1.5 to avoid disturbed absorption of the active substances. An interval of at least two hours should elapse between the ingestion of Aminoral 1.5 and these drugs.
- The susceptibility to cardioactive glycosides, and hence the risk for arrhythmia will increase if Aminoral produces elevated serum calcium levels (see section 4.8).
- As the severity of uremic symptoms decrease under the influence of Aminoral 1.5, the dose aluminium hydroxide administration should be reduced. Pay attention to a reduction of serum phosphate.

4.6 Fertility, Pregnancy and lactation

There is no report about usage on pregnancy.

Caution should be exercised when prescribing to pregnant women.

4.7 Effects on ability to drive and use machines

None

4.8 Undesirable effects

Hypercalcemia may occur

If hypercalcaemia occurs, the intake of vitamin D should be reduced. In case of persisting hypercalcaemia, the dose of Aminoral 1.5 as well as the intake of any other calcium sources has to be reduced. (See also section 4.5)

4.9 Overdosage

No case of overdose has been reported

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Amino acids, including combinations with polypeptides, ATC code: V06DD

5.1 Pharmacodynamic Properties

-

5.2 Pharmacokinetics Properties

-

5.3 Preclinical safety data

-

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Povidone

Macrogol 6000 (Polyethylene Glycol / PEG 6000)

Maize starch

Talc

Silica, Colloidal Anhydrous

Crospovidone

Magnesium stearate

Isopropyl Alcohol

Purified Water

Titanium dioxide

Quinolin Yellow E 104

Eudragit E-100

Acetone

Triacetin (Glycerol Triacetate)

6.2 Incompatibilities

Not applicable

6.3 Shelflife

2 years

6.4 Special precautions for storage

Store at temperature below 30°C. Protect from light. Keep out of reach of children.

HARUS DENGAN RESEP DOKTER

6.5 Nature and Contents of Container

Ten strips of 10 caplets are packed in a carton

Pack size: 100 caplets

6.6 Special Precautions for Disposal

None

7. MARKETING AUTHORIZATION HOLDER

PT. Ethica Industri Farmasi

Kawasan Industri Jababeka Tahap V, Blok B1B1,

Desa Jayamukti, Kecamatan Cikarang Pusat

Kabupaten Bekasi, Jawa Barat

8. MARKETING AUTHORIZATION NUMBER

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10. DATE OF RELEASE OF THE TEXT

11. VERSION NUMBER

AMINORAL 1.5
KETOACID
ESSENTIAL AMINO ACIDS
Film-Coated Caplet

COMPOSITION:

Each film-coated caplet contains:

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L-Threonine	79.5 mg
L-Tryptophan	34.5 mg
L-Histidine	57 mg
L-Tyrosine	45 mg

INDICATION:

Therapy of chronic renal insufficiency in connection with high calory-low protein diet 40 g/day or less in compensated or decompensated retention i.e generally in patients with a glomerular filtration rate (GFR) between 5 and 50 ml/minutes

DOSAGE AND METHOD OF ADMINISTRATION:

For oral use.

If not otherwise prescribed, 8 – 16 caplets in total per day during meals divided into three times. Swallow whole.

This dosage applies to adults (70 kg/body weight)

Aminoral 1.5 film-coated caplets are given as long as the glomerular filtration rate is between 5 and 50 ml/minute, and concomitantly, dietary should contain 40 g/day protein or less (adults).

SIDE EFFECT:

Hypercalcaemia may occur

If hypercalcaemia occurs, the intake of vitamin D should be reduced. In case of persisting hypercalcaemia, the dose of Aminoral as well as the intake of any other calcium sources has to be reduced

WARNING AND PRECAUTIONS:

- It is important to ensure sufficient calories provided to the patient
- Precautions shall be taken in case of concomitant administration of calcium preparations which may cause hypercalcaemia. The serum calcium level should be monitored regularly.
- In the presence of hereditary phenylketonuria, attention should be given to the fact that Aminoral 1.5 contains phenylalanine.
- Monitoring of the serum phosphate levels is needed in case of concomitant administration of aluminium hydroxide
- There is no experience in children and pregnant women from the use of Aminoral.

CONTRAINDICATION:

- Hypercalcaemia, disturbances of amino acid metabolism.
- Hypersensitivity to the active substances or to any of the excipients

DRUG INTERACTION:

- Concomitant administration calcium-containing drugs may cause or aggravate elevated serum calcium levels.
- Drugs that form hardly soluble compounds with calcium (e.g. tetracyclines, quinolones such as ciprofloxacin and norfloxacin as well as drugs containing iron, fluoride or estramustine) should not be taken at the same time with Aminoral 1.5 to avoid disturbed absorption of the active substances. An interval of at least two hours should elapse between the ingestion of Aminoral and these drugs.
- The susceptibility to cardioactive glycosides, and hence the risk for arrhythmia will increase if Aminoral produces elevated serum calcium levels.
- As the severity of uremic symptoms decrease under the influence of Aminoral, the dose aluminium hydroxide administration should be reduced. Pay attention to a reduction of serum phosphate.

PRESENTATION:

Box, 10 strips @ 10 film-coated caplets

Reg No ...

STORE BELOW 30°C
PROTECT FROM LIGHT
KEEP OUT OF REACH OF CHILDREN
ON MEDICAL PRESCRIPTION ONLY

Produced By:
PT. Fresenius Kabi Combiphar
Bandung – Indonesia

For:
PT. Ethica Industri Farmasi
Bekasi – Indonesia

AMINORAL 1.5
ASAM KETO
ASAM AMINO ESSENSIAL
Kaplet Salut Selaput

KOMPOSISI:

Tiap kaplet salut selaput mengandung:

α -Ketoleucine, <i>Calcium salt</i>	100.5 mg
α -Ketoleucine, <i>Calcium salt</i>	151.5 mg
α -Ketophenylalanine, <i>Calcium salt</i>	102 mg
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INDIKASI:

Untuk terapi insufisiensi ginjal kronik bersama dengan diet tinggi kalori-rendah protein 40g/hari atau kurang, dalam retensi yang terkompensasi atau dekompensasi, yaitu umumnya pada penderita dengan laju filtrasi ginjal antara 5 dan 50 mL/menit.

DOSIS DAN CARA PEMBERIAN:

Untuk pemakaian oral. Jika tidak diresepkan lain, total 8 – 16 kaplet per hari sewaktu makan dibagi menjadi tiga kali. Telan sekaligus. Dosis ini untuk dewasa dengan berat badan 70 kg.

Kaplet Aminoral 1.5 diberikan selama laju filtrasi glomerulus antara 5 dan 50 mL/menit, dan secara bersamaan, makanan harus mengandung protein 40g/hari atau kurang (dewasa).

EFEK SAMPING:

Dapat terjadi hiperkalsemia.

Jika hiperkalsemia terjadi, asupan vitamin D harus dikurangi. Jika terjadi *persisting hypercalcemia*, dosis Aminoral dan asupan sumber kalsium lainnya harus dikurangi.

PERINGATAN DAN PERHATIAN:

- Penting untuk memastikan pemberian kalori yang cukup pada pasien.
- Hati-hati jika diberikan bersamaan dengan obat yang mengandung kalsium karena bisa terjadi hiperkalsemia. Kadar serum kalsium harus dimonitor secara periodik.
- Hati-hati pemberian Aminoral pada pasien yang memiliki riwayat *phenylketonuria* secara genetik, karena pemberian Aminoral pada Jika memiliki riwayat *phenylketonuria*, karena Aminoral 1.5 mengandung *phenylalanine*.
- Jika diberikan bersamaan dengan obat yang mengandung Aluminium hidroksida, diperlukan monitoring terhadap kadar serum fosfat.
- Belum ada pengalaman penggunaan Aminoral pada kehamilan dan anak-anak.

KONTRAINDIKASI:

- Hiperkalsemia, gangguan metabolisme asam amino.
- Hipersensitif terhadap zat aktif atau zat tambahan yang terkandung dalam Aminoral.

INTERAKSI OBAT:

- Pemberian bersama obat-obat yang mengandung kalsium dapat menyebabkan atau memperburuk peningkatan kadar serum kalsium.
- Obat-obatan yang membentuk senyawa dengan kalsium yang bersifat sukar larut (misal. Tetrasiklin, golongan

kuinolin seperti *ciprofloxacin* dan *norfloxacin* serta obat-obatan yang mengandung zat besi, *fluoride* atau *estramustine*) tidak boleh dikonsumsi bersamaan dengan Aminoral 1.5 untuk menghindari gangguan penyerapan zat aktif. Interval pemberian Aminoral dengan obat-obat tersebut setidaknya dua jam.

- Berpengaruh terhadap *cardioactive glycoside*, karenanya risiko aritmia akan meningkat jika terjadi peningkatan kadar serum kalsium saat penggunaan Aminoral.
- Karena adanya perbaikan gejala uremia akibat pemberian Aminoral, maka dosis Aluminium Hidroksida harus dikurangi. Lakukan monitoring terhadap penurunan serum fosfat.

KEMASAN:

Dus, 10 strip @ 10 kaplet salut selaput
Reg No ...

SIMPAN DIBAWAH SUHU 30°C
TERLINDUNG DARI CAHAYA
JAUHKAN DARI JANGKAUAN ANAK-ANAK
HARUS DENGAN RESEP DOKTER

Produced By:

PT. Fresenius Kabi Combiphar
Bandung – Indonesia

For:

PT. Ethica Industri Farmasi
Bekasi – Indonesia