SUMMARY OF PRODUCT CHARACTERISTICS

KINTHOMOL (METHOCARBAMOL TABLETS USP 500 MG)

1 NAME OF THE MEDICINAL PRODUCT:

KINTHOMOL
METHOCARBAMOL TABLETS USP 500 MG

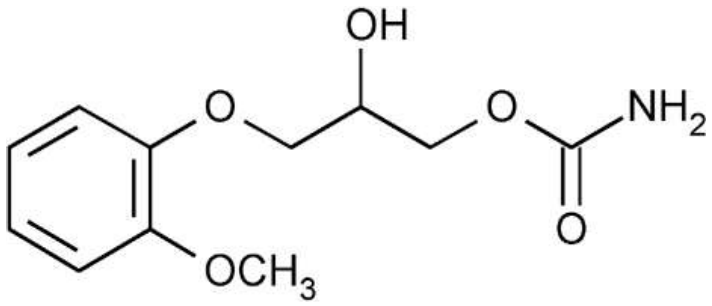
2 QUALITATIVE AND QUANTITATIVE COMPOSITIONS:

CHEMICAL NAME AND THE STRUCTURAL FORMULA OF EACH ACTIVE INGREDIENT:-

METHOCARBAMOL

Chemical Name:
[2-hydroxy-3-(2-methoxyphenoxy)propyl] carbamate

Chemical Structure:



MOLECULAR FORMULA
C11H15NO5

MOLECULAR WEIGHT
241.24g/mol

NAME AND QUANTITY OF EACH INGREDIENT:

UNIT DOSE

Ingredients	**Qty./ TAB In mg**	**Use/Function**
Active Ingredient		
$ **Methocarbamol** USP	510.0	Muscle relaxant(Active)
In Active Ingredients		
* Starch BP	40.0	Diluents / Binder
Starch for paste BP	25.0	Binder
# Purified Water BP	q.s.	Vehicle
Purified Talc BP	3.00	Glidant
Gelatin BP	5.0	Vehicle
Methyl paraben BP	0.7	Preservative
Propyl paraben BP	0.4	Preservative
Colloidal Silica BP	2.00	Lubricant
Magnesium Stearate BP	3.00	Lubricant
Crosscarmellose Sodium BP	8.00	Disintegrant
Starch BP	3.0	Lubricant

* Quantity of this material is variable as the quantity of active material changes.
# Quantity of these materials will not be calculated in the final weight of the tablets.
$ Includes 2% Overages & Calculation Based.

Reference:
USP= United States Pharmacopeia
BP = British Pharmacopoeia
IHS= In- House Specification

3 PHARMACEUTICAL FORMS:
Oral uncoated tablets
White coloured round shape uncoated tablet, one side break line and plain on other side.

CLINICAL PARTICULARS:
4 INDICATIONS FOR USE:
Methocarbamol is indicated as an adjunct to rest, physical therapy, and other measures for the relief of discomfort associated with acute, painful musculoskeletal conditions. The mode of action of methocarbamol has not been clearly identified, but may be related to its sedative properties. Methocarbamol does not directly relax tense skeletal muscles in man.

5 CONTRAINDICATIONS:
Methocarbamol is contraindicated in patients hypersensitive to methocarbamol or to any of the tablet components.

6 PRECAUTIONS :

Patients should be cautioned that methocarbamol may cause drowsiness or dizziness, which may impair their ability to operate motor vehicles or machinery. Because methocarbamol may possess a general CNS-depressant effect, patients should be cautioned about combined effects with alcohol and other CNS depressants.

7 ADVERSE REACTIONS:

Adverse reactions reported coincident with the administration of methocarbamol include:

Body as a whole: Anaphylactic reaction, angioneurotic edema, fever, headache Cardiovascular system: Bradycardia, flushing, hypotension, syncope, thrombophlebitis

Digestive system: Dyspepsia, jaundice (including cholestatic jaundice), nausea and vomiting

Hemic and lymphatic system: Leukopenia

Immune system: Hypersensitivity reactions

Nervous system: Amnesia, confusion, diplopia, dizziness or lightheadedness, drowsiness, insomnia, mild muscular incoordination, nystagmus, sedation, seizures (including grand mal), vertigo

Skin and special senses: Blurred vision, conjunctivitis, nasal congestion, metallic taste, pruritus, rash, urticarial

8 USES DURING PREGNANCY, LACTATION:

Pregnancy

Animal reproduction studies have not been conducted with methocarbamol. It is also not known whether methocarbamol can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Methocarbamol should be given to a pregnant woman only if clearly needed.

Safe use of methocarbamol has not been established with regard to possible adverse effects upon fetal development. There have been reports of fetal and congenital abnormalities following in utero exposure to methocarbamol. Therefore, methocarbamol should not be used in women who are or may become pregnant and particularly during early pregnancy unless in the judgment of the physician the potential benefits outweigh the possible hazards.

Nursing Mothers

Methocarbamol and/or its metabolites are excreted in the milk of dogs; however, it is not known whether methocarbamol or its metabolites are excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when methocarbamol is administered to a nursing woman.

Pediatric Use

Safety and effectiveness of methocarbamol in pediatric patients below the age of 16 have not been established.

9 DRUG INTERACTIONS:

Methocarbamol may inhibit the effect of pyridostigmine bromide. Therefore, methocarbamol should be used with caution in patients with myasthenia gravis receiving anticholinesterase agents.

10 DOSAGES AND ADMINISTRATION:

Methocarbamol, 500 mg — Adults:

Initial dosage: 3 tablets q.i.d. Maintenance dosage: 2 tablets q.i.d.

Six grams a day are recommended for the first 48 to 72 hours of treatment. (For severe conditions 8 grams a day may be administered). Thereafter, the dosage can usually be reduced to approximately 4 grams a day. OR AS DIRECTED BY PHYSICAN.

11 OVERDOSAGE:

Limited information is available on the acute toxicity of methocarbamol. Overdose of methocarbamol is frequently in conjunction with alcohol or other CNS depressants and includes the following symptoms: nausea, drowsiness, blurred vision, hypotension, seizures, and coma.
In post-marketing experience, deaths have been reported with an overdose of methocarbamol alone or in the presence of other CNS depressants, alcohol or psychotropic drugs.

Treatment

Management of overdose includes symptomatic and supportive treatment. Supportive measures include maintenance of an adequate airway, monitoring urinary output and vital signs, and administration of intravenous fluids if necessary. The usefulness of hemodialysis in managing overdose is unknown.

12 PHARMACOLOGY:

The mechanism of action of methocarbamol in humans has not been established, but may be due to general central nervous system (CNS) depression. It has no direct action on the contractile mechanism of striated muscle, the motor end plate or the nerve fiber.

13 PHARMACOKINETICS:

In healthy volunteers, the plasma clearance of methocarbamol ranges between 0.20 and 0.80 L/h/kg, the mean plasma elimination half-life ranges between 1 and 2 hours, and the plasma protein binding ranges between 46% and 50%.

Methocarbamol is metabolized via dealkylation and hydroxylation. Conjugation of methocarbamol also is likely. Essentially all methocarbamol metabolites are eliminated in the urine. Small amounts of unchanged methocarbamol also are excreted in the urine.

14 STORAGE:

Store below 25°C in a dry place in original package. Do not use later than the date of expiry.
KEEP OUT OF REACH OF CHILDREN.

15 SHELF-LIFE:

36 MONTHS