

Product proprietary name: **MEDDEV**

Applicant/PHCR: **MDI Healthcare CC**

Dosage form and strength: **Suspension** (5 mg Dicyclomine HCl, Compressed Aluminium Hydroxide Gel equivalent to Dried Aluminium Hydroxide 400 mg, 200 mg Light Magnesium Oxide per 10 ml).

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## 1.3.2 South African Patient Information Leaflet (PIL)

### PATIENT INFORMATION LEAFLET

**SCHEDULING STATUS: S2**

#### MEDDEV Suspension

**Dicyclomine hydrochloride 5 mg, compressed aluminium hydroxide gel equivalent to dried aluminium hydroxide 400 mg and light magnesium oxide 200 mg per 10 ml.**

**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.**

**Read all of this leaflet carefully because it contains important information for you**

MEDDEV is available without a doctor's prescription, for you to treat a mild illness. Nevertheless you still need to use MEDDEV carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share MEDDEV with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve within 2 weeks.

#### What is in this leaflet

1. What MEDDEV is and what it is used for
2. What you need to know before you take MEDDEV
3. How to take MEDDEV
4. Possible side effects

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5. How to store MEDDEV
6. Contents of the pack and other information

## 1. What MEDDEV is and what it is used for

MEDDEV belongs to a group of medicines called acid-neutralisers with antispasmodics and used as an antacid.

## 2. What you need to know before you take MEDDEV

### Do not take MEDDEV

- if you are allergic to dicyclomine, aluminium hydroxide and magnesium oxide or to any of the ingredients in MEDDEV,
- if you suffer from prostatic enlargement, intestinal obstruction or pyloric (where stomach opens in duodenum) obstruction where it can lead to obstruction,
- if you suffer from severe inflammation of the colon,
- if you suffer from glaucoma (eye disease),
- If you suffer from myasthenia gravis (neuromuscular disease with muscle weakness),
- if you suffer from renal failure
- if you suffer from urinary tract disease,
- if you suffer from hyperthyroidism (disease of thyroid gland) or
- if you suffer from heart failure.

Should not be given to:

- children under two years or
- children less than 6 months with infantile colic due to safety concerns.

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### **Warnings and precautions**

Take special care with MEDDEV:

- if you suffer from conditions characterised by tachycardia (abnormal rapid heart rate) such as hyperthyroidism and cardiac insufficiency or cardiac failure
- in elderly men, liver and kidney impairment and in conditions characterised by tachycardia
- if you have impaired renal function magnesium is absorbed, and may lead to neurological, neuromuscular and cardiovascular impairment
- if you have gastrointestinal atony (muscle lost its strength) or obstruction because mucosal (lining of organ) irritation and absorption of magnesium may occur
- if you are on a low phosphate diet
- if you have with hiatal hernia (part of your stomach pushes upward through your diaphragm) associated with reflux oesophagitis because anticholinergic medicines may aggravate the condition

### **Other medicines and MEDDEV**

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

- 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 medication may be increased or reduced when the medication is used concurrently
- Concurrent use of MEDDEV with other medication with anticholinergic activity may intensify the anticholinergic effect (blocks neurotransmitter acetylcholine). 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 (used for allergies), amantadine (antiviral

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and anti-parkinsons), butyrophenones (for psychiatric disorders), phenothiazines (mental emotional disorders) and tricyclic antidepressants.

- magnesium may interfere with the absorption of tetracyclines (antibiotic).
- aluminium hydroxide reduces the absorption of medicines such as tetracyclines and vitamins and warfarin (blood thinner), quinidine (anti-dysrhythmic), quinine (treat malaria), anticholinergic medicines (for cramps and spasms), barbiturates (central nervous depressants) and digoxin (heart medicine).

#### **MEDDEV with food and drink:**

MEDDEV may be taken with or without food.

#### **Pregnancy and breastfeeding**

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

MEDDEV is excreted in breast milk.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice, before taking this medicine.

#### **Driving and using machines**

MEDDEV may make you feel drowsy and could interfere with your ability to drive safely. Do not operate any tools or machines.

#### **MEDDEV contains sorbitol**

MEDDEV contains sorbitol and may have a laxative effect. If you have been told that you have an intolerance to some sugars, you should not take MEDDEV.

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### 3. How to take MEDDEV

Do not share medicines prescribed for you with any other person.

Always take MEDDEV exactly as described in this leaflet or as your doctor or pharmacist told you. Check with your doctor or pharmacist if you are not sure.

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

Shake the bottle before use.

The usual dose is:

**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.

If you have the impression that the effect of MEDDEV is too strong or too weak, talk to your doctor or pharmacist.

#### **If you take more MEDDEV than you should:**

In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

#### **If you forget to take MEDDEV:**

Do not take a double dose to make up for forgotten individual doses.

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#### **4. Possible side effects**

MEDDEV can have side effects.

Not all side effects reported for MEDDEV are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking MEDDEV please consult your health care provider for advice.

A very serious allergic reaction to MEDDEV is rare. However, seek immediate medical attention if you notice any symptoms of a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.

#### **Tell your doctor if you notice any of the following:**

- dry mouth with difficulty in swallowing and talking,
- thirst,
- reduced bronchial secretions,
- chalky taste in mouth,
- fatigue (tiredness),
- sedation (state of calm or sleep),
- headache,
- dizziness,
- confusion,
- hyperthermia (elevated body temperature),
- photophobia (sensitive for light), blurred vision, mydriasis (dilation of the pupils) with loss of accommodation, increased intraocular pressure
- transient bradycardia (slow heart rate) followed by tachycardia (rapid heart rate) with palpitations (irregular heartbeat) and dysrhythmias,
- stomach cramps,

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- constipation, faecal impaction, intestinal obstruction, watery diarrhoea,
- gastrointestinal irritation,
- nausea (feeling sick) and vomiting,
- flushing and dryness of the skin and rash,
- urinary retention, difficulty in passing urine,
- hypersensitivity may appear as conjunctivitis (itchiness and watering of eyes) or a skin rash,
- osteomalacia (softening of bones),
- encephalopathy (disorder of brain),
- hypercalciuria (elevated calcium in urine),
- hypermagnesaemia or other electrolyte imbalance,
- paralytic ileus (intestinal blockage)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

### **Reporting of side effects**

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of MEDDEV.

### **5. How to store MEDDEV**

Store all medicine out of reach of children.

- Store at or below 25 °C.
- Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

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## **6. Contents of the pack and other information**

### **What MEDDEV contains**

- The active substances are dicyclomine hydrochloride, aluminium hydroxide gel and light magnesium oxide.
- MEDDEV contains preservatives (nipastat, chloroform, benzyl alcohol and ethyl alcohol).
- MEDDEV contains sugar (sorbitol 70 % solution)
- The other ingredients are: methyl hydroxyl ethyl cellulose (tylose), oil cinnamon leaf, peppermint oil, saccharin sodium, silicone emulsion, sodium cyclamate, sodium lauryl sulphate, spirits of chloroform (chloroform, ethyl alcohol, purified water), and purified water.

### **What MEDDEV looks like and contents of the pack**

A white homogenous suspension with slight peppermint flavour.

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

### **Holder of Certificate of Registration**

MDI Healthcare CC

374 Anderson Street

Menlo Park

Pretoria, 0081

### **This leaflet was last revised in**

25 October 2022

### **Registration number**

46/11.4.2/0086

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### **Access to the corresponding Professional Information (PI)**

An online copy of the PI is available at

<https://unimedhealthcare.co.za/WP-content/uploads/2022/04/MEDDEV-PI.pdf>