

**Alfagen** 3X10 Capsules  
(Alfacalcidol) 0.5mcg

الفاجن  
(الفاكليسيدول)  
3X10 كبسولات  
0.5 ملغ/كوبول

**COMPOSITION:**

Each Capsule Contains:

Alfacalcidol .....0.5mcg

(Finished product complies with Genome specifications)

**PROPERTIES**

Alfacalcidol (Alfagen) (1 $\alpha$ -hydroxy vitamin D<sub>3</sub>) is rapidly converted in the liver to 125-dihydroxyvitamin D<sub>3</sub>, the metabolite of vitamin D which acts as a regulator of calcium and phosphate homeostasis. As compared with Vitamin D, the main advantage of Alfacalcidol (Alfagen) is the more rapid onset and reversal of action which allows a more accurate dose titration and decreases the risk of prolonged hypercalcaemia.

**PHARMACOKINETICS**

**ABSORPTION:**

Alfacalcidol given orally is well absorbed from small intestine.

**DISTRIBUTION**

Alfacalcidol binds to specific alpha globulins. Peak plasma concentration is achieved approximately 12 hours after single oral dose. Plasma half life is about 3 hours.

**METABOLISM:**

Alfacalcidol is metabolised rapidly in liver. the side chain at position 25 is hydrolyzed by 25-hydroxy lase of hepatitis microsomes and biotransformed into its active metabolite 125-dihydroxy vitamin D<sub>3</sub> hepatic.

**EXCRETION**

Approximately 72 hours of an oral dose of alfacalcidol is excreted in the urine and faeces within 48 hours and almost 100% excreted in 07 days.

**INDICATIONS**

Diseases caused by disturbances in the calcium metabolism in consequence of reduced endogenous production of 125-dihydroxyvitamin D<sub>3</sub>.

- ! Renal osteodystrophy, postoperative or idiopathic hypoparathyroidism
- ! Vitamin D-resistant rickets or osteomalacia
- ! Vitamin D-dependent rickets
- ! Neonatal hypocalcaemia or rickets
- ! Malabsorption of calcium
- ! Osteoporosis

**DOSAGE**

The dosage of Alfacalcidol (Alfagen) should be adjusted according to careful monitoring of the patient's serum calcium level.

ADULTS & CHILDREN ABOVE 20Kg	
Disease	Dose/Day
Renal osteodystrophy	0.5 to 1.0 mcg
Hypoparathyroidism & other diseases associated with anomalies of vitamin D metabolism	(Adult dose) 1.0 to 4.0 mcg (pediatric dose) 0.01 to 0.03 mcg/Kg
Postmenopausal Osteoporosis	1 mcg
Maintenance dose:	0.25 mcg to 1mcg / Day

Children under 20 kg body weight: 0.05 mcg / Kg/Day Neonates: 0.01 mcg / Kg/Day Elderly: 0.5 mcg / Day

It is important to adjust the dosage according to the biochemical responses to avoid hypercalcaemia.

**PRECAUTIONS**

Throughout the treatment with Alfacalcidol (Alfagen) regular serum calcium determinations are essential, and the dosage

should be adjusted so that the serum calcium level does not exceed the normal range. If hypercalcaemia develops, Alfalcidol (Alfagen) should be immediately withdrawn until plasma calcium levels return to normal. Alfalcidol (Alfagen) may then be started at half the previous dose.

*Geriatric use:* Since physiological function is generally decreased in the elderly. Caution should be exercised in the dosage.

*Pediatric use:* Treatment in children should be started at low dosage and gradually increased.

#### **PREGNANCY AND LACTATION**

Alfalcidol (Alfagen) should only be used in pregnancy and during lactation if considered essential by the physician.

#### **DRUG INTERACTIONS**

- ! If taken with preparations containing magnesium, hypermagnesemia is reported to occur.
- ! Concomitant administration with digitalis preparations may cause arrhythmia.
- ! Co administration with calcium preparations may cause hypercalcaemia.
- ! Patient taking barbiturates or anticonvulsants may require larger doses of Alfalcidol (Alfagen)

#### **SIDE-EFFECTS**

Apart from hypercalcaemia, following are the few adverse effects infrequently .

Anorexia, nausea, vomiting, abdominal distention, diarrhoea, constipation, itching etc.

#### **CONTRAINDICATION**

Alfalcidol (Alfagen) is contraindicated in hypercalcaemia.

#### **OVERDOSAGE**

Hypercalcaemia is treated by stopping treatment with Alfagen. Severe hypercalcaemia may require additional treatment with a loop diuretic, intravenous fluids and corticosteroids.

#### **HOW SUPPLIED**

Pack of 3x10 capsules in Alu-Alu Blister.

Shelf life: 02years

**To be sold on the prescription of a registered medical practitioner only.**

**Keep all medicines out of the reach of children.**

**Store below 30°C. Protect from heat, light and moisture.**

خوراک:

ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

ہدایات:

دوا کو ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔

روشنی، نمی اور گرمی سے بچائیں۔

تمام ادویات بچوں کی پہنچ سے دور رکھیں۔



Manufactured by:  
**GENOME PHARMACEUTICALS (PVT.) LTD.**  
Plot # 16/1, Phase IV, Industrial Estate Hattar-Pakistan.

Marketed by:



ALLIANZE MED PHARMA