CHUPET®
VITAMIN B12 INJECTION
1MG/ 2ML

COMPOSITION: Each 1 mL contains 500 micrograms (1 mg)
Cyanocobalamin BP 0.5mg

(SMPC)

1. Name of the medicinal product

CHUPET® VITAMIN B12 INJECTION 1MG/ 2ML

2. Qualitative and quantitative composition

Each 1 mL contains 500 micrograms (1 mg)

Cyanocobalamin BP 0.5mg.

3. Pharmaceutical form

Solution for Injection

4. Clinical particulars

4.1 Therapeutic indications
Addisonian pernicious anaemia. Prophylaxis and treatment of other macrocytic anaemias associated with vitamin B12 deficiency. Tobacco amblyopia and Leber's optic atrophy

4.2 Posology and method of administration
Posology

Adults and Paediatric population

The following dosage are suitable for adults and children.

Addisonian pernicious anaemias and other macrocytic anaemias without neurological involvement.

Initially 250 to 1000 micrograms intramuscularly on alternate days for one or two weeks, then 250 micrograms weekly until the blood count is normal

Maintenance: 1000 micrograms every two to three months

Addisonian pernicious anaemia and other macrocytic anaemias with neurological involvement

Initially:1000 micrograms on alternate days as long as improvement is occurring.

Maintenance:1000 micrograms every two of three months.

Prophylaxis of macrocytic anaemia associated with vitamin B_{12} deficiency resulting from gastrectomy, some malabsorption syndromes and strict vegetarianism

1000 micrograms every two or three months.

Tobacco amblyopia and Leber's optic atrophy

Initially:1000 micrograms daily by intramuscular injection for two weeks then twice weekly as long as improvement is occurring.

Maintenance: 1000 micrograms every one to three months as required.

Method of Administration

Intramuscular injection

4.3 Contraindications
Hypersensitivity to Cyanocobalamin or to any of the ingredient in this preparation.

4.4 Special warnings and precautions for use
It is advisable to confirm the diagnosis of Vitamin B12 deficiency before giving Cyanocobalamin; regular monitoring of the blood is recommended..

If megaloblastic anaemia fails to respond, folate metabolism should be investigated. Doses in excess of 10 micrograms daily may produce a haematological response in patients with folate deficiency. Indiscriminate administration may mask the true diagnosis.

Cardiac arrhythmias secondary to hypokalaemia during initial therapy have been reported. Plasma potassium should therefore be monitored during this period.

4.5 Interaction with other medicinal products and other forms of interaction

Chloramphenicol

Parenteral chloramphenicol may attenuate the effect of Cyanocobalamin in anaemia.

Oral contraceptives

The serum concentration of Cyanocobalamin may be lowered.

The above interactions are unlikely to be of clinical significance but should be taken into account when performing assays for blood concentrations.

Vitamin B12 assays by microbiological techniques are invalidated by antimetabolites and most antibiotics.

Paediatric population

Interaction studies have only been performed in adults.

4.6 Fertility, pregnancy and lactation

Pregnancy

Cyanocobalamin injection should not be used for the treatment of megaloblastic anaemia of pregnancy.

Breast-feeding

Cyanocobalamin is secreted into breast milk but is unlikely to harm the infant.

Fertility

No data available

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

The following undesirable effects may occur with the use of Cyanocobalamin Acetate in the following frequencies:

Very common (> 1/10)

Common (> 1/100, <1/10)

Uncommon (> 1/1,000, <1/100)

Rare (> 1/10,000, <1/1,000)

Very rare (<1/10,000), (cannot be estimated from the available data) are not known.

There are no modern clinical studies available that can be used to determine the frequency of undesirable effects. Therefore, all the undesirable effects listed are classed as “frequency unknown”.

The following effects have been reported and are listed below by body system:

System organ class	Frequency	Undesirable effects
Blood and lymphatic system disorders	Not Known	Reactive thrombocytosis can occur during the first weeks of use in megaloblastic anaemia.
Immune system disorders	Not Known	Hypersensitivity reactions including rash; itching; exanthema. Antibodies to Cyanocobalamin-transcobalamin II complex have developed during Cyanocobalamin therapy. Anaphylaxis
Metabolism and nutrition disorders	Not Known	Initial hypokalaemia

Nervous system disorders	Not Known	Headache, paraesthesia, tremor.
Cardiac disorders	Not Known	Arrhythmias secondary to hypokalaemia.
Gastrointestinal disorders	Not Known	Nausea, vomiting, diarrhoea.
General disorders and administration site conditions	Not Known	Fever, chills, hot flushes; dizziness; malaise; pain; Injection site reactions including injection site pain, injection site erythema, injection site pruritus, injection site induration, and injection site swelling.
Skin and subcutaneous tissue disorders	Not Known	Acneiform and bullous eruptions
Renal and urinary disorders	Not Known	Chromaturia

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

4.9 Overdose
Treatment is unlikely to be required in the case of overdose.

5. Pharmacological properties

5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Antianaemic preparations -Vitamin B_{12}

ATC code: B03BA03

Cyanocobalamin is used in the treatment and prevention of Vitamin B12 deficiency. For adults, the daily requirement of Vitamin B12 is probably about 1 to 2 micrograms and this amount is present in most normal diets. However, Vitamin B12 only occurs in animal products, not in vegetables, and therefore strict vegetarian or vegan diets that exclude dairy products may provide an inadequate amount, although a deficiency may not be apparent for many years.

Deficiency is more likely in patients with malabasorption syndromes or metabolic disorders, nitrous-oxide induced megalobastosis, or following gastrectomy or extensive ileal resection. Deficiency leads to megaloblastic anaemias and demyelination and other neurological damage.

On oral intake, Vitamin B12 substances bind to intrinsic factor, a glycoprotein secreted by the gastric mucosa, and are then actively absorbed from the gastrointestinal tract. A specific anaemia known as pernicious anaemia develops in patients with an absence of intrinsic factor. Absorption is also impaired in patients with disease or abnormality of the gut.

Treatment usually results in rapid haematological improvement and a striking clinical response. However, neurological symptoms respond more slowly.

5.2 Pharmacokinetic properties
Distribution: Transcobalamin II appears to be involved in the rapid transport of the cobalamins to tissues. Cyanocobalamin is extensively bound to specific plasma proteins (transcobalamins).

Elimination: Cyanocobalamin is stored in the liver, excreted in the bile, and undergoes extensive enterohepatic recycling; part of the dose is excreted in the urine, most of it in the first 8 hours.

Cyanocobalamin diffuses across the placenta and also appears in breast milk. Cyanocobalamin is better retained than cyanocobalamin; 90% of a 100 microgram dose and 30% of a 1000 microgram dose are retained, a range believed to be sufficient for body requirements for 2 to 10 months.

5.3 Preclinical safety data
There is no additional information relevant to the prescriber.

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6. Pharmaceutical particulars

6.1 List of excipients
Glacial acetic acid Ph Eur

Sodium chloride Ph Eur

Water for injection Ph Eur

6.2 Incompatibilities
None known.

6.3 Shelf life
24 months

6.4 Special precautions for storage
Store at or below 30°C. Protect from light.

6.5 Nature and contents of container
Type I glass ampoules in cardboard box.

5 ampoules per pack.

6.6 Special precautions for disposal and other handling
None.

7. Marketing authorisation holder

DISTRIBUTOR/ MARKETER
18/20, Ogungbesan Street, Coker, Surulere,
Lagos.

Manufactured by:
TIANJIN KINGYORK GROUP HUBEI TIANYAO PHARMACEUTICAL CO., LTD
No. 99, Hanjiang Bei Road, Xiangyang, Hubei, China