

## PACKAGE LEAFLET: INFORMATION FOR THE USER

*Name of the medicinal product*

**NOTEZINE 100 mg, scored tablets**

**Diethylcarbamazine citrate**

*Text box*

**Read all of this leaflet carefully before you start using this medicine because it contains important information for your treatment.**

If you have any further questions, ask your doctor or pharmacist.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve.

If any of the side effects gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

*Leaflet summary*

### **What is in this leaflet:**

1. WHAT NOTEZINE 100 mg, scored tablets IS AND WHAT IT IS USED FOR
2. WHAT YOU NEED TO KNOW BEFORE YOU USE NOTEZINE 100 mg, scored tablets
3. HOW TO USE NOTEZINE 100 mg, scored tablets
4. POSSIBLE SIDE EFFECTS
5. HOW TO STORE NOTEZINE 100 mg, scored tablets
6. FURTHER INFORMATION

### **1. WHAT NOTEZINE 100 mg, scored tablets IS AND WHAT IT IS USED FOR**

*Pharmacotherapeutic group*

ANTHELMINTHICS.

*Therapeutic indications*

This medicine is an antiparasitic agent.

It is recommended for the treatment of:

- certain lymphatic forms of filariasis (infestation by *Wuchereria bancrofti*, *Brugia malayi*, *Brugia timori*),
- loiasis (infestation by *Loa loa*),
- and onchocerciasis (infestation with *Onchocerca volvulus*).

### **2. WHAT YOU NEED TO KNOW BEFORE YOU USE NOTEZINE 100 mg, scored tablets**

*List of information necessary before taking the medicinal product*

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

*Contraindications*

### **Do not use NOTEZINE 100 mg, scored tablets:**

- if you are allergic to any of the ingredients,
- if you have serious eye damage in the context of onchocerciasis,
- if you have gluten intolerance, as this medicine contains wheat starch (gluten).

You should check with your doctor or pharmacist if you are not sure.

*Precautions for use; special warnings*

### **Special warnings**

This medicine should only be used if you have a parasitic infestation or if one is strongly suspected. It is not effective as preventive treatment for individual parasitic infestation.

This medicinal product contains lactose. It should not be used in patients with galactosemia, glucose or galactose malabsorption syndrome or lactase deficiency (rare metabolic diseases).

### Precautions for use

If you suffer from kidney disorders, INFORM YOUR DOCTOR who will adjust your dose.

You should check with your doctor or pharmacist if you are not sure.

#### *Interactions with other medicinal products*

### Other medicines and NOTEZINE 100 mg, scored tablets

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

#### *Interactions with food and drink*

Not applicable.

#### *Interactions with herbal or alternative therapies should be addressed where necessary*

Not applicable.

#### *Use by pregnant or breast-feeding women*

### Pregnancy and breast-feeding

This medicine should preferably not be used during pregnancy.

If you discover that you are pregnant while taking this medicine, consult your doctor who will be able to determine whether you should continue this treatment.

As a precaution, you should avoid taking this medicine while breast-feeding.

As a general rule, during pregnancy or breast-feeding, you should always ask your doctor or pharmacist for advice before taking a medicine.

#### *Athletes*

Not applicable.

#### *Effects on the ability to drive or to use machines*

### Driving and using machines

If you drive or use machines, you should be aware that this medicine can cause drowsiness.

#### *List of excipients with specific effects*

**Important information about some of the ingredients of NOTEZINE:** This medicine contains: Wheat starch (gluten), lactose.

### 3. HOW TO USE NOTEZINE 100 mg, scored tablets

#### *Instructions for proper use*

Not applicable.

#### *Dosage, Method and/or route(s) of administration, Frequency of administration and Duration of treatment*

### Dosage

Follow your doctor's prescription.

### **Treatment of lymphatic filariasis (*Wuchereria bancrofti*, *Brugia malayi*, *Brugia timori*):**

Treatment should preferably be administered in divided doses, after meals.

Individual treatment: 3 mg/kg/day of diethylcarbamazine base for 12 to 14 consecutive days.

The course of treatment can be repeated if necessary, after an interval of at least 10 days.

In the event of mass treatment, your doctor will prescribe you a single annual dose of 3 mg/kg of diethylcarbamazine base as combined treatment, as per the WHO recommendations.

**Occult filariasis (tropical pulmonary eosinophilia):**

3 mg/kg/day for 14 to 21 days. The course of treatment can be repeated if symptoms reappear.

**Treatment of loiasis (infestation with *Loa loa*):**

The treatment should be started under strict medical supervision. The higher the numbers of microfilariae in the blood, the lower the dose of diethylcarbamazine base(3 mg).

As an indication:

1<sup>st</sup> day: 1/32<sup>nd</sup> of a tablet (the dilution should be performed by a pharmacist),

the dose should be doubled on subsequent days, until a daily dose of 3 mg/kg of diethylcarbamazine base, is reached after one week, taken as 2 divided doses.

The effective dose should be maintained over 21 days.

Corticosteroids can be given along with diethylcarbamazine to minimise or prevent side effects.

**Treatment of onchocerciasis (infestation with *Onchocerca volvulus*):**

To limit the occurrence of side effects to the treatment (Mazzotti reaction), the treatment can be started at low, progressively increasing doses.

As an indication:

1<sup>st</sup> day of treatment: 0.5 mg/kg of diethylcarbamazine base as a single dose, depending on the patient's clinical condition, the dose can be doubled on subsequent days until an effective dose of 3 mg/kg/day of diethylcarbamazine base is reached, taken as 2 divided doses.

The effective dose should be maintained for about 10 days.

Corticosteroids can be given along with diethylcarbamazine to minimise or prevent side effects.

**Route and method of administration**

Oral use.

*Symptoms in case of overdose and actions to be taken*

**If you take more NOTEZINE than you should:**

Consult a doctor promptly.

*Actions to be taken when one or more doses have been missed*

Not applicable.

*Indication of the risk of withdrawal effects*

Not applicable.

**4. POSSIBLE SIDE EFFECTS**

*Description of side effects*

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

The incidence and seriousness of the side effects most often depend on parasite levels and the dose of diethylcarbamazine administered.

- When administered in patients with lymphatic filariasis or loiasis:
    - general reactions: fever, headaches, dizziness, loss of appetite, hives, vomiting, asthma attack,
    - possible nervous system disorders, sometimes serious, in patients with loiasis when the parasitic infestation is severe,
    - inflammation of lymphatic vessels in patients with lymphatic filariasis.
  - When administered in patients with onchocerciasis:
    - general reactions: fever, headaches, dizziness, loss of appetite, hives, vomiting, asthma attack,
    - skin disorders: itching, hives, oedema,
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- o eye disorders: tears, glare, superficial inflammation of the eye, iris and eyelashes, increased pressure inside the eye in patients with massive infestation, damage to the retina and optic nerve during prolonged treatment.

**Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system: French national Agency for the Safety of Medicinal and Health Products (ANSM) and the network of Regional Pharmacovigilance Centers - Website: [www.ansm.sante.fr](http://www.ansm.sante.fr)

By reporting side effects you can help provide more information on the safety of this medicine.

**5. HOW TO STORE NOTEZINE 100 mg, scored tablets**

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

*Expiry date*

Do not use NOTEZINE 100 mg, scored tablets after the expiry date which is stated on the outer packaging.

*Storage conditions*

No special storage conditions.

*Where appropriate, warning against certain visible signs of deterioration*

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

**6. FURTHER INFORMATION**

*Complete list of active substances and excipients*

**What NOTEZINE 100 mg, scored tablets contains**

**The active substance is:**

Diethylcarbamazine citrate ..... 196.4 mg  
(equivalent to diethylcarbamazine ..... 100.0 mg)

For one scored tablet

**The other ingredients are:**

Wheat starch, lactose monohydrate, colloidal hydrated silica, magnesium stearate.

*Pharmaceutical form and contents*

**What NOTEZINE 100 mg, scored tablets looks like and contents of the pack**

This medicine is in the form of scored tablets. Box of 20.

*Name and address of the marketing authorisation holder and of the manufacturing authorisation holder responsible for batch release, if different*

**Marketing Authorisation Holder**

**SANOFI-AVENTIS FRANCE**  
1-13, boulevard Romain Rolland  
75014 PARIS  
FRANCE

**Operating company**

**SANOFI-AVENTIS FRANCE**  
1-13, boulevard Romain Rolland  
75014 PARIS  
FRANCE

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**Manufacturer**

**FAMAR LYON**

AVENUE DU GENERAL DE GAULLE  
69230 SAINT GENIS LAVAL  
FRANCE

*Names of the medicinal product in the Member States of the European Economic Area*

Not applicable.

*Date of leaflet approval*

**This leaflet was last approved in {date}.**

*For products approved under "exceptional circumstances"*

Not applicable.

*Information on the internet*

Detailed information on this medicine is available on the ANSM website (France).

*Information intended for healthcare professionals*

Not applicable.

*Other*

Not applicable.

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