SUMMARY OF PRODUCT CHARACTERISTICS

1. TRADE NAME OF THE MEDICINAL PRODUCT

Mentex® 125 ml Syrup

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Diphenhydramine Hydrochloride 12.5 mg, -Dextromethorphan Hydrobromide 15 mg & -Pseudoephedrine Hydrochloride 30 mg /5mL SYRUP

3. PHARMACEUTICAL FORM

Dosage form: Syrup.

Description: Dark brown colored syrupy liquid with pleasant fruity flavor.

4. Clinical particulars

4.1 Therapeutic indications

Mentex is used for the relief of cough and its congestive symptoms and in the treatment of hay fever and other allergic conditions affecting the upper respiratory tract.

4.2 Posology and method of administration

Adults: 5 ml every four to six hours.

This medication should not be used for the treatment of cough and cold symptoms in children under 12 years of age.

If you take more Mentex than you should

In case of overdosage, the following measures should be taken:

- Gastric lavage.
- Treatment with diazepam to control convulsions.
- Supportive symptomatic treatment.

4.3 Contraindications

Mentex is contraindicated in:

• Intolerance to it or to any of its ingredients.
• Severe hypertension or coronary artery disease.
• This medication should not be used for the treatment of cough and cold symptoms in children under 6 years of age.
• If the patient has or at risk of developing respiratory failure, Dextromethorphan, in common with other centrally acting antitussive agents, should not be given in this case.

4.4 Special warnings and precautions for use

• Severe hepatic dysfunction.
• Severe renal dysfunction.

In the above cases, dosage adjustment is recommended.

• Hypertension.
• Narrow-angle glaucoma.
• Prostatic hypertrophy.
• Bladder-neck obstruction.
• Ischemic heart disease.
• Hyperthyroidism.
• Diabeticpatients.

If symptoms did not improve during 7 days or if they were accompanied by fever, the patient should see the doctor.

Important information about some ingredients of Mentex

If the patient has an intolerance to some sugars or if he/she is a diabetic patient, care should be taken as Mentex contains sucrose.

4.5 Interaction with other medicinal products and other forms of interaction

• Other sympathomimetics decongestants.
• Appetite suppressants.
• Amphetamine and amphetamine like psycostimulants.
• Antihypertensive agents.
• Antihistamines.
• (MAO) inhibitors: Concomitant use of Mentex and monoamine oxidase (MAO) inhibitors could cause a rise in blood pressure.

• Alcohol: This product contains diphenhydramine and therefore may potentiate the effects of alcohol, and other CNS depressants.
• Anticholinergic: As diphenhydramine possess some anticholinergic activity, the effects of anticholinergics (e.g. somepsychotropic drugs and atropine) may be potentiated by this product. This may result in tachycardia, mouth dryness, gastrointestinal disturbances (e.g. colic), urinaryretention and headache.

4.6 Pregnancyandlactation
Care should be taken in administration during pregnancy.

4.7 Effects on ability to drive and use machines
Caution should be taken in driving or operating machinery, as Mentex may cause drowsiness

4.8 Undesirable effects
Diphenhydramine may cause: drowsiness, dizziness, gastrointestinal disturbance, dry mouth, nose and throat, difficulty in urination or blurred vision.
Dextromethorphan: dizziness, nausea, vomiting, or gastro-intestinal disturbance may occur.
Adverse reactions to menthol at the low concentration present in Mentex are not anticipated.
Pseudoephedrine may cause: Nervousness, restlessness and trouble in sleeping.

In general:
Epigastric discomfort, loss of appetite, nausea, vomiting, diarrhea or constipation, tachycardia, palpitation, ECG changes, arrhythmias, hypotension, hypertension, bronchial secretions darkening, hypersensitivity reactions, sensitivity to light, and can be seen in cross-sensitivity to chemically similar preparations. especially in patients with prostatic hypertrophy, urinary retention is reported to be. Rare side effects: dizziness, tremor, and rarely hallucinations, sleep disturbances, headaches, coordination difficulties, skin rashes, fotosensitive, dryness of the throat.
If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

4.9 Overdose
In case of overdosage, the following measures should be taken:
• Gastric lavage.
• Treatment with diazepam to control convulsions.
• Supportive symptomatic treatment.

5. Pharmacological properties

5.1 Pharmacodynamic properties
ATC Code
Diphenhydramine : R06AA52
Dextromethorphan: R05DA09
Pseudoephedrine : R01BA02

Dextromethorphan
Dextromethorphan is a non-opioid antitussive drug. It exerts its antitussive activity by acting on the cough centre in the medulla oblongata, raising the threshold for the cough reflex. A single oral dose of 10-20 mg dextromethorphan produces its antitussive action within 1 hour and lasts for at least 4 hours.

Diphenhydramine
Diphenhydramine possesses antitussive, antihistaminic, and anticholinergic properties. Experiments have shown that the antitussive effect (resulting from an action on the brainstem) is discrete from its antihistaminic effect. The duration of activity of diphenhydramine is between 4 and 8 hours.

Pseudoephedrine
Pseudoephedrine has direct and indirect sympathomimetic activity and is an orally effective upper respiratory tract decongestant.

5.2 Pharmacokinetic properties

Absorption
Mentex is well absorbed from the gut following oral administration. Peak serum levels of diphenhydramine following a 50 mg oral dose are reached at between 2 and 2.5 hrs after an oral dose.
Due to individual differences in the metabolism of dextromethorphan [See Metabolism & Elimination], pharmacokinetic values are highly variable. After the administration of a 20 mg dose of dextromethorphan to healthy volunteers, the Cmax varied from < 1 µg/l to 8 µg/l, occurring within 2.5 hrs of administration.

Distribution
Diphenhydramine
Diphenhydramine is widely distributed throughout the body, including the CNS. Following a 50 mg oral dose of diphenhydramine, the volume of distribution is in the range 3.3 - 6.8 L/kg and it is some 78% bound to plasma proteins.
Dextromethorphan
Due to extensive pre-systemic metabolism by the liver, detailed analysis of the distribution of orally administered dextromethorphan is not possible.
Pseudoephedrine
It is well distributed throughout body fluids and tissues

Metabolism and elimination
Diphenhydramine
Diphenhydramine undergoes extensive first pass metabolism. Two successive N demethylations occur, with the resultant amine being oxidised to a carboxylic acid. Values for plasma clearance of a 50 mg oral dose of diphenhydramine lie in the range 600 - 1300 ml/min, and the terminal elimination half-life lies in the range 3.4 - 9.3 hours. Little unchanged drug is excreted in the urine.
Dextromethorphan
Dextromethorphan undergoes rapid and extensive first-pass metabolism in the liver after oral administration. Genetically controlled O-demethylation is the main determinant of dextromethorphan pharmacokinetics in human volunteers. It appears that there are distinct phenotypes for this oxidation process resulting in highly variable pharmacokinetics between subjects. Unmetabolised dextromethorphan, together with the three demethylated morphinan metabolites; dextrorphan (also known as 3-hydroxy-N-methylmorphinan), 3-hydroxymorphinan and 3-methoxymorphinan have been identified as conjugated products in the urine. Dextrorphan, which also has antitussive action, is the main metabolite.
Pseudoephedrine
Approximately 50% of the drug is excreted unchanged, the remainder undergoes metabolism to inactive metabolites. About 6% is converted to the active metabolite norpseudoephedrine.

Pharmacokinetics in Renal Impairment
The results of a review on the use of diphenhydramine in renal failure suggest that in moderate to severe renal failure, the dose interval should be extended by a period dependent on the glomerular filtration rate (GFR).
There have been no specific studies of Mentex or dextromethorphan in renal impairment.

Pharmacokinetics in Hepatic Impairment
After intravenous administration of 0.8 mg/kg diphenhydramine, a prolonged half-life was noted in patients with chronic liver disease which correlated with the severity of the disease. However, the mean plasma clearance and apparent volume of distribution were not significantly affected.
There have been no specific studies of Mentex or dextromethorphan in hepatic impairment.

Pharmacokinetics in the Elderly
Pharmacokinetic studies indicate no major differences in distribution or elimination of diphenhydramine compared to younger adults.
There have been no specific studies of Mentex or dextromethorphan in the elderly.

5.3 Preclinical Safety Data
The active ingredients of Mentex are well-known constituents of medicinal products and their safety profiles are well documented. The results of pre-clinical studies do not add anything of relevance for therapeutic purposes.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ammonium Chloride
Sodium Citrate Dihydrate
Menthol
Saccharin Sodium
Sodium Benzoate
Sucrose
Sorbitol Solution
Propylene Glycol
Citric Acid Monohydrate
Caramel
Liquid Flavor Chocolate Bourbon
Liquid Flavor Vanilla Extra Strong pH
Liquid Flavor Orange (Quest)
Purified Water

6.2 Incompatibilities
Not applicable

6.3 Shelf life
3 years. After opening, it should be used within one month.

6.4 Special precautions for storage

Store Below 30°C.

6.5 Nature and contents of container

Amber Glass Bottle of 125 ml Syrup closed with tamper evident child resistant cap, labeled and packed in printed carton with plastic measuring cup and a folded leaflet

6.6 Special precautions for disposal and other handling

No special requirements.

7. Marketing authorisation holder

Tabuk Pharmaceutical Manufacturing Company

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8. Marketing authorisation number(s)

Mentex ® Syrup 125 ml
Marketing Authorization Number in Ethiopia : 06575/08555/ NMR/2020

9. DATE OF FIRSTAUTHORISATION/RENEWAL OF THEAUTHORISATION

Mentex ® Syrup 125 ml:
Date of first authorization in Ethiopia: (14/10/2021)

10. Date of revision of the text

August 2023