1.3.3.1 Professional Information (PI)

SCHEDULING STATUS: S2

1 NAME OF THE MEDICINE

MEDDEV (suspension)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 10 ml of the suspension contains:

Dicyclomine Hydrochloride	5 mg
Compressed Aluminium Hydroxide Gel equivalent to:	
Dried Aluminium Hydroxide	400 mg
Light Magnesium Oxide	200 mg
Preservatives: Nipastat	0,2 % *m/v*
Chloroform	0,2 % *v/v*
Benzyl Alcohol	0,3 % *v/v*
Ethyl Alcohol	0,3 % *v/v*

Contains sugar: sorbitol 70 % solution 1 300 mg per 10 ml

Contains sweetener: sodium cyclamate 30,0 mg per 10 ml and saccharin sodium 3,25 mg per 10 ml.

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Suspensions.

A white homogenous suspension with slight peppermint flavour.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

MEDDEV is indicated as an antacid in adults and children over 2 years of age.

4.2 Posology and method of administration

Shake the bottle before use.

MEDDEV should be taken at least 2 to 3 hours before or after other oral medicines.

Adults:

Two to four medicine measures (10 – 20 ml) three to four times daily.

Children over 2 years of age:

One to two medicine measures (5 – 10 ml) three to four times daily.

Paediatric population: MEDDEV is contraindicated in children under 2 years of age (see section 4.3).

4.3 Contraindications

Hypersensitivity to dicyclomine, aluminium hydroxide and magnesium oxide or to any of the ingredients of **MEDDEV.**

Prostatic enlargement, paralytic ileus or pyloric stenosis or other stenosis in the gut where its use may lead to obstruction,

Ulcerative colitis,

Myasthenia gravis,

Glaucoma,

Patients with renal failure.

Obstructive uropathy,

Hyperthyroidism,

Cardiac failure.

Should not be given to children under two years.

Infantile colic in children less than 6 months due to safety concerns.

4.4 Special warnings and precautions for use

MEDDEV should be used with caution in conditions characterised by tachycardia such as hyperthyroidism and cardiac insufficiency or cardiac failure.

MEDDEV should be used with caution in elderly men, hepatic and renal impairment and in conditions characterised by tachycardia.

5 – 10 % of magnesium is absorbed, and retention in patients with impaired renal function may lead to neurological, neuromuscular and cardiovascular impairment. The urine of normal persons may become alkaline which decreases excretion of medicines that are weak bases.

Mucosal irritation and absorption of magnesium may occur if there is gastrointestinal atony or obstruction.

Aluminium hydroxide such as **MEDDEV** absorbs phosphates and excessive doses or normal doses with a low phosphate diet may lead to phosphate depletion with renal rickets or osteomalacia.

Use with care in patients with hiatal hernia associated with reflux oesophagitis because anticholinergic medicines such as **MEDDEV** may aggravate the condition.

MEDDEV contains sorbitol and may have a laxative effect

Patients with the rare hereditary condition of sorbitol intolerance should not take **MEDDEV**.

4.5 Interaction with other medicines and other forms of interaction

Because of **MEDDEV**'s ability to change gastric or urinary pH and to adsorb or form complexes with other medicines, the rate and/or extend of absorption of other medicine may be increased or reduced when used concurrently. Patient should be advised not to take any other oral medications within 2 to 3 hours of antacids.

Concurrent use of **MEDDEV** with other medicines with anticholinergic activity may intensify the anticholinergic effect. Occurrence of gastrointestinal problems should be reported promptly since paralytic ileus may occur with concurrent therapy.

MEDDEV's effects may be enhanced by other medicines with anticholinergic properties such as antihistamines, amantadine, butyrophenones, phenothiazines and tricyclic antidepressants.

Magnesium may interfere with the absorption of tetracyclines.

Aluminium hydroxide reduces the absorption of medicines such as tetracyclines and vitamins and warfarin, quinidine, quinine, anticholinergic medicines, barbiturates and digoxin.

4.6 Fertility, pregnancy and lactation

The safety of **MEDDEV** in pregnancy and lactation has not been established.

MEDDEV is excreted in breast milk.

4.7 Effects on ability to drive and use machines

The use of **MEDDEV** may lead to drowsiness and blurred vision which is aggravated by the simultaneous intake of alcohol and it is dangerous to drive a vehicle or be in charge of machinery while on treatment with **MEDDEV.**

4.8 Undesirable effects

Dicyclomine hydrochloride:

The following side effects have been reported but the frequencies are unknown.

Nervous system disorders:

Dizziness, headache, confusion, sedation

Respiratory disorders:

Reduced bronchial secretions

Eye disorders:

Photophobia, blurred vision, mydriasis with loss of accommodation (cycloplegia), increased intraocular pressure

Cardiac disorders:

Transient bradycardia followed by tachycardia with palpitations and dysrhythmias

Gastrointestinal disorders:

Thirst, dry mouth with difficulty in swallowing and talking, constipation, nausea and vomiting

Skin and subcutaneous tissue disorders:

Flushing, dryness of skin, rash, hypersensitivity may occur as conjunctivitis or a skin rash

Renal and urinary disorders:

Urinary retention, difficulty in micturition

General disorders:

Fatigue, hyperthermia

Aluminium hydroxide

Gastrointestinal disorders:

Frequent: chalky taste, constipation, stomach cramps

Less frequent: nausea, vomiting

Frequency unknown: faecal impaction, intestinal obstruction (large doses).

The following side effects have been reported and the frequency are unknown:

Osteomalacia or adynamic bone disease, encephalopathy, dementia and microcytic hypochromic anaemia have been associated with aluminium accumulation in patients suffering from renal failure.

Excessive doses of aluminium hydroxide or even normal doses in patients on low phosphate diets may lead to phosphate depletion accompanied by increased bone resorption and hypercalciuria with the risk of osteomalacia. (see “Warnings and Special precautions”)

Magnesium oxide:

Gastrointestinal disorders:

Frequent: chalky taste, watery diarrhoea, gastrointestinal irritation,

Less frequent: nausea, vomiting, stomach cramps, paralytic ileus

Blood disorders:

Less frequent: hypermagnesaemia or other electrolyte imbalance

4.9 Overdose

Overdosage of dicyclomine cause hyperthermia, hypertension, tachycardia, rapid or stertorous respiration, nausea and vomiting.

A rash may appear on the face and upper trunk. Toxic doses cause restlessness, confusion and excitement, ataxia, incoordination, paranoid and psychotic reactions, and hallucinations passing into delirium and occasionally seizures. In severe intoxication central stimulation may cause

depression, coma, circulatory and respiratory failure and death. Large doses of aluminium hydroxide may cause intestinal obstruction.

See “side effects” section 4.8. Treatment is symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

Pharmacological classification

Category A 11.4.2 Acid Neutralisers with antispasmodics.

5.1 Pharmacodynamic properties

The combination of dicyclomine, aluminium hydroxide and magnesium oxide has antacid properties.

5.2 Pharmacokinetic properties

Dicyclomine:

Half-life (elimination) – 1,8 hours (initial phase) and 9 to 10 hours (secondary phase).

Aluminium hydroxide:

Absorption – Small amounts of the aluminium in aluminium hydroxide are absorbed from the intestine.

Magnesium oxide:

Absorption – Approximately 10% of the magnesium in magnesium hydroxide (magnesia) is absorbed from the intestine.

Elimination (Aluminium hydroxide and magnesium oxide) – Renal and faecal; 15 to 30% of the salts formed are absorbed and are then excreted by the kidneys.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl hydroxyl ethyl cellulose (Tylose),

Oil cinnamon leaf (flavour),

Peppermint oil (flavour),

Purified water,

Saccharin sodium,

Silicone emulsion,

Sodium cyclamate,

Sodium lauryl sulphate.

Sorbitol 70 % solution

Nipastat

Chloroform

Spirits of chloroform

Ethyl alcohol

Benzyl alcohol

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store at or below 25 °C.

6.5 Nature and contents of container

Packed in 200 ml or 350 ml amber round PVC bottles and 2,5 litre amber rectangular HDPE bottles.

6.6 Special precautions for disposal and other handling

No special requirements.

7 HOLDER OF CERTIFICATE OF REGISTRATION

MDI Healthcare CC

374 Anderson Street

Menlo Park

0081

8 REGISTRATION NUMBER

46/11.4.2/0086

9 DATE OF FIRST AUTHORISATION

Date of registration: 25 March 2019

10 DATE OF REVISION OF THE TEXT

25 October 2022

MED-2-140622PI