SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

1.1 Product Name : KINTHOMOL(METHOCARBAMOL USP 500MG)

1.2 Strength:

Each uncoated bilayered tablet contains:

Methocarbamol USP	500 mg
Excipients	Q.S.
Color: Erythrosine	

2. Qualitative and Quantitative Composition

1. QUALITATIVE AND QUANTITATIVE COMPOSITION

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 to be calculated on the basis of its potency
** Quantity to be compensates on increasing quantity of active material.
*** The materials that will not remain in the final product.

3. Pharmaceutical Forms

White coloured, round shaped, biconvex, uncoated bilayered tablet having break line on one side and plain on other side.

4. Clinical Particulars

4.1 Therapeutic Indications

As a short-term adjunct to the symptomatic treatment of acute musculoskeletal disorders associated with painful muscle spasms.

4.2 Posology and Method of administration

Route of Administration: Oral Bilayer Uncoated Tablet

Adults:
The usual dose is 2 tablets four times daily but therapeutic response has been achieved with doses as low as 1 tablet three times daily.

Elderly:
Half the maximum dose or less may be sufficient to produce a therapeutic response.

Children: Not recommended.

Adults including elderly and children over 12 years: One to two tablets every 4-6 hours as required, to a maximum of 8 tablets daily in divided doses.

Children 6-12 years*:*
Half to one tablet every 4-6 hours as necessary, to a maximum of 4 tablets daily in divided doses.

Children under 6 years:
Not recommended for children under 6 years of age.

4.3 Contraindications

Hypersensitivity to methocarbamol or any of the other excipients. Coma or pre-coma states. Known brain damage or epilepsy. Myasthenia gravis.

4.4 Special warning and precaution for use

Caution needed for patients with history of heart, liver or kidney disease, mental illness, electrolyte imbalance, any allergy, who are taking other medications, during pregnancy and breastfeeding. Avoid concomitant use of drugs known to prolong QT interval. It may

cause dizziness, do not drive a car or operate machinery while taking this medication. Do not eat grapefruit or drink grapefruit juice while taking this medication.

4.5 Interaction with other medicinal products and other forms of interactions

Methocarbamol

It may potentiate the effects of other central nervous system depressants and stimulants including alcohol, barbiturates, anaesthetics and appetite suppressants. The effects of anticholinergics, e.g. atropine and some psychotropic drugs may be potentiated by methocarbamol. Methocarbamol may inhibit the effect of pyridostigmine bromide. Therefore methocarbamol should be used with caution in patients with myasthenia gravis receiving anticholinesterase agents.

4.6 Fertility, pregnancy and lactation

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

4.7 Effects on ability to drive and use machines

If you experience drowsiness, dizziness, hypotension or a headache as side-effects when using Methocarbamol Tablet medicine then it may not be safe to drive a vehicle or operate heavy machinery. One should not drive a vehicle if using the medicine makes you drowsy, dizzy or lowers your blood-pressure extensively. Pharmacists also advise patients not to drink alcohol with medicines as alcohol intensifies drowsiness side-effects. Please check for these effects on your body when using Methocarbamol Tablet. Always consult with your doctor for recommendations specific to your body and health conditions.

4.8 Undesirable effects

Adverse reactions reported coincident with the administration of methocarbamol include Angioneurotic oedema, anaphylactic reaction, fever, headache, Bradycardia, flushing, hypotension, syncope, Dyspepsia, jaundice , nausea and vomiting, Leucopenia, Restlessness, anxiety, tremor, amnesia, confusion, diplopia, dizziness or light-headedness, vertigo, drowsiness, insomnia, mild muscular incoordination, nystagmus, seizures Blurred vision, conjunctivitis with nasal congestion, metallic taste, pruritus, rash, urticaria.

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4.9 Overdose

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.

Management of overdose of methocarbamol 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 haemodialysis in managing overdose is unknown.

5. Pharmacological properties

5.1 Pharmacodynamic Properties

Methocarbamol

Pharmacotherapeutic group: Muscle relaxants, centrally acting agents; Carbamic acid esters, ATC code: M03BA03.

KINTHOMOL is used as a short-term adjunct to the symptomatic treatment of acute musculoskeletal disorders associated with painful muscle spasms.

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

The peripheral action may also be due to inhibition of prostaglandin synthesis or to inhibition of the synthesis or actions of other substances that sensitise pain receptors to mechanical or chemical stimulation.

hypothalamic heat-regulation centre to produce peripheral vasodilation resulting in increased blood flow through the skin, sweating and heat loss. The central action probably involves inhibition of prostaglandin synthesis in the hypothalamus.

5.2 Pharmacokinetic Properties

Methocarbamol
Methocarbamol is absorbed from the gastro-intestinal tract and produces peak plasma concentrations after about 1-3 hours. Its activity derives from the intact molecule and only a small proportion is converted to guaiphenesin.

Renally impaired
The clearance of methocarbamol in renally-impaired patients on maintenance haemodialysis was reduced about 40% compared to a normal population, although the mean elimination half-life in these two groups was similar (1.2 versus 1.1 hours, respectively).

Hepatically impaired
In patients with cirrhosis secondary to alcohol abuse, the mean total clearance of methocarbamol was reduced approximately 70% compared to a normal population (11.9 L/hr), and the mean elimination half-life was extended to approximately 3.4 hours. The fraction of methocarbamol bound to plasma proteins was decreased to approximately 40 to 45% compared to 46 to 50% in an age- and weight-matched normal population.

5.3 Preclinical Safety data

Methocarbamol
No information is available.

6. Pharmaceutical Particulars

6.1 List of Excipients
Maize Starch BP
Hydroxy Propyl Cellulose (LH-11) BP

Sodium Lauryl Sulphate BP
Sodium Starch Glycolate BP
Povidone (K-30) BP
Purified Water BP
Color Supra Erythrosine IH
Magnesium Stearate BP
Croscarmellose Sodium BP

6.2 Incompatibilities

None

6.3 Shelf Life

36 months from the date of manufacturing

6.4 Special precautions for storage

Store at a temperature not exceeding 30ºC in a dry place. Protect from light. Keep out of reach of children.

6.5 Nature and contents of container

1 X 10 Tablets in Alu-PVC Blister Pack

Exported by:

ROENTGEN IMPEX

NO. 2063/A, RABARI VAS, KHORAJ
VILLAGE, DIST. GANDHINAGAR-382735,
GUJARAT, INDIA

Manufactured by:

Naxcure Healthcare Pvt. Ltd.
SURVEY NO.-889/1,B/H CHADASANA ONGC, CHADASANA-
JHULASAN ROAD, AT & POST.- JHULASAN, TA.- KADI, DIST.-
MEHSANA-382705
GUJARAT, INDIA
