

## Package leaflet: Information for the user

Fluidema 2.5 mg hard capsules

Indapamide

Read all of this leaflet carefully before you start taking this medicine as it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you are not sure, talk to your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. You should not give it to others. The medicine can be harmful to them even if they show the same signs of illness.
- If you get any side effects, including possible side effects not listed in this leaflet, talk to your doctor, pharmacist or nurse. See section 4.

What's in this leaflet:

1. What Fluidema is and what it is used for
2. What you need to know before you take Fluidema
3. How to take Fluidema
4. Possible undesirable effects
5. How to Maintain Fluidema
6. Package contents and other information

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

This medicine is intended for the treatment of essential high blood pressure

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

Do not take Fluidema

- if you are allergic to indapamide or any of the other ingredients of this medicine (listed in section 6).
- if you have severe kidney disease.
- if you have suffered from a recent stroke.

Warnings and precautions

Talk to your doctor or pharmacist before taking Fluidema.

Take special care:

- if you suffer from gout, as urikaemia should be monitored.
- if you have a problem with your kidneys
- if you have a known allergy to sulfamides.

If you experience a decrease in vision or eye pain. These can be symptoms of fluid buildup in the vascular layer of the eye (choroidal effusion) or an increase in pressure in the eye and can occur within hours up to a week after taking Fluidema,

If you think any of these may apply to you or if you have any questions or concerns about taking this medicine, you should talk to your doctor or pharmacist.

#### Other medicines and Fluidema

Tell your doctor or pharmacist if you are taking, or have recently taken or might take any other medicines.

It should not be combined with proximal diuretics or potassium depletors, and surveillance of kalaemia is advised in patients predisposed to potassium depletion.

#### Pregnancy, breastfeeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or plan to become pregnant, ask your doctor or pharmacist for advice before taking this medicine.

As with all medicines, use in pregnancy should be done under medical supervision, although no teratogenic effects have been shown.

#### Fluidema contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

### 3. How to take Fluidema

The recommended dose is 1 capsule per day orally with a little liquid without chewing.

Take this medication exactly as directed by your doctor or pharmacist. Check with your doctor or pharmacist if you are not sure.

#### If you forget to take Fluidema

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

#### Will stop taking Fluidema

As treatment for high blood pressure is usually prolonged, you should talk to your doctor before you stop taking this medicine.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

### 4. Possible undesirable effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Common (may affect up to 1 in 10 people):

- Low levels of potassium in the blood

Uncommon (may affect up to 1 in 100 people):

- Low sodium levels in the blood, which can lead to dehydration and low blood pressure
- Impotence (inability to get or maintain an erection).

Rare (may affect up to 1 in 1,000 people):

- Low levels of chloride in the blood
- Low levels of magnesium in the blood

It may rarely present undesirable effects, always of a mild and transient nature, namely asthenia, orthostatic hypotension or alteration of glycaemia, uremia and kalaemia.

Frequency not known (frequency cannot be estimated from the available data):

- Decreased vision or pain in the eyes due to high pressure (possible signs of fluid accumulation in the vascular layer of the eye (choroidal effusion) or acute angle-closure glaucoma).

#### Reporting of undesirable effects

If you experience any side effects, including side effects not listed in this leaflet, talk to your doctor or pharmacist. You can also report undesirable effects directly to INFARMED, I.P through the contacts below. By reporting side effects, you are helping to provide more information about the safety of this medicine.

Sítio da internet: <http://www.infarmed.pt/web/infarmed/submissaoram>  
(preferably)

or through the following contacts:

Direção de Gestão do Risco de Medicamentos

Parque da Saúde de Lisboa, Av. Brasil 53

1749-004 Lisboa

Tel: +351 21 798 73 73

Linha do Medicamento: 800222444 (gratuita)

E-mail: [farmacovigilancia@infarmed.pt](mailto:farmacovigilancia@infarmed.pt)

#### 5. How to Maintain Fluidema

Store at a temperature below 25 °C.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton, and on the blister after EXP. The expiry date corresponds to the last day of the month indicated.

Do not dispose of any medicines in the sewer or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

## 6. Package contents and other information

What Fluidema contains

- The active substance is: indapamide

- The other ingredients are: Polyvinylpyrrolidone, lactose, magnesium stearate and deionized water.

What Fluidema looks like and contents of the pack

Fluidema comes in packs of 10, 30 and 60 capsules.

Marketing authorization Holder and Manufacturer

Holder of the A.I.M.

BALDACCI PORTUGAL, S.A.

Rua Cândido de Figueiredo, 84-B

1549-005 LISBOA

Tel: 00351217783031

Fax: 00351217785457

E-mail: [medico@baldacci.pt](mailto:medico@baldacci.pt)

Manufacturer

Medinfar Manufacturing S.A.

Armando Martins Tavares Industrial Park

Rua Outeiro da Armada, nº 5

3150-194 Condeixa-a-Nova

Portugal

Date of approval of this leaflet: march 2024